

ADVANCING TREATMENT OPTIONS FOR TOBACCO CESSATION, PREVENTION AND RELATED ILLNESSES, WITH PARTICULAR REFERENCE TO INDIGENOUS POPULATIONS

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Doctor of Philosophy

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*“Nothing in life is to be feared,
it is only to be understood.*

*Now is the time to understanding more,
so that we may fear less.”*

~ Marie Curie

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Declaration

I certify that this work contains no material which has been accepted for the award of any other degree or diploma in my name in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text. In addition, I certify that no part of this work will, in the future, be used in a submission in my name for any other degree or diploma in any university or other tertiary institution without the prior approval of the University of Adelaide and where applicable, any partner institution responsible for the joint award of this degree.

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Signed.....

Date

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Family and friends

“You can kiss your family and friends good-bye and put miles between you, but at the same time you carry them in your heart, your mind, your stomach, because you do not just live in a world but a world lives in you.”

~ Fredrick Buechner

This PhD would not have been possible without some very exceptional people who I have the profound honour to call my family, friends and mentors.

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“Friendship is born at the moment one person says to another: What? You too? I thought I was the only one.”

~ C. S. Lewis

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“We are all visitors to this time, this place. We are just passing through. Our purpose here is to observe, to learn, to grow, to love... and then we return home.”

~ Aboriginal proverb

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Supervisors

“Tell me and I forget, teach me and I may remember, involve me and I learn.”

~ Benjamin Franklin

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*“I would spread the cloths under your feet; But I, being poor, have only my dreams;
I have spread my dreams under your feet; Tread softly because you tread on my dreams.”*

~ William Butler Yates

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“What is a teacher? I'll tell you: it isn't someone who teaches something, but someone who inspires the student to give of her best in order to discover what she already knows.”

~ Paulo Coehlo

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“Education is only the most fully conscious of the channels whereby each generation influences the next”

~ C. S. Lewis

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Abbreviations

5A	Ask, Assess, Advise, Assist and Arrange
6MWD	Six Minute Walking Distance
$\alpha 4\beta 2$	Alpha 4 beta 2
ABS	Australian Bureau of Statistics
ACT	Australian Capital Territory
Adj	Adjusted
ADSCA	Alcohol and other Drug Services Central Australia
AE	Adrian Esterman
AIHW	Australian Institute of Health and Welfare
AMSWS	Aboriginal Medical Service Western Sydney
ANBL	All Nations Breath of Life
ANCOVA	Analysis of Covariance
ANOVA	Analysis of Variance
Approx.	Approximately
APY	Anangu Pitjantjatjara Yankunytjatjara (APY lands, central Australia)
ASM	Annual Scientific Meeting
ASMR	Australian Society for Medical Research
ATS	American Thoracic Society
AU	Australian
AV	Antony Veale
BHI	Basil Hetzel Institute for Translational Health Research
b.i.d.	Twice daily

BJS	Brian James Smith
BMI	Body Mass Index
BOABS	Be Our Ally Beat Smoking
BS	Brian Smith
CA	Continuous Abstinence
CATS	Chronically Addicted Tobacco Smokers
CBT	Cognitive Behavioural Therapy
CCT	Controlled Clinical Trial
CD	Compact Disk
CDC	Centres for Disease Control
CEITC	Centre for Excellence in Indigenous Tobacco Control
CEO	Chief Executive Officer
CI	Confidence Intervals
CNS	Central Nervous System
CO	Carbon Monoxide
COPD	Chronic Obstructive Pulmonary Disease
COAG	Council of Australian Governments
cpd	Cigarettes per day
CPO	Controlled Purchase Operations
CYP1A1	Cytochrome P450 1A1
CYP1A2	Cytochrome P450 1A2
CYP2A6	Cytochrome P450 2A6
DASSA	Drug and Alcohol Services South Australia
Deff	Design Effect

Dent	Dentists
DHS	Doctors Helping Smokers
DNA	Deoxyribonucleic acid
DOC/Doc	Doctor
DOI	Digital Object Identifier
DVD	Digital Versatile Disk
E-cigarettes	Electronic cigarettes
EEG	Electroencephalogram
EGF	Epithelial Growth Factor
ENT	Ears, Nose and Throat (specialist)
EORTC	European Organisation for Research and Treatment of Cancer
EOT	End of Treatment
EPOC	Effective Practice Organisation of Care (Cochrane group)
EQD	Estimated Quit Date
ESS	Effective Sample Size
ETS	Environmental Tobacco Smoke
F	Female
FAX	Facsimile
FDA	Food and Drug Administration
FEV ₁	Forced Expiratory Volume in 1 second
FRACP	Fellow of the Royal Australasian College of Physicians
Fri	Friday
FVC	Forced Vital Capacity
GAINS	Give American Indians No-smoking Strategies

GG	Gillian Gould
GIV	Generic Inverse Variance
GLIM	Generalised Linear Interactive Modelling
GLMM	Generalised Linear Mixed Modelling
GP	General Practitioner
GUTS	Give Up The Smokes
h	Hour
HB	Helen Bradley
HDA	Healthy Development Adelaide
HJ	Harshani Jayasinghe
HMO	Health Maintenance Organisation
HPV	Human Papillomavirus
HREC	Hospital Research Ethics Committee
I-ANBL	Internet All Nation Breath of Life
IARC	International Agency for Research on Cancer
ICMJE	International Committee of Medical Journal Editors
IQR	Inter Quartile Range
ISRCTN	International Standard Randomised Controlled Trial Number
IV	Inverse Variance
JN	Jeffrey Newchurch
KC	Kristin Carson
KCSH	Key Community Stakeholder
KS	Kuljit Singh
KVC	Kristin Veronica Carson

LMH	Lyell McEwin Hospital
LMICs	Low to Middle Income Countries
LST	Life Skills Training
M	Male or Mean (difference specified in each publication)
MASAC	Medical And Scientific Advisory Committee (Asthma Foundation of SA)
max	Maximum
MB	Malcolm Brinn
MeSH	Medical Subject Headings
mg	Milligram
M-H	Mantel Haenszel
min	Minute
ml	Millilitres
MMWR	Morbidity Mortality Weekly Report
Mon	Monday
MP	Matthew Peters
MSOAP	Medical Specialist Outreach Assistance Program
mth	Month
MV	Marjolein Verbiest
N/A	Not Applicable
NACCHO	National Aboriginal Community Controlled Health Organisation
NHANES	National Health And Nutrition Examination Survey
NHL	Non-Hodgkin's Lymphoma
NHMRC	National Health and Medical Research Council
NI	Non-Indigenous

NIH	National Institute of Health
NL	Nadina Labiszewski
NNT	Number Needed to Treat
N-O-T	Not On Tobacco
NRT	Nicotine Replacement Therapy
NS	Not Significant
NSW	New South Wales
NT	Northern Territory
NY	New York
OR	Odds Ratio
OTC	Over The Counter
PAFC	Port Adelaide Football Club
PBS	Pharmaceutical Benefits Scheme
PhD	Doctor of Philosophy
pH	Potential Hydrogen
P:I	Prevalence:Incidence
PIS+C	Participant information sheet plus consent form
PO Box	Post Office Box
ppm	parts per million
PRISMA	Preferred Reporting Item for Systematic reviews and Meta-Analyses
Priv	Private
PsyQol	Psychological Quality of Life
QLD	Queensland
Qol	Quality of Life

RAH	Royal Adelaide Hospital
RCT	Randomised Controlled Trial
R.E.A.L.	Refuse, Explain, Avoid and Leave
RELIQ	Reduced Levels of nicotine in cigarettes to Increase Quitting
rho	Interclass Correlation Coefficient
ROB	Risk of Bias
RR	Risk ratio
RT	Rachada To-A-Nan
SA	South Australia
SAHMRI	South Australian Health and Medical Research Institute
SAS	Statistical Analysis Software
Sat	Saturday
SD	Standard Deviation
SE	Standard Error
SES	Socio-Economic Status
SF36	Short Form 36
SMD	Standardised Mean Difference
SNAP	Smoking, nutrition, alcohol and physical activity
SODAS	Stop, Options, Decide, Act/communication skills, Self-praise
SR	Sustained Release
SSA	Site Specific Assessment
STOMP	STOp smoking by Mobile Phone
STOP	Smoking Termination Opportunity for inPatients
T	Time point

tab	Tablet
TAP	Tobacco Action Project
Tas	Tasmania
TEL	Telephone
THP	Training Health Professionals
TM	Trade Mark
TQEH	The Queen Elizabeth Hospital
TQEHLMH	The Queen Elizabeth Hospital and Lyell McEwin Hospital
TR	Thomas Robertson
TRIP	Translating Research In to Practice
TSANZ	Thoracic Society of Australia and New Zealand
TSI	Torres Strait Islander
Tue	Tuesday
TV	Television
Txt2Quit	Text to Quit
UK	United Kingdom
UoA	University of Adelaide
US	United States
USA	United States of America
Uni	University
UV	Ultraviolet
VAMC	Veteran Affairs Medical Centres
VT	Varenicline Tartrate
VT+C	Varenicline Tartrate plus Counselling

WA	Western Australia
WCH	Women's and Children's Hospital
WEA	Workers Education Association
Wed	Wednesday
WHO	World Health Organisation
Wk	Week
WMD	Weighted Mean Difference
YAA	Young Achiever Awards
Yr	Year

Awards (Total number of awards/finalist positions n=24)

- 2016 Finalist and oral presenter for the Ann Woolcock Young Investigator Award for the Thoracic Society of Australia and New Zealand (top five abstracts are selected as finalists and oral presenters for the April 2016 ASM to be held in Perth); presentation title:
Superiority of a course of varenicline tartrate plus counselling over counselling alone for smoking cessation: a 24 month randomised controlled trial for inpatients
- 2015 Best oral presentation by a Senior Clinical Researcher for The Queen Elizabeth Hospital Research Day for 2015; presentation title:
Superiority of a course of varenicline tartrate plus counselling over counselling alone for smoking cessation: a 12 month randomised controlled trial for inpatients
- 2015 Recipient of the **Australian Financial Review and Westpac 100 Women of Influence**; One of the winners in the Young Leader category
- 2015 Recipient of the 2015 South Australian Tall Poppy award presented on the 27th of July at Government House by the Governor the Honourable Hieu Van Le
- 2015 Recipient of the Australian Society for Medical Research Ross Wishart Memorial Award for best oral presentation at the South Australia conference, (top four abstracts are chosen as finalists and oral presenters), June 2015, Adelaide ASM; presentation title:
Superiority of a course of varenicline tartrate plus counselling over counselling alone for smoking cessation: a 12 month randomised controlled trial for inpatients

- 2015 Best oral presentation for the Evidence Based Medicine TSANZ (Thoracic Society of Australia and New Zealand) Special Interest Group: Gold Coast ASM; presentation title:
Culturally-tailored interventions for smoking cessation in Indigenous populations: A Cochrane systematic review and meta-analysis
- 2015 Best oral presentation Tobacco Control Prize for the TSANZ (Thoracic Society of Australia and New Zealand): Gold Coast ASM; presentation title:
Can nicotine replacement therapy delivered via continuous patch cause auto-induction (up-regulation) of receptors? A pilot study
- 2015 Honorary Member of the Golden Key International Honour Society for the University of South Australia Chapter; Golden Key recognises the top 15% of students graduating from Universities worldwide and membership is by invitation only; Made an Honorary Member and Keynote speaker during the May 2015 annual ceremony
- 2015 Thoracic Society of Australia and New Zealand Award for recognition of dedication to Respiratory Medicine and being named the Young Australian of the Year presented at the 2015 Gold Coast Annual Scientific Meeting Opening Ceremony
- 2015 **National finalist for the Young Australian of the Year for Australia** (South Australian representative) including attendance at ceremonies in Canberra on Australia Day eve including morning tea at The Lodge with the Prime Minister Tony Abbott and lunch with the Governor General at Parliament House
- 2015 Young Citizen of the Year for the City of Holdfast Bay announced on Australia Day 2015 during a public ceremony in Glenelg
- 2014 Finalist and oral presenter for the South Australian and Northern Territory Thoracic Society of Australia and New Zealand Young Investigator Award; presentation title:

Respiratory health service delivery and utilisation by Aboriginal Australians: A qualitative analysis

- 2014 **Recipient of the Young Australian of the Year for South Australia 2014/15**
- 2014 **Winner of the Premier's and Channel 9 Young Achiever of the Year.** Chosen as the recipient of the award from over 200 applications and across 8 categories including; Online achievement, sports, arts, career kick-start, Aboriginal achievement, science and technology, rural health, and environment.
- 2014 Winner of the Channel 9 Young Achiever Award for The University of Adelaide Faculty of Sciences, Science and Technology Category
- 2014 Channel 9 Young Achiever Award Finalist (one of four) for the Australian Super Career Kick Start Award
- 2013 Finalist (one of five out of 11 applications) and oral presenter for the South Australian and Northern Territory Thoracic Society of Australia and New Zealand Young Investigator Award; presentation title:
Barriers and enablers for the use of smoking cessation pharmacotherapy in Aboriginal and Torres Strait Islander populations: A qualitative synthesis
- 2013 Semi-finalist (1 of 8 selected for an oral presentation) for the 2013 South Australian Young Investigator Award, following short listing from audio recording, CV and written application (lay summary)
- 2013 Recipient of the Young Professionals Group Development Grant Program Award for the development activity titled 'Leaders in Lung Health and Respiratory Services'
- 2013 Finalist (one of four) for the Catherine Helen Spence (CHS) Memorial Scholarship, through submission of a detailed grant application and following CHS committee panel interview

- 2012 Recipient of the South Australian and Northern Territory Thoracic Society of Australia and New Zealand Young Investigator Award; presentation title: *Interventions for tobacco prevention in Indigenous youth: A Cochrane review and narrative synthesis*
- 2012 TSANZ (Thoracic Society of Australia and New Zealand) Tobacco Control Prize for best oral presentation: Canberra ASM; presentation title: *Interventions for tobacco cessation in Aboriginal Australians and other Indigenous populations*
- 2012 Recipient of the South Australian and Northern Territory Thoracic Society of Australia and New Zealand Young Investigator Award; presentation title: *Interventions for tobacco prevention in Indigenous youth: A Cochrane review and narrative synthesis*
- 2011 Finalist and oral presenter for the South Australian and Northern Territory Thoracic Society of Australia and New Zealand Young Investigator Award; presentation title: *Interventions for tobacco cessation in Indigenous populations: A Cochrane meta-analysis*

Fellowships, grants and scholarships (Total \$1,153,022.20 related to PhD)

2016-18 Smith BJ (CIA), **Carson KV (CIB)**, Esterman AJ (CIC), Peters MJ (CID), Gould G (CIE). National Health and Medical Research Council (NHMRC) Project grant. 'Training health professionals in tobacco cessation and evidence translation for Aboriginal Australians' **\$832,723.20** over three years

2015-17 **Carson KV. (CIA)** NHMRC TRIP Fellowship (National Health and Medical Research Council, Translating Research In to Practice Fellowship). Title of research 'Training health professionals in smoking cessation and tobacco abuse prevention for Aboriginal Australians'. **\$172,911.00** for 0.5 salary and professional development over two years

2015-17 **Carson KV. (CIA)** Cancer Australia co-funding for the NHMRC TRIP Fellowship (National Health and Medical Research Council, Translating Research In to Practice). Title of research 'Training health professionals in smoking cessation and tobacco abuse prevention for Aboriginal Australians'. **\$100,000.00** over two years including \$20,000.00 p.a. for salary support and \$30,000.00 p.a. for research support

2015 **Carson KV.** Robert Pierce Grant-In-Aid for Indigenous Lung Health awarded once annually via the Thoracic Society of Australia and New Zealand to honour the memory of the late Respiratory Professor Rob Pierce for research focusing on understanding and improving the lung health of Indigenous people in Australia and/or New Zealand. Title of study '*Training health professionals in smoking cessation and tobacco prevention interventions for Aboriginal Australians*' **\$15,000.00**

2015 **Carson KV,** Smith BJ. Research activity sponsorship from Seeley International made by Frank and Kathy Seeley following a presentation of research by Kristin and Brian on the 04/03/2015 to support a scholarship position within the department **\$18,000.00**

- 2015 **Carson KV.** Recipient of the international travel grant from Healthy Development Adelaide for final year PhD students to attend Res Health 2015: 1st International Respiratory and Sleep Medicine Conference **\$500.00**
- 2015 **Carson KV.** Recipient of a competitive Travel grant from the Thoracic Society of Australia and New Zealand (TSANZ) to attend the 2015 conference in the Gold Coast; **\$388.00**
- 2014 **Carson KV.** Janet Elder International Travel Award; Awarded from the submitted abstract '*Barriers and enablers for the use of smoking cessation pharmacotherapy in Aboriginal and Torres Islander populations: A qualitative analysis*' **\$2,500.00**
- 2013-14 **Carson KV.** Australian and New Zealand School of Government Grant to write a policy document for the journal *Evidence Base* titled 'Interventions for smoking cessation and tobacco abuse prevention in Indigenous populations; **\$10,000.00**
- 2013 **Carson KV.** Recipient of the Young Professionals Group Development Grant for the development activity titled '*Leaders in Lung Health and Respiratory Services*' to attend the TSANZ 2014 conference in Adelaide **\$500.00**
- 2012 **Carson KV.** Recipient of a competitive Travel grant from the Thoracic Society of Australia and New Zealand (TSANZ) to attend the 2012 conference in Canberra; **\$500.00**

Peer-reviewed journal publications (Total Impact Factor (IF) 49.815)

Submitted (n= 2 related to PhD work)

1. **Carson KV**, Singh K, Smith BJ. A national survey of current practice by Respiratory Specialists and Allied Health Professionals in treating Aboriginal and TSI tobacco use. *Submitted to the Medical Journal of Australia* 2015 (IF 3.789)
2. **Carson KV**, Brinn MP, Peters MJ, Chang AB, Veale AJ, Esterman AJ, Smith BJ. Smoking cessation pharmacotherapy and health service utilisation for tobacco addiction among Aboriginal and Torres Strait Islander Australians: A qualitative analysis *Submitted to Tobacco Control* 2015 (IF 5.150)

Published (n= 12 related to PhD work)

3. **Carson KV**, Jayasinghe H, Smith BJ, Newchurch J, Brinn MP, Veale A, Peters M, Esterman AJ, Singh K and Members of the TSANZ Indigenous Lung Health Working Party. Smoking cessation and tobacco abuse prevention in Indigenous populations; *Evidence Base; Issue 3; 2014* <https://journal.anzsog.edu.au/publications> (IF N/A)
4. **Carson KV**, Smith BJ. Methodological challenges and options for addressing them in Aboriginal and Torres Strait Islander health research. *Australasian Epidemiology* 2014; 21(2): 47-50 (IF N/A)
5. **Carson KV**, Smith BJ, Brinn MP, Peters M, Fitridge R, Koblar S, Jannes J, Veale A, Singh K, Goldsworthy S, Litt J, Edwards D, Esterman AJ. Safety of a course of varenicline tartrate and counselling over counselling alone for smoking cessation: A 52 week randomised controlled trial for inpatients (STOP Study). *Nicotine and Tobacco Research* 2014 Jul 16 <http://www.ncbi.nlm.nih.gov/pubmed/25031315> (IF 2.805)
6. Smith BJ, **Carson KV**, Brinn MP, Labiszewski NA, Peters M, Fitridge R, Koblar S, Jannes J, Veale A, Goldsworthy S, Litt J, Edwards D, Esterman AJ. Smoking Termination Opportunity for inPatients (STOP): Superiority of a course of

varenicline tartrate plus counselling over counselling alone for smoking cessation: A 12-month randomised controlled trial for inpatients. *Thorax* 2013; 68(5): 485-6 doi:10.1136/thoraxjnl-2012-202484 (IF 8.376)

7. **Carson KV**, Usmani ZA, Robertson T, Mysore S, Brinn MP. Smoking cessation interventions for lung cancer management. *Lung Cancer Management* 2013; 2(1): 61-74; ISSN 1758-1966 (IF N/A)
8. **Carson KV**, Brinn MP, Robertson T, To-A-Nan R, Esterman AJ, Peters M, Smith BJ. Current and emerging pharmacotherapeutic options for smoking cessation. *Substance Abuse, Research and Treatment* 2013; 7(5): 85-105 (IF N/A)
9. **Carson KV**, Jurisevic MA, Smith BJ. Is cancer still reduced if you give up smoking in later life? *Substance Abuse, Research and Treatment* 2013; 2(5): 357-68; ISSN 1758-1966 (IF N/A)
10. **Carson KV**, Labiszewski NA, Brinn MP, Veale A, Chang AB, Esterman AJ, Smith BJ. Interventions for tobacco prevention in Indigenous youth. *Cochrane Database of Systematic Reviews* 2012, Issue 8. Art. No.: CD009325. DOI: 10.1002/14651858.CD009325.pub2 (IF 5.939)
11. **Carson KV**, Verbiest MEA, Brinn MP, Crone MR, Esterman AJ, Assendelft WJJ, Smith BJ. Training health professionals in smoking cessation (Review). *Cochrane Database of Systematic Reviews* 2012, Issue 5. ART. No.: CD000214. DOI: 10.1002/14651858.CD000214.pub2 (IF 5.939)
12. **Carson KV**, Brinn MP, Peters M, Veale A, Esterman AJ, Smith BJ. Interventions for smoking cessation in Indigenous populations (Review). *Cochrane Database of Systematic Reviews* 2012, Issue 1. Art. No.: CD009046. DOI: 10.1002/14651858.CD009046.pub.2 (IF 5.939)
13. **Carson KV**, Labiszewski NA, Brinn MP, Veale A, Chang AB, Esterman AJ, Smith BJ. Interventions for smoking prevention in Indigenous youth. PROTOCOL. *Cochrane Database of Systematic Reviews* 2011, Issue 9. Art. No.: CD009325. DOI: 10.1002/14651858.CD009325 (IF 5.939)

14. **Carson KV**, Brinn MP, Veale A, Esterman AJ, Smith BJ. Interventions for smoking cessation in Indigenous populations. Protocol: *Cochrane Database of Systematic Reviews* 2011, Issue 3. Art. No.: CD009046. DOI: 10.1002/14651858.CD009046 (IF 5.939)

Peer-reviewed book chapters (n= 2 related to PhD work)

15. **Carson KV**, Verbiest MEA, Brinn MP, Crone MR, Esterman AJ, Assendelft WJJ, Smith BJ. Chapter 2 in hard copy (2014): ‘Training health professionals in smoking cessation care’ in the book ‘The implementation of smoking cessation care in general practice’. Editor: Verbiest MEA. 2014 pp23-80; Publisher: Optima BV Rotterdam, The Netherlands; ISBN: 978-90-9028611-2
16. **Carson KV**, Robertson T, Brinn MP, Peters M, Veale A, Esterman AJ, Smith BJ. Chapter title: Tobacco use, prevention and cessation for Indigenous populations around the world: A systematic review and narrative synthesis. Chapter 1; Book title: *Health Disparities: Epidemiology, Racial/Ethnic and Socioeconomic Risk Factors and Strategies for Elimination*. Edited by: Jackson OT, Evans KA. (*Hard copy and print; 2013*) p1-38; ISBN: 978-1-62618-570-8; Nova Publishers

Presentations: (Total number of PhD presentations n=70)

Keynote speaker presentations at conferences:

1. Carson KV. Keynote speaker for the YWCA (Young Women's Christian Association) of Adelaide for SHE Leads Young Women Conference about my journey to becoming a scientist and what young women can do to take charge and make a positive change in their lives; Conference theme is Power to change Women's Leadership (21/08/2015; Stamford Plaza Hotel)
2. Carson KV. Keynote speaker for the YWCA (Young Women's Christian Association) of Adelaide for SHE Leads High Conference about my journey to becoming a scientist and what young women can do to take charge and make a positive change in their lives (08/05/2015; Stamford Plaza Hotel)
3. Carson KV, Brinn MP, Labiszewski NA, Peters MJ, Veale AJ, Smith BJ. Interventions for smoking cessation in Indigenous populations: A Cochrane Systematic Review. *Thoracic Society of Australia and New Zealand*, March 2012, Canberra; Invited by Dr Peter Franklin, Chair of the Tobacco Special Interest Group, TSANZ
4. Carson KV, Brinn MP, Labiszewski NA, Peters MJ, Veale AJ, Smith BJ. Interventions for smoking cessation in Aboriginal Australians: A Meta-analysis. *Thoracic Society of Australia and New Zealand*, March 2012, Canberra; Invited by Dr Peter Franklin, Chair of the Tobacco Special Interest Group, TSANZ

(NOTE: The two abstracts above were selected as a combined 'key note' oral presentation (30 minute duration), which subsequently received an award being 'The Tobacco Control Prize' for the best oral presentation)

Invited conference presentations

5. Carson KV. Smoking cessation in COPD – current evidence and future directions. *South Australian and Northern Territory Annual Scientific Meeting for the Thoracic Society of Australia and New Zealand, September, 2014 Adelaide* (15 minutes + 5 minutes question time); Invited by President of the Society Dr Chien-Li Holmes-Liew, TSANZ

Oral conference presentations:

6. Carson KV, Jayasinghe H, Van Agteren J, Ameer F, Smith BJ. Mass media interventions for preventing smoking in young people: A Cochrane systematic analysis. *Asia Pacific Society of Respiriology*, Kuala Lumpur, Malaysia, 2nd to the 6th of December 2015
7. Carson KV, Smith BJ, Peters MJ, Veale AJ, Esterman AJ. Superiority of a course of varenicline tartrate plus counselling over counselling alone for smoking cessation: A 24-month randomised controlled trial for inpatients. *Asia Pacific Society of Respiriology*, Kuala Lumpur, Malaysia, 2nd to the 6th of December 2015
8. Carson KV, Smith BJ, Jayasinghe H, Van Agteren J, Peters MJ, Veale A, Singh K, Esterman AJ. Culturally tailored programs to help Indigenous smokers quit may be successful in closing the gap. *Oceania Tobacco Control Conference*, Perth, Australia, 20th to the 22nd of October 2015
9. Carson KV, Jayasinghe H, Van Agteren J, Peters MJ, Veale A, Esterman AJ, Smith BJ. Indigenous youth tobacco prevention programs may be causing more harm than good. *Oceania Tobacco Control Conference*, Perth, Australia, 20th to the 22nd of October 2015
10. Carson KV, Smith BJ, Peters MJ, Veale A, Singh K, Esterman AJ. Inpatient smokers quit following acute life threatening event with use of varenicline plus Quitline counselling. *Oceania Tobacco Control Conference*, Perth, Australia, 20th to the 22nd of October 2015
11. Carson KV, Smith BJ, Brinn MP, Peters MJ, Fitridge RA, Litt JC, Koblar SA, Jannes J, Veale AJ, Goldsworthy SJ, Singh K, Esterman AJ. Superiority of varenicline tartrate plus counselling over counselling alone for long-term smoking cessation: 24 month follow-up of a randomised controlled trial. Basil Hetzel Institute for Translational Health Research 2015 Research Day, October 2015
(Awarded best oral presentation by a Senior Clinical Researcher)

12. Carson KV, Peters MJ, Esterman AJ, Veale AJ, Smith BJ. Superiority of a course of varenicline tartrate plus counselling over counselling alone for smoking cessation: A 12-month randomised controlled trial for inpatients. *Australians Society for Medical Research Annual Scientific Meeting*, Adelaide June 3 at the National Wine Centre (***Award winning oral 'Ross Wishart Memorial Award for best presentation at the Australian Society of Medical Research conference'***)
13. Carson KV, Brinn MP, To-A-Nan R, Jayasinghe H, Mackenzie L, Medley G, Liu X, Esterman AJ, Roberts M, Smith BJ. Can nicotine replacement therapy delivered via continuous patch cause auto-induction (up-regulation of receptors)?: A pilot study. *TSANZ April 2015, Gold Coast, Queensland* (***Award winning oral 'The Tobacco Control Prize' for the best oral presentation***)
14. Carson KV, To-A-Nan R, Robertson M, King C, Smith BJ. Community pharmacy personnel interventions for smoking cessation: A Cochrane systematic review and meta-analysis. *TSANZ April 2015, Gold Coast, Queensland*
15. Carson KV, Jayasinghe HP, Ali A, Singh K, Peters M, Esterman AJ, Gould G, Veale A, Newchurch J, Smith BJ. Culturally-tailored interventions for smoking cessation in Indigenous populations: A Cochrane systematic review and meta-analysis. *TSANZ April 2015, Gold Coast, Queensland* (***Awarded 'Best oral presentation for the TSANZ Evidence Based Medicine Special Interest Group'***)
16. Carson KV. Barriers and enablers for the use of smoking cessation pharmacotherapy in Aboriginal and Torres Strait Islander populations: A qualitative analysis. *TQEH (The Queen Elizabeth Hospital), Basil Hetzel Institute for Translational Health Research: Research Day Conference* Adelaide, October 2014
17. Carson KV, Peters M, Esterman AJ, Veale A, Brinn MP, Bradley H, Newchurch J, Meagher S, Smith BJ. Barriers and enablers to the use of smoking cessation pharmacotherapy in Aboriginal and Torres Strait Islander populations: A qualitative analysis. *Thoracic Society of Australia and New Zealand, April 2014, Adelaide* (***Award winning abstract – Selected for the TSANZ Janet Elder International Travel Award***)

18. Hnin K, Carson KV, Brinn MP, Jannes J, Esterman AJ, Smith BJ. Triggers resulting in relapse: Cohort analysis from the Smoking Termination Opportunity for inpatients (STOP) trial. *Thoracic Society of Australia and New Zealand, April 2014, Adelaide*
19. Carson KV, Peters M, Esterman AJ, Veale A, Brinn MP, Bradley H, Newchurch J, Meagher S, Smith BJ. Respiratory health service delivery and utilisation by Aboriginal and Torres Strait Islander Australians: A qualitative analysis of the barriers and enablers to optimal medical management. *Thoracic Society of Australia and New Zealand, April 2014, Adelaide*
20. Carson KV, Labiszewski NA, Brinn MP, Peters M, Chang A, Veale A, Esterman A, Smith BJ. Interventions for tobacco prevention in Indigenous youth: A Cochrane review and a narrative synthesis. *Thoracic Society of Australia and New Zealand, March 2013, Darwin*
21. Dalziel K, Brinn M, Carson K, Labiszewski N, Esterman A, Smith B. Cost effectiveness of an inpatient smoking cessation intervention for patients with tobacco related illnesses (STOP trial): A multi-centre randomised controlled study. *Health Services Research Association of New Zealand. Wellington New Zealand, December 2013*
22. Carson KV. Interventions for tobacco prevention in Indigenous youth: A Cochrane review and narrative synthesis. *TQEH (The Queen Elizabeth Hospital), Basil Hetzel Institute for Translational Health Research: Research Day Conference Adelaide, October 2013*
23. Brinn MP, Dalziel K, Carson KV, Labiszewski NA, Esterman AJ, Smith BJ. Cost effectiveness of an inpatient smoking cessation intervention for patients with tobacco related illnesses (STOP Trial): A multi-centre RCT. *Thoracic Society of Australia and New Zealand, March 2013, Darwin (Award winning oral 'The Tobacco Control Prize' for the best oral presentation)*
24. Smith BJ, Carson KV, Brinn MP, Labiszewski NA, Peters MJ, Fitridge RA, Litt JC, Koblar SA, Jannes J, Veale AJ, Goldsworthy SJ, Edwards D, Esterman AJ. Superiority of varenicline tartrate plus counselling over counselling alone for

smoking cessation: A 52 week randomized controlled trial. ATS May 2012, San Francisco, California

(NOTE: Of all abstracts submitted for the 2012 ATS, this research was one of only seven selected for an oral presentation in the 'Late breaking clinical trials' session, chaired by Dr David Hau, Chair of the International Conference Committee (ATS International conference 'Highlights for Clinicians'))

25. Carson KV, Verbiest MEA, Brinn MP, Crone MR, Esterman AJ, Assendelft WJJ, Smith BJ. Training health professionals in smoking cessation: A Cochrane Systematic Review. *Thoracic Society of Australia and New Zealand*, March 2012, Canberra
26. Carson KV, Brinn MP, Labiszewski NA, Peters MJ, Veale AJ, Smith BJ. Interventions for smoking cessation in Indigenous populations: A meta-analysis. *TQEH (The Queen Elizabeth Hospital), Basil Hetzel Institute for Translational Health Research: Research Day Conference Adelaide*, October 2011

Poster conference presentations:

27. Carson KV, Jayasinghe H, Pollok J, Singh K, Peters MJ, Veale A, Van Agteren J, Esterman AJ, Smith BJ. Smoking cessation pharmacotherapy: An underutilised quit smoking resource for Aboriginal and Torres Strait Islander Australians. *Oceania Tobacco Control Conference, Perth, Australia, 20th to the 22nd of October 2015*
28. Carson KV, Jayasinghe H, Peters MJ, Esterman AJ, Veale AJ, Smith BJ. Barriers and enablers for use of smoking cessation pharmacotherapy for tobacco addiction among Aboriginal and Torres Strait Islander Australians: A mixed method analysis. *The University of Adelaide, Faculty of Health Sciences Post-graduate research conference: National Wine Centre, Adelaide, August 2015*
29. Carson KV, Jayasinghe HP, Peters MJ, Esterman AJ, Veale A, Brinn MP, Bradley H, Newchurch J, Smith BJ. Barriers and enablers for the use of smoking cessation pharmacotherapy in Aboriginal and Torres Strait Islander populations: A

qualitative analysis. *Postgraduate Research Conference; National Wine Centre, September 2014, Adelaide*

30. Carson KV, Brinn MP, Peters M, Veale A, Esterman AJ, Smith BJ. Interventions for tobacco use cessation in Indigenous populations: A Cochrane meta-analysis. 2014 May. *American Thoracic Society Conference* San Diego, California, United States of America
31. Carson KV, Peters M, Esterman AJ, Veale A, Brinn MP, Clifton V, Bradley H, Newchurch J, Meagher S, Smith BJ. Smoking during pregnancy and tobacco abuse prevention in Aboriginal and Torres Strait Islander youth: A qualitative analysis. *Thoracic Society of Australia and New Zealand, April 2014, Adelaide*
32. Carson KV, Brinn MP, Peters MJ, Veale A, Esterman AJ, Smith BJ. Interventions for tobacco use prevention in Indigenous youth: A Cochrane review and a narrative synthesis. *Postgraduate Research Conference; National Wine Centre, August 2013, Adelaide*
33. Carson KV, Brinn MP, Labiszewski NA, Peters MJ, Veale AJ, Smith BJ. Interventions for smoking cessation in Indigenous populations: A meta-analysis. The University of Adelaide, Faculty of Health Sciences Post-graduate research conference: National Wine Centre, Adelaide, August 2011

Other (non-conference) ‘keynote’ oral presentations:

34. Carson KV. Invited Plenary Speaker for The Queen Elizabeth Hospital Grand Rounds for the 1st of September 2015 about the Indigenous tobacco research undertaken during the PhD; Invited by Professor John Beltrame, Michell Professor of Medicine, 45 minute presentation to approximately 100 clinicians, scientists, doctors, trainees and allied health professionals
35. Carson KV, with Gill Hicks, John Swann and Vince Coulthard as representatives of the South Australian, Australian of the Year national finalists. A tour of honour is scheduled for June 2015, which will include multiple presentations across three days in schools and other forums around South Australian including inner regional Australia (Yorke Peninsula).

36. Carson KV. Invited speaker for the Playford Trust Networking Evening; Spoke about my journey to becoming a scientist and how to network in a scientific research setting (14/05/2015) at The Queen's Head Hotel, North Adelaide
37. Carson KV. Keynote speaker for the City of Marion Youth Recognition Awards as part of National Youth Week; Spoke about my journey to becoming a scientist, the research that I do and positive messages for young people (13/04/2015)
38. Carson KV. 'My journey to becoming a scientist'; *University of South Australia Golden Key new member reception* as Honorary Member and Keynote speaker for the Golden Key International Honour Society (Uni SA chapter) at Brookman Hall, UniSA City East Campus (approx. 500 people;)
39. Carson KV (Young Australian of the Year for SA), with Gill Hicks (Australian of the Year for SA), John Swan (Senior Australian of the Year for SA) and Vince Coulthard (SA Local Hero) invited for a corporate Panel Discussion hosted by Brand South Australia with ABC radio personality Ian Henschke as the MC. Each of us spoke about our journey to becoming SA Australian of the Year representatives, what we do now and what we plan on doing next (50 minutes; 17/02/2015; Adelaide Convention Centre; approx. 250 guests)
40. Carson KV, Special Guest Speaker for the Ocean View College Year 12 Graduation Ceremony to talk about my journey since leaving year 12 and how I became a scientist. 6th of August 2014 (20 minute oral to graduates, teachers and student's family/friends – approximately 250 people; 09/12/2014).
41. Carson KV, Special Guest Speaker for the Kildare College Annual Awards Ceremony to encourage young women into science about to talk about my journey to becoming a scientist. 6th of August 2014 (15 minute oral to the entire school assembly).
42. Carson KV, Special Guest Speaker for the Morphett Vale East Primary School Year 7 Graduation Ceremony to talk about my journey from school to becoming a scientist. 6th of August 2014 (10 minute oral to graduates, teachers and student's family/friends – approximately 400 people; 14/11/2014)

Other (non-conference) invited oral presentations:

43. Carson KV, Invited Plenary Speaker for The Queen Elizabeth Hospital Ground Rounds, September 2015 by Prof John F Beltrame (Michell Professor of Medicine, The University of Adelaide), related to PhD Indigenous research, with a specific focus on the clinical aspects of evidence translation (approximately 100 professors, doctors, registrars, interns, medical students and other allied health professionals; 45 minutes)
44. Carson KV, Special Guest Speaker for the Asthma Foundation of South Australia to speak about my journey to becoming a scientist and the work being done at The Queen Elizabeth Hospital, particularly related to smoking and Aboriginal health as per my PhD. Invited by David Bedson, CEO of Asthma Foundation South Australia (13/05/2015); Presented at the Asthma Foundation, South Road, Hilton in the presence of the CEO for Asthma Foundation Australia, Mark Brooke
45. Carson KV, Special Guest Speaker for the Rotary Club of Adelaide Light where I spoke about becoming a scientist and winning the Young Australian of the Year for South Australia as well as a brief showcase of research activities from my work at TQEH (approximately 40 people; 05/03/2015)
46. Carson KV, Special Guest Speaker for the Rotaract Club of Adelaide (youth chapter of Rotary) where I spoke about becoming a scientist and winning the Young Australian of the Year for South Australia as well as a brief showcase of research activities from my work at TQEH (approximately 30 people; 09/02/2015)
47. Carson KV, Special Guest Speaker for the Rotary Club of Prospect (45 minutes) where I spoke about how I became the Premier's and Channel 9 Young Achiever of the Year and gave a summary of the research being undertaken at The Queen Elizabeth Hospital in Respiratory Medicine (Approximately 35 people; 05/11/2014)
48. Carson KV, Special Guest Speaker for Lung Foundation Australia '2014 Lung Health Education Day' at AAMI Stadium on 'How do we know this treatment

works? Information for patients (consumers) needs to be a 2-way process' (Approximately 60 people; 30/10/2014)

49. Carson KV. Launch of the Premier's Channel 9 Young Achiever of the Year for 2015. Invited to give a speech relating to winning the 2014 overall award and the achievements within the last six months since winning the award at Ri Aus, Adelaide City Centre (16/09/2014)
50. Carson KV, 'I almost failed year 12 but look who's a scientist now'; invited speaker for the Science Alive Careers Day at the Adelaide Show Grounds by Ian Maynard
51. Carson KV, 'The importance of networking and how to become an academic Kardashian' 1st of August 2014; Invited guest speaker for the Early Career Research Career Development Session for PhD students in Marketing, Management and International Business, The University of Adelaide, School of Engineering; (40 minute oral presentation and 20 minute Q+A panel session)
52. Carson KV, 'Networking through a PhD' 3rd of June 2014; One of three guest speakers invited by The Australian Society of Medical Research in collaboration with Healthy Development Adelaide for a paid dinner presentation evening held at the University of South Australia, North Terrace (20 minute presentation)
53. Carson KV, 'A research overview from the Respiratory Medicine Department, TQEH: The good, the bad and the breathless', 13th of May 2014; Invited by Prof Alastair Burt, Dean of Medicine, Head of the School of Medicine, The University of Adelaide for the Research Highlights session at the University (20 minute presentation + 10 minute discussion time)
54. Carson KV, 'Tobacco use, cessation and prevention: Current evidence for practice and research initiatives' Repatriation General Hospital, 28th of June 2013; Invited by Dr Nick Antic and Dr Staya Mysore for the Adelaide Institute of Sleep Health (45 minute presentation)
55. Carson KV, 'Research, capacity building and clinical practice improvement initiatives', Flinders University 25th of June 2013; Invited by Dr Dimitar Sajkov

(CEO Australian Respiratory and Sleep Medicine Institute and Director Southern sleep) for the Southern Respiratory Services Academic Meeting (40 minute presentation)

56. Carson KV, 'Improving health for Aboriginal people through tobacco related research'; Nunkuwarrin Yunti Health Service Wakefield Street, April 2013; Invited by Aboriginal Health Council of South Australia tackling smoking co-ordinator (1 hour presentation)
57. Carson KV, Current evidence for smoking cessation and tobacco prevention; 12th of July 2012, Aboriginal Health Council of South Australia, invited by Ruth Miller (tackling smoking co-ordinator); Also discussed current research we are doing and asked advice from the Elders present (approximately 15 Elders; 30 minute presentation)
58. Carson KV, 'The Clinical Practice Unit: Research, capacity building and clinical practice improvement initiatives' Lyell McEwin Health Service, Grand Round; July 2012; Invited by Professor Brian Smith, Director of Respiratory Medicine, The Lyell McEwin Health Service (10 minutes)

Other oral presentations:

59. Carson KV. Advancing treatment options for tobacco cessation, prevention and related illnesses, with particular reference to Indigenous populations and Aboriginal Australians. Post-graduate final presentation for the University of Adelaide. *Basil Hetzel Institute for Translational Health Research (30 minutes)* Adelaide, July 7th 2015
60. Carson KV. Advancing the understanding of tobacco use, prevention, cessation and related illnesses in Indigenous populations, with particular reference to Aboriginal Australians. Post-graduate annual presentation for the University of Adelaide. *Basil Hetzel Institute for Translational Health Research (20 minutes)* Adelaide, September 2014

61. Carson KV. Advancing the understanding of tobacco use, prevention, cessation and related illnesses in Indigenous populations, with particular reference to Aboriginal Australians. Post-graduate annual presentation for the University of Adelaide. *Basil Hetzel Institute for Translational Health Research (20 minutes)* Adelaide, October 2013
62. Carson KV. \$1.6 billion... up in smoke. Written application, publication and voice recording accepted as 1 of 8 finalists for the South Australian Young Investigator Award, Adelaide, Women's and Children's Hospital, Queen Victoria Lecture Theatre, September 2013 (5 minutes + question time)
63. Carson KV. Aboriginal health research at The Queen Elizabeth Hospital. *Aboriginal Health Research Network Meeting (5 minutes)* Cottage A, 223 Angus St Adelaide, August 2013
64. Carson KV. Research and capacity building in Respiratory Medicine: The role of the CPU. *The Queen Elizabeth Hospital Respiratory Medicine Business Meeting (20 minute)*; Adelaide, September 2013
65. Carson KV. \$1.6 billion... up in smoke. Oral presenter for the University of Adelaide's Three Minute Thesis Faculty of Health Sciences Final; The University of Adelaide, Hone Lecture Theatre, July 2013
66. Carson KV, Labiszewski NA, Brinn MP, Peters M, Chang A, Veale A, Esterman A, Smith BJ. Interventions for tobacco prevention in Indigenous youth: A Cochrane review and a narrative synthesis. Abstract accepted as 1 of 4 finalists for the South Australian and Northern Territory TSANZ Young Investigator Award; Adelaide, Ayres House Nov 2012 (10 minute oral presentation) (**Award winning presentation – Recipient of the SA/NT TSANZ Young Investigator Award**)
67. Carson KV, Brinn MP, Labiszewski NA, Peters MJ, Veale AJ, Smith BJ. Interventions for smoking cessation and tobacco prevention in Indigenous populations: Post-graduate annual presentation for the University of Adelaide. *Basil Hetzel Institute for Translational Health Research (20 minutes)* Adelaide, May 2012

68. Carson KV, Brinn MP, Labiszewski NA, Peters MJ, Veale AJ, Smith BJ. Interventions for smoking cessation in Indigenous populations: A Cochrane meta-analysis. *The Queen Elizabeth Hospital Respiratory Medicine Business Meeting (20 minute)*; Adelaide, April 2012
69. Carson KV, Brinn MP, Labiszewski NA, Peters MJ, Veale AJ, Smith BJ. Interventions for smoking cessation and tobacco prevention in Indigenous populations: Core components for post-graduate studies for the University of Adelaide. *Basil Hetzel Institute for Translational Health Research (20 minutes)* Adelaide, July 2011
70. Carson KV. Tobacco use cessation for Indigenous populations. Abstract accepted as 1 of 5 finalists for the South Australian and Northern Territory TSANZ Young Investigator Award; Adelaide, Ayres House Oct 2011 (10 minute oral presentation + 5 minutes for questions)

Membership of committees and working parties associated with the PhD

- 2015-Present TSANZ: Elected Primary Chairperson of the Evidence Based Medicine Special Interest Group at the Gold Coast ASM
- 2015-Present Advisory board member for “Kick.it” smoking cessation application for android and mobile phones that connects with the Apple watch; The apple watch connected with the phone tracks cigarettes, cravings and suggests different interventions/techniques to help patients get through the craving and quit smoking
- 2013-2015 TSANZ: Elected Primary Chairperson of the Tobacco and Addictive Substances Special Interest Group at the Darwin ASM
- 2013-Present Member of the National Aboriginal and Torres Strait Islander Social Survey Reference Group for the Australian Bureau of Statistics
- 2013-Present Member of the SA Health Young Professionals Group
- 2013-Present Member of the SA Aboriginal Health Research Network
- 2013-Present Research member of Healthy Development Adelaide (The University of Adelaide)
- 2012-present Founding member of the ‘Indigenous Respiratory Health Working Party’ for the ‘Thoracic Society of Australia and New Zealand’ supported by the society and the current President of the TSANZ: Professor Matthew Peters and Chief Executive Officer of the TSANZ: Rita Perkins (Became recognised as an official research branch within the TSANZ in 2013)
- 2012-2013 TSANZ: Elected Deputy Convenor of the Tobacco and Addictive Substances Special Interest Group at the Canberra ASM
- 2011-Present Invited member of the Aboriginal and Torres Strait Islander Health working party
- 2010-Present Voting member of the Tobacco and Addictive Substances and Evidence Based Medicine Special interest groups of the Thoracic Society of Australia and New Zealand

- 2010-Present Invited member of The Central Northern Adelaide Health Service Smoke Free policy steering committee
- 2009-Present Invited member of The Queen Elizabeth Hospital Smoke Free policy steering committee

Summary

Despite the substantial progress made over the past decade, tobacco use is still a leading cause of preventable morbidity and premature mortality in the world. This thesis examined how to improve the uptake and success of smoking cessation and tobacco prevention interventions among some of the most prevalent tobacco users in Australia, being Indigenous populations and long-term tobacco users who have already developed tobacco-related illnesses.

Although mainstream tobacco cessation programs have reduced population-level smoking, they have done little to close the gap between Indigenous and non-Indigenous populations. Therefore options specifically tailored for the Indigenous setting need to be considered. A meta-analysis of four culturally-tailored smoking cessation interventions in Indigenous populations (*Chapter 4*) produced some limited evidence of efficacy in favour of the interventions ($p=0.03$). Likewise, a similar evaluation for youth tobacco prevention found only two studies, limiting the ability to draw reliable conclusions (*Chapter 5*).

Building on these findings, qualitative studies of Aboriginal Elders, key community stakeholders and health professionals revealed several barriers and facilitators for smoking cessation pharmacotherapy amongst Aboriginal Australian populations (*Chapter 6*). A national survey of current practice by Respiratory doctors and allied health professionals found similar results (*Chapter 7*). Finally a commissioned systematic literature review, found that combined pharmacotherapy and culturally-adapted interventions are effective in reducing tobacco prevalence (*Chapter 8*). Research in the Indigenous setting often poses methodological challenges, but options are available to overcome these problems (*Chapter 9*).

Several pharmacotherapeutic options are available to aid long-term abstinence including varenicline tartrate, bupropion hydrochloride and nicotine replacement therapy (*Chapter 10*). However, amongst some populations where attitudes of nihilism and clinical indifference are common, the benefits of tobacco cessation are not considered worth the effort it would take to quit. Smoking cessation can result in improved treatment outcomes amongst lung cancer patients (*Chapter 11*) and quitting in later life can still reduce the risk of developing some smoking-related illnesses (*Chapter 12*).

Following hospitalisation of current smokers due to a serious tobacco-related illness, a randomised controlled trial found varenicline tartrate plus Quitline counselling to be superior to Quitline counselling alone with 31.1% (n=61) and 21.4% (n=42) continuously abstinent respectively at 12-month follow-up (*Chapter 13*). Despite safety concerns of increased cardiovascular and neuropsychological events in acutely unwell people, none were identified amongst the 392 subjects recruited into the trial (*Chapter 14*).

Finally a third Cochrane meta-analysis (*Chapter 15*) revealed that patients of health professionals trained in smoking cessation techniques were more likely to achieve smoking abstinence (p=0.03) compared to untrained health professionals.

The evidence produced in this thesis suggests that with appropriate training and resources, health professionals working in Indigenous populations can facilitate smoking cessation and reduce the uptake of smoking. Translational research is needed to explore the most effective ways to achieve these outcomes and bridge the gap between resource development and implementation into policy and practice. Until a greater focus is placed on evidence translation, we cannot effectively advance treatment options for tobacco cessation, prevent uptake amongst youth and ultimately avoid tobacco-related illnesses.

Chapter 1. Introduction

Sixty five years ago this year, 2015, the landmark case-control study by Sir Richard Doll was published in the British Medical Journal reporting for the first time in medical literature the association between smoking and lung cancer (1). Six years later, Doll *et.al*, went on to report the link between smoking and heart disease (2) and in 1981 Hirayama *et.al*, from Japan reported the link between passive smoking and lung cancer (3). Despite these and the many other known health effects caused by smoking, global efforts to curtail tobacco use and the subsequent health effects that ensue have been unsuccessful in eradicating what is known today as the ‘tobacco epidemic’.

1.1 Smoking related disease burden

Smoking accounts for 15% of all deaths, 80% of all lung cancer deaths and is responsible for the greatest disease burden in Australia (4, 5). Lifelong smokers have a 50-60% chance of dying from smoking-related diseases such as peripheral vascular disease, which frequently requires limb amputation (6-8). Smoking also causes impaired vascular endothelial function, which leads to atherosclerosis. In 2015 a study published in the New England Journal of Medicine revealed several conditions not previously believed to be associated with tobacco use, including subjects with renal failure, infections, various respiratory diseases, breast and prostate cancer and hypertensive heart disease amongst others, resulting in significant mortality (9). A 2008 economic evaluation estimated the social cost of tobacco use in Australia (including health related costs) to be \$31.5 billion per annum (10), with annual health care costs of \$6 billion attributable to tobacco use (11). Smokers on the lowest incomes are the most affected financially as smoking exacerbates poverty (12).

1.1.1 Reductions in population-level smoking:

Post World War II there have been substantial reductions in the prevalence of smoking in Australia, going from rates of 72% amongst males in 1945 (13) to 27% only 50 years later in 1995 (14). However, over this same period of time prevalence amongst females increased from 26% in 1945 to 33% in 1976, then dropped to 21% in 2001 (13). Over the past 20 years primary prevention initiatives have had some impact on reducing population-level smoking rates, but the majority of smoking related problems in society persist (15). The population decline in tobacco use observed since World War II has now plateaued.

These early reductions were believed to be associated with government funded anti-smoking campaigns that focussed on scare-tactics. However, given that the rates of decline have now stalled, there is evidence to suggest that the health-scare approach is no longer effective (15).

1.1.2 Smoking is difficult to stop:

Nicotine dependence is a chronic disease and often requires multiple quit attempts for successful long-term abstinence. Just over half of all current smokers are seriously thinking about quitting in the next six months, and nearly half made a quit attempt in the last 12 months (7). Of the available initiatives, General Practitioner's (GPs) significantly under-use counselling services or medications, and only 6% of patients who are encouraged to use Quitline counselling, by their GP do so (7). Smokers, for their part, rarely plan quit attempts (16), and the 12 month follow-up of unassisted quit attempts demonstrates only 3-5% success (17).

1.1.3 Benefits of quitting:

Cessation of smoking by age 40 almost normalises life expectancy, adding approximately 9 years of "healthy life" compared to ongoing smokers, with favourable cost effectiveness ratios of less than 10,000 British pounds per quality adjusted life year gained (18). The excess risk of cardiovascular disease halves within one year of smoking cessation, peripheral vascular disease prognosis improves considerably, cancer risk reduces by 30-50% after 10 years abstinence, and lung function improves by 5% within months of quitting (6). One Australian study found that a hypothetical 1% reduction in absolute smoking over 12-months (between 2001-2) would have resulted in 1000 fewer hospitalisations for acute myocardial infarction and 350 fewer hospitalisations for stroke, producing a cost saving of over \$20.4 million in direct health care costs (19). Abstinence from smoking, following an admission to hospital, has been associated with reduced readmissions. (20) Five year follow-up of patients who stop smoking by the time of discharge resulted in:

1. 31% less hospital admission bed days;
2. 13% less outpatient visits, and
3. 50% less bed days used compared to those that continue smoking (20).

1.2 Tobacco use among Indigenous populations globally

Prevalence for tobacco use amongst the Indigenous populace is often double that of the relevant non-Indigenous population, with estimates of 41% vs 18% in Australia (21), 41% vs 15% in New Zealand (22) and 26% vs 18% in the United States for American Indians and Alaska Natives (23), respectively. Several studies discussed the importance of tobacco use in cultural and spiritual traditions among numerous Indigenous populations (24-26).

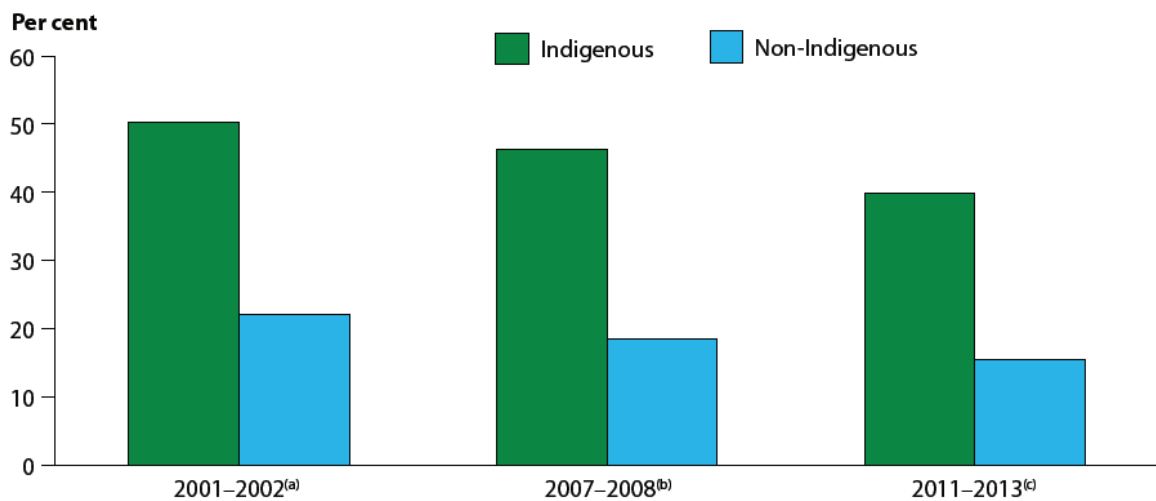
For South American native communities tobacco is important for ceremonial, religious and medicinal purposes (27, 28), including use as burial offerings, for spiritual protection or as a gift to the Creator (29, 30). Among American Indians tobacco use has a long and complicated history, with early use for ceremonial and therapeutic means, and later cultivation and trade with European settlers (29). On a similar note, tobacco trading developed quickly among New Zealand Māori during early European settlement (31). Tobacco has a deep-rooted history in many Indigenous settings with cultural implications that need to be respected. There is, however, a clear distinction between traditional tobacco use and the abuse of tobacco, which led to health inequalities (32) and over-representation of Indigenous peoples in the burden of tobacco-related morbidity and premature mortality.

1.2.1 Tobacco use among Aboriginal and Torres Strait Islander Australians:

The historical evolution of tobacco in the Indigenous Australian setting stems from its use as part of government rations, as a means of payment for services (33, 34), and as one report suggests, to pacify and exploit the Indigenous owners of the land (24). Unlike the non-Indigenous population where tobacco prevalence has steadily decreased since its wide-spread use during World War II (13), in the Indigenous setting tobacco smoking remains more than two and a half times that of the non-Indigenous (35). Recent studies cited stress relief and a means of signalling a few personal moments of ‘time out’ to be chief amongst the reasons for the high prevalence of smoking (36, 37). The way stress is experienced in the Indigenous setting is reported to be different to the non-Indigenous with factors such as socio-economic conditions (low income, housing problems and unemployment), family and work expectations, relationship problems, family violence, racism, life-threatening events and deaths in the extended family (36). Prevalence estimates have fallen significantly from 49% down to 41% between 2002 and 2014, indicating that smoking cessation interventions can be effective. Although population-wide reductions in tobacco prevalence have been observed over the past decade (35), mainstream smoking cessation strategies have done little to close the gap between Indigenous and non-Indigenous populations (38). This consistent gap is evident when

comparing percentage change over time for Indigenous and non-Indigenous current daily smokers, as presented in *Figure 1*.

Figure 1: Percentage of current daily smokers in Australia by Indigenous status, people aged 18 and over (age-standardised), 2001–2002 to 2011–2013



(a) Data from 2001 National Health Survey (39) and 2002 National Aboriginal and Torres Strait Islander Social Survey (40). (b) Data from 2008 National Aboriginal and Torres Strait Islander Social Survey (41) and 2007–08 National Health Survey (42). (c) Data from 2011–12 Australian Health Survey (43) and 2012–13 National Aboriginal and Torres Strait Islander Health Survey (21, 44).

Moreover, it is well established that addiction to nicotine usually begins during early adolescents. One Queensland study found experimentation to begin as early as 7 years of age and by the age of 12, 26% of Indigenous and 19% of non-Indigenous youth had begun smoking (45). Similar results were found in Western Australia, with the average age of reported first use of tobacco being 9.7 years amongst Aboriginal Australians (46). Moreover, 24% had begun smoking before eight years of age and 71% of the study population had commenced tobacco use by age 13 (46).

Even with this enduring gap and evidence of tobacco use commencing at an early age, very little methodologically rigorous research has been conducted to evaluate and/or enhance the uptake of smoking cessation and tobacco prevention interventions among Aboriginal and Torres Strait Islander Australians.

1.2.2. Smoking related disease burden among Indigenous Australians:

Tobacco use is considered to be the biggest contributor to the epidemic of non-communicable disease in the Western Pacific region (36), with smokers being more susceptible to diseases such as tuberculosis and pneumonia. Tobacco use among Indigenous Australians is reported to contribute to 80% of chronic obstructive pulmonary disease (47), 80% of all lung cancer deaths (36), 37% of ischemic heart disease, 9% of all strokes and 5% of all low birth-weight babies (36). One Queensland study analysing morbidity and mortality amongst Aboriginal and Torres Strait Islander (TSI) Australians found that the contribution of tobacco to the total burden of disease was six times greater for Indigenous than non-Indigenous people (48). Approximately 80% of the Indigenous mortality gap (in terms of potential years of life lost) can be attributed to chronic disease and an analysis of 11 risk factors related to death and illness among Indigenous Australians calculated that tobacco smoking accounted for 12.1% of the entire burden of disease, which was more than any other risk factor and more than the burden attributable to alcohol and illicit drugs combined (36). Subsequently, national statistics report that Aboriginal and TSI people are twice as likely to be admitted to hospital compared to the non-Indigenous population, despite likely under-reporting of Indigenous separation statistics (36). Indigenous health care expenditure accounts for 3.3% of national expenditure and 8.5% of all government expenditure in 2008-9, or AUD\$3.60 for every \$1.00 spent per non-Indigenous Australian (49). Moreover, recent estimates of the economic impact from an 8% reduction in the prevalence of tobacco smoking in Australia would result in 158,000 fewer incident cases of disease, 5000 fewer deaths, 2.2 million fewer lost working days, 3000 fewer early retirements and would reduce health sector costs by AUD\$491 million (50). Currently, Australia has one of the world's worst life expectancy gaps (of more than 10 years) between Indigenous and non-Indigenous people, despite government funded initiatives in excess of AUD\$2.34 billion aimed at eliminating the inequality gap and improving health (36, 51).

1.2.3 Smoking cessation interventions amongst Indigenous populations:

See related publication Chapter 4.

Despite the high prevalence of tobacco use amongst Indigenous populations, the majority of research programs continues to occur within the non-Indigenous setting, with little cultural-tailoring for the former population (52-55). The inability of these programs to reduce the gap in tobacco prevalence between Indigenous and non-Indigenous peoples could be due to several factors. For example, campaigns may not reach the target audience, may not be linguistically or culturally appropriate, may not be evidence based or may not

be delivered by an appropriate person or medium. Even if smoking is accepted as harmful, it may be a low priority behind other concerns such as substance abuse problems, levels of education or other environmental or familial concerns. Another possibility is that there is in fact no difference in program reach or efficacy and that the ongoing differences in smoking rates are associated with poverty, unemployment or other aspects of the social context of smoking. As such, a systematic review and meta-analysis that aims to consolidate evidence of effectiveness for smoking cessation interventions that are culturally-tailored for the Indigenous population is required to inform clinical practice, policy and research (*presented in Chapter 4*).

1.2.4 Tobacco prevention interventions amongst Indigenous youth:

See related publication Chapter 5.

Amongst Indigenous youth there is a greater emphasis for tobacco use in a social context above that of the typical social cues experienced by all smokers. One Australian report suggests that this has resulted in current smoking (smoked in previous seven days) amongst 33% of 16-17 year olds and 17% of 12-15 year olds compared to 15% and 7% for non-Indigenous youth respectively (56). Recent evidence from the 2012 Surgeon General's Report (57) has found setbacks in smoking prevention, reporting that one in five high school students are smoking in the United States of America. They advise that some progress on the tobacco front has been made up until the past decade. However, rates of decline for tobacco smoking have now slowed and decline for smokeless tobacco use stalled completely, with prevalence among some groups actually increasing. Alarming, the report states that for every one smoker dying each year from tobacco-related illnesses, they are being replaced by two young smokers just starting out. The effects of advertising and promotional activities by tobacco companies were also examined, which are believed to be partly responsible for the onset of continuation of smoking among adolescents and young adults, particularly with tobacco companies spending more than a million dollars an hour in America alone to market their products (57). For these reasons a strong case can be made for research to systematically identify and assess interventions that are culturally-tailored to Indigenous populations, as the lack of a significant reduction in tobacco use within recent years warrant attention (*presented in Chapter 5*).

1.2.5 Smoking cessation amongst Indigenous Australians:

See related manuscripts for publication Chapter 6 and Chapter 7.

Smokers, for their part, rarely plan quit attempts (58), though according to the most recent National Aboriginal and TSI Social Survey, nearly two-thirds of current daily smokers had indeed tried to quit or reduce smoking in the 12 months prior to interview, with general health concerns being the primary reason (59). In 2010 the South Australian Department of Health released the Aboriginal Health Care Plan, recognising smoking as the number one cause of chronic conditions and disease among Aboriginal Australians (60). Within this, smoking cessation for Aboriginal Australians was identified as a key health priority. Yet despite being over represented in the burden of tobacco-related morbidity and mortality, very little research has been successfully conducted to evaluate and/or enhance the uptake of smoking cessation programs amongst Indigenous Australians (34, 61, 62). In 2014 the Australian government announced \$130 million in funding cuts (effectively one third of the programs annual funding of \$65 million per year) to the Indigenous Tackling Smoking budget (63, 64), which according to renowned Elder Tom Calma will mean:

“that there will be people who don't receive that [tobacco] information to make an informed choice, and that will contribute to their early demise” and “the chances of reaching that [reduced smoking prevalence and closing the gap] 2018 target is near impossible now” (65).

The lack of appropriate studies means no one is in a position to make substantive evidence based recommendations concerning smoking intervention. Combined with the known intricate context of the Indigenous setting, substantial differences between urban, regional and remote locations and presence of numerous satellite communities with their own traditions, beliefs and often dialects, the available literature indicates that the next phase of Aboriginal tobacco related research should avoid the traditional randomised placebo-controlled trial of another tobacco cessation pharmacotherapy (66). Instead, assessment involving descriptive and qualitative data should first be undertaken to help determine the barriers and enablers for implementation of culturally tailored tobacco programs (66, 67). For these reasons, one-on-one interviews held in urban and regional communities, are better situated to evaluate the views of Aboriginal and Torres Strait Islander Elders, key community stakeholders, doctors, researchers and Aboriginal healthcare workers at the ‘grass-roots’ level (*presented in Chapter 6*). In addition, quantitative data from health professionals across Australia who work with Aboriginal and Torres Strait Islander patients will provide a different perspective (more generalised), which will aid triangulation of the data to confirm reliability and validity of the findings (*presented in Chapter 7*). Combined, this information could be useful for improving the health of

Aboriginal and Torres Strait Islander people by identifying inadequacies in current tobacco education and identify what is working. The aim of this is to help inform future research for smoking cessation and tobacco use prevention and improved guidelines for medical consultations and healthcare provision.

1.2.6 Translation of information for policy and practice in the Indigenous setting:

See related publication Chapter 8.

This project collaborates with Aboriginal Elders and communities and aims to translate the findings from evidence presented in this thesis back into Aboriginal communities. It will do this by sharing information through as many sources as possible including:

1. Wide-spread community feedback via mass media (see Appendix 8: Evidence of dissemination for results),
2. Small group presentations, publication, presentation at national and international conferences and forums (see list of ‘Peer reviewed journal publications’ and ‘Presentations’ above),
3. Public policies (*presented in Chapter 8*),
4. National and local health steering and policy committees (see list of ‘Membership of committees and working parties associated with the PhD’ above), and
5. Any other sources suggested by community members and participants of this research beyond the period of the PhD.

1.2.7 Methodological issues in Indigenous Australian health research:

See related publication Chapter 9.

There are reports from within Aboriginal communities of significant distrust of research, researchers, government officials and doctors, which should not come as a surprise particularly when considering how often Aboriginal people are portrayed as ‘broken’ ‘helpless’ and in need of outside ‘expert’ assistance in existing research publications (68). Subsequently, well-funded randomised controlled trials in the urban Aboriginal setting failed due to a lack of mutual understanding and engagement resulting in low numbers of willing participants (69). Importantly, author’s report that clinic, patient, Aboriginal health worker and GP factors, interacting with the study design, contributed to their inability to implement the trial as intended. Moreover, some healthcare workers and doctors on the frontline are reporting feelings of pointlessness in providing health care to Aboriginal and TSI Australians, with comments such as:

“we don’t understand why they don’t...[come, present earlier, attend, look after themselves, etc.]” (70).

Therefore, examining some of the key methodological issues surrounding successful research with suggestions on how to address them are also needed to improve the likelihood of reducing the gap between Indigenous and non-Indigenous Australians *(presented in Chapter 9)*.

1.3 What we know works: smoking cessation and current practice in Australia

1.3.1 Pharmacotherapeutic interventions for smoking cessation:

See related publication Chapter 10.

Varenicline tartrate, bupropion hydrochloride and nicotine replacement therapy are considered to be first line pharmacotherapy for smoking cessation (71) with treatment efficacy from most effective to least respectively. Several other medications for smoking cessation have also been trialled over the years with varying success including nicotine receptor agonists, anxiolytics, antidepressants, cannabinoid type 1 receptor antagonists and silver amongst others. However, very little is known about the efficacy of these medications in marginalised groups such as: Indigenous, those with mental illnesses, youth and pregnant or breastfeeding women. Therefore a systematic review that consolidates this evidence is needed to inform current practice and direct future evaluations and research *(presented in Chapter 10)*.

1.3.2 Smoking cessation interventions for people with lung cancer:

See related publication Chapter 11.

Amongst smokers already diagnosed with a tobacco related-illness such as lung cancer there can be a perception that the damage has already been inflicted therefore smoking cessation is not necessary (72). Evidence suggests that there are several short and long-term benefits associated with smoking cessation that can improve treatment outcomes, recovery and prevent exacerbations and subsequently hospitalisations (73, 74). Ensuring that health professionals and patients are aware of these benefits is essential to enhance desire for smoking cessation and implementation of smoking cessation interventions *(presented in Chapter 11)*.

1.3.3 Reduced risk of cancer development with quit smoking interventions in later life:

See related publication Chapter 12.

Smoking cessation in later years can also be seen as an unnecessary measure amongst some smokers due to the perception that either the harm has already occurred or that if illness hasn't occurred by now it is not going to. Thus the question of pursuing smoking cessation in later life can be a contentious one amongst some smokers. Therefore a summary of the ability for smoking cessation to influence cancer risk reduction in later years is necessary to provide an evidence based resource to underpin clinical practice (*presented in Chapter 12*).

1.4 Inpatient initiation of smoking cessation interventions

See related publications Chapter 13 and Chapter 14.

Smoking cessation interventions delivered in the hospital setting need to be effective in achieving long term abstinence as well as controlling acute symptoms of withdrawal. These patients may be recalcitrant, on-going smokers who were previously unreceptive to primary prevention smoking cessation initiatives. However, given their acute smoking-related illness some may become more receptive, transiently at least, to smoking cessation efforts. Unfortunately, current “usual” hospital practice in South Australia is that almost all people admitted to hospital as smokers, are discharged as smokers, despite perhaps only receiving nicotine replacement therapy to placate cravings whilst an inpatient. There is a lack of co-ordinated and systematic post-discharge counselling and medication advice for smokers admitted with smoking-related illnesses on a global scale. A 2014 survey of 85 hospital nurses in Spain found that 92% reported ambiguity of smoking cessation practices amongst hospitalised patients (75), whilst in the United States of America a 2014 evaluation of clinicians across nine centres found that less than half (42%) reported asking their patients about smoking, less than a third (33%) advised or assisted smoking cessation and very few (10%) reported referring smokers to telephone Quitlines (76).

Smoking-related hospitalisations provide a channelling of some of the community's smokers into the health system, where an opportunity for holistic intervention exists. Following a new diagnosis of stroke, cancer, lung disease, or diabetes mellitus, patients were 3.2 times ($p<0.001$) more likely to quit smoking because of their diagnosis (77). This magnitude increased to 5 times if an individual was diagnosed with heart disease and 6.1 ($p<0.001$) if multiple conditions were diagnosed (77). Targeting inpatients during the

period of hospital confinement where admissions result from smoking-related diseases is an approach that has the potential to be associated with high cessation rates. A ‘perfect storm’ of opportunity to use a best practice approach in the inpatient setting can:

1. provide a “reflection” opportunity during an inpatient stay to reconsider lifestyle factors contributing to their illness/admission, and resolve to make long-term abstinence decisions,
2. make it difficult (although not impossible) to smoke through enforced initiation of abstinence, allowing patients to focus on the achievement that they have already “quit” by the time of discharge, and can build on this event to achieve long-term gains,
3. provide an opportunity for a holistic approach to patient care from the health professionals perspective during the days of admission beyond merely the focus of the disease, to address major preventable causative factors, and to initiate potential available interventions, which have been well proven in outpatient settings,
4. facilitate the initiation of smoking cessation medication under supervision, which
 - a. allows monitoring of nausea, craving and titration related adverse events
 - b. facilitates compliance
 - c. ensures that the patient has an action plan

1.4.1 The case for varenicline tartrate (Champix):

Varenicline tartrate (commercially known as Champix in Australia or Chantix in the United States of America), is the first smoking cessation product that acts at the same brain receptor targeted by nicotine inhaled from smoke (78). Unlike nicotine replacement therapy it has a dual action through its partial nicotinic acetylcholine receptor agonist activity that not only eases cravings but also blunts smoking associated pleasure (79). The latter effect may assist in reducing the desire to smoke as an inpatient, which will serve to offset the longer half-life of varenicline, compared to nicotine replacement therapy. A Cochrane review of smoking cessation interventions concluded that varenicline is the most effective pharmacological agent for smoking cessation (80). Wu et al (81) also conducted a systematic meta-analysis demonstrating a 66% increase in smoking abstinence at 12 weeks for varenicline through indirect comparisons with nicotine replacement therapy, and also superiority over bupropion. Furthermore, a recent head-to-head comparison confirmed a significant reduction in cravings, withdrawal symptoms and smoking satisfaction for

varenicline, compared with nicotine replacement therapy (82), though both of these reports relate to outpatient Caucasian-predominant settings.

1.4.2 Safety concerns for varenicline tartrate:

Targeting hospital patients admitted for smoking-related disease has the potential to yield high rates of smoking cessation but also increased adverse events. This amplification of adverse events can be attributed to commencement of additional pharmacotherapies in patients presenting to hospital with an acute illness episode. Medical comorbidities, poly-pharmacy, and drug–drug interactions may increase the potential risk of experiencing adverse events and need to be considered when implementing smoking cessation pharmacotherapies for patients in this setting (83). Moreover, some neuropsychiatric symptoms (suicidal ideation and depression (84) and severe skin reactions (Stevens-Johnson Syndrome and erythema multiforme) have occurred with this medication, as outlined by a United States of America Food and Drug Administration review (85). There have also been reports of serious adverse cardiovascular events (86), which given the acute inpatient setting that includes cardiovascular patients, concerns around safety of inpatient initiated varenicline are raised.

1.4.3 Quit smoking counselling services South Australia (SA):

Quit SA is the main provider for counselling programs that promote and support quitting and tobacco education in South Australia and is the vanguard for the states strategic plan for tobacco control. They provide a telephone based counselling service to assist smokers towards long-term abstinence. Through medical referral or self-register following awareness campaigns, Quit SA typically provide individualised telephone counselling support over periods of up to 12 weeks. Timing of ongoing contacts is tailored to likely relapse times according to each smoker’s unique lifestyle and trigger factors. Quit SA counselling is based upon the reported 5A approach: Ask, Assess, Advise, Assist, and Arrange (87). Several reviews demonstrated the potential value and cost effectiveness of quit lines (88). However, such services remain grossly under-utilised (7).

The combination of counselling, best practice medication and the use of the inpatient setting provide a synergy which needs to be evaluated. Therefore, a strong case can be made for the need to evaluate the efficacy (*presented in Chapter 13*) and safety (*presented in Chapter 14*) of an inpatient initiated smoking cessation program using a combination of current, evidence based, best practice smoking cessation interventions, specifically structured counselling combined with varenicline tartrate (Champix) (89).

1.5 Training health professionals in smoking cessation interventions

See related publication Chapter 15.

Collaborating with health services provides a unique opportunity to deliver smoking cessation programs, as health professionals consult many people each year and are perceived to be influential sources of information (90). Reviews and meta-analyses have consistently shown that individual counselling from smoking cessation specialists increase the chances of successful abstinence compared to less intensive support (91, 92). Providing training in smoking cessation care is one approach that may increase the number and quality of smoking cessation offers by health professionals (93). Furthermore, training health professionals as part of a smoking cessation intervention is likely to offer cost effectiveness with the intervention requiring few resources and the ability to produce a sustainable outcome beyond the life of the intervention delivery period (94). It is therefore disappointing that despite ongoing developments in this field worldwide, the number of patients who report receiving advice on smoking cessation from health professionals is still low (95, 96). Hence, a systematic evaluation of the current evidence from published randomised controlled trials that studied the effects of training health professionals in smoking cessation advice is warranted (*presented in Chapter15*).

Chapter 2. Overview of aims and hypotheses

A summary of the aims/hypotheses for each manuscript presented in this thesis are below.

Interventions for smoking cessation in Indigenous populations (*Chapter 4*)

The aim of this Cochrane systematic meta-analysis is to evaluate the effectiveness of smoking cessation interventions in Indigenous populations and to summarise these approaches for future cessation programmes and research.

Interventions for tobacco use prevention in Indigenous youth (*Chapter 5*)

The aim of this Cochrane systematic meta-analysis is to evaluate the effectiveness of intervention programmes to prevent tobacco use initiation or progression to regular smoking amongst young Indigenous populations and to summarise these approaches for future prevention programmes and research.

Barriers and enablers for use of smoking cessation pharmacotherapy for tobacco addiction among Aboriginal and Torres Strait Islander Australians: A mixed method analysis (*Chapter 6*)

The aim of this mixed method research paper submitted for publication is to identify the barriers and facilitators for the use of smoking cessation pharmacotherapies amongst Indigenous Australians, for use in future smoking cessation initiatives and research, by conducting multiple one-on-one interviews with doctors who treat Aboriginal and Torres Strait Islander patients and interviews with key stakeholders (including Elders, health professionals, researchers and other community leaders).

A national survey of current practice by Respiratory Specialists and Allied Health Professionals in treating Aboriginal and TSI tobacco use (*Chapter 7*)

The aim of this editorial submitted for publication is to identify opinions, beliefs, attitudes and characteristics of Respiratory Specialists and other Allied Health Professionals that may influence responses about delivery of treatment for Aboriginal and Torres Strait Islander smokers as part of standard clinical care, in order to inform future policy, practice and research.

Smoking cessation and tobacco prevention in Indigenous populations (*Chapter 8*)

The aim of this invited policy document *1 is to systematically review all smoking cessation and tobacco prevention studies (including grey literature) that have been culturally tailored for Indigenous populations around the world, with a particular focus on Aboriginal and Torres Strait Islander Australians, for use in future government-led policy initiatives, current practice and future research by the Australian and New Zealand School of Government and other organisations involved in policy (translational research).

Methodological challenges and options for addressing them in Aboriginal and Torres Strait Islander health research (Chapter 9)

The aim of this invited review*2 is to summarise some of the existing barriers for conducting research in collaboration with Aboriginal and Torres Strait Islander Australians and provides opinions to consider when addressing these issues.

Current and emerging pharmacotherapeutic options for smoking cessation (Chapter 10)

The aim of this invited review*1 is to summarise the evidence for the effectiveness of pharmacotherapeutic and other aids for smoking cessation and to identify gaps in current clinical practice in order to provide recommendations for future evaluation and research.

Smoking cessation interventions for lung cancer patients (Chapter 11)

The aim of this invited review*1 is to summarise the latest evidence for smoking cessation interventions in lung cancer patients, identify gaps in current clinical practice and highlight the priority areas for future research.

Is cancer risk still reduced if you give up smoking in later life? (Chapter 12)

The aim of this invited review*3 is to summarise the experimental and epidemiological evidence examining the ability of smoking cessation to influence cancer risk reduction in later life.

Smoking Termination Opportunity for inPatients (STOP): Superiority of a course of varenicline tartrate plus counselling over counselling alone for smoking cessation: A 12-month randomised controlled trial for inpatients (Chapter 13)

¹ Kristin was commissioned (\$10,000.00 grant) to write this policy document by the Australian and New Zealand School of Government, published in the journal *Evidence Base*

² Brian Smith was commissioned by the editor of this journal to write the review

*³ Kirstin was commissioned by the editors of each respective journal to write these review articles

The primary hypothesis is that: Administration of varenicline tartrate plus counselling delivered to patients admitted to one of three hospitals following an acute tobacco-related illness will result in improved long-term (12-month) smoking cessation measured via continuous abstinence, when compared to subjects who received counselling alone.

The secondary hypotheses are that: Varenicline tartrate plus counselling delivered to patients admitted to one of three hospitals following an acute tobacco-related illness will result in improved short-term quit attempts (3 months (end of treatment) and 6 months) measured via continuous smoking abstinence, when compared to subjects who received counselling alone.

Safety of varenicline tartrate and counselling versus counselling alone for smoking cessation: A randomised controlled trial for inpatients (STOP study) (*Chapter 14*)

Following from the previous publication, additional secondary hypotheses include that: Administration of varenicline tartrate plus counselling delivered to patients admitted to one of three hospitals following an acute tobacco-related illness, when compared to subjects who received counselling alone, will result in:

- 1) Drug-related adverse events similar in frequency and severity to those reported in outpatient studies
- 2) Mortality rates similar between groups
- 3) No increase in cardiovascular or neuropsychological symptoms
- 4) Improved treatment efficacy (smoking abstinence) measures by 7-day point prevalence at 4 and 12 weeks (end of treatment)
- 5) Improved craving control, lower levels of anxiety, improved confidence and improved motivation to quit

Training health professionals in smoking cessation (*Chapter 15*)

The aim of this Cochrane systematic meta-analysis is to determine the effectiveness of training health care professionals in the delivery of smoking cessation interventions to their patients, and to assess the additional effects of training characteristics such as intervention content, delivery methods and intensity.

Chapter 3. Methods

For the majority of publications/manuscripts included in this thesis a detailed description of methodology is reported within the manuscripts itself (*Chapters 4, 5, 8, 9, 10, 11, 12 and 15*). Additional information pertaining to study methodology not reported in the proceeding publication is provided below for *Chapters 6, 7, 13 and 14*.

3.1 Qualitative and quantitative research in Aboriginal health (*related to Chapter 6*)

One-on-one interviews and surveys were conducted with participants across multiple states and territories in Australia to determine the barriers and facilitators for the use of smoking cessation pharmacotherapies. Study methodology is expanded upon in the proceeding sections (results presented in Chapters 6).

3.1.1 Participant recruitment:

Up to 20 one-on-one interviews were scheduled to be conducted, or less if data saturation was reached earlier. The information obtained from these interviews was expected to provide an overall picture of the barriers and enablers for use of smoking cessation pharmacotherapy from the perspectives of the various individuals involved in healthcare delivery for Aboriginal and TSI smokers, being:

- Key stakeholders in Aboriginal health including Aboriginal liaison officers, Aboriginal health councils, Elders & influential figures in communities (10 one-on-one interviews or until data saturation)
- Respiratory consultants or medical consultants who have Aboriginal patients (10 one-on-one interviews, or until data saturation) including General Practitioners and disciplines of cardiology and psychology

Recruitment occurred via identified contacts within the health and Aboriginal communities in addition to word of mouth through existing contacts in health. These could be people working within Aboriginal health or be an identified representative to particular communities across Australia. Potential participants were approached with a copy of the patient information sheet and consent form. The participant was given sufficient time to discuss participation with friends and/or family members. Potential participants were also contacted by phone if their details had been forwarded by a researcher collaborator or

community representative/healthcare worker. A contact script for the phone conversation had been prepared and awarded Aboriginal Health Council ethics approval, as were flyers distributed to advertise the study via local health networks and community locations. Copies of the participant information sheet and consent form were also distributed via local Aboriginal healthcare workers. Opportunistic sampling was conducted based on location, involvement in Aboriginal and Torres Strait Islander health and willingness to participate in the study.

3.1.2 Interview and moderator guide:

One-on-one interview's (for doctors and key stakeholders from around Australia) were predicted to take approximately 40-60 minutes and were conducted in a place and time nominated by the interviewee. Informed consent was required before commencement of the interview and data collection. The interview was audio taped on two separate devices (a mobile phone and via Notability using an iPad, which following the interview, was immediately uploaded to Dropbox) to ensure the recorded interviews were securely stored and relevant data saved. All interviewees would remain anonymous, unless the individual preferred to be named. In cases where participants were happy to be acknowledged for their participation their names were included in the acknowledgement section of all publications and presentations.

3.1.3 Inclusion and exclusion criteria:

Key community stakeholder inclusion criteria: Willing to participate, has provided healthcare to Aboriginal people (who self-report being of Aboriginal heritage) for at least 25% of their employment hours over the past 12 months, or has provided healthcare to Aboriginal people for at least 5 years of their working career or currently working/has worked in Aboriginal health as a primary focus of the position; is a qualified healthcare worker, is a community Elder, or is influential in Aboriginal health/communities.

GP and specialist inclusion criteria: Willing to participate; has provided clinical care to Aboriginal people over a 12 month period (at least one consult per week or is a qualified General Practitioner or, is a qualified doctor specialising in one of the following disciplines: respiratory, vascular, neurology, oncology, cardiology, psychology.

Exclusion criteria: Unwilling or unable to sign a consent form

3.1.4 Data analysis:

Qualitative data was entered into NVivo ® software, utilising thematic categories based on Triandis Model of Interpersonal Behaviour (1977) (97):

Probability of act = [habit + intention*] x [motivation x facilitating conditions]

*Intention = social factors (subjective culture) + affect + value of perceived consequence (positives and negatives)

The Triandis model of Interpersonal Behaviour belongs to a school of cognitive models and considers intentions and habit as immediate antecedents of behaviour, both of which are influenced by facilitating conditions (97). According to Triandis, behaviour in any situation can be attributed to intention, habitual response and situational constraints and conditions. In the case of Indigenous smoking intentions to quit or continue to smoke are influenced by social and affective factors (such as peer and Elder tobacco use and the smoking 'norms' within communities) as well as rational deliberations (in order to fit in and make friends or not be perceived as anti-social). As such no action is either fully deliberative or fully automatic, according to the Triandis model. Likewise, no action is completely autonomous or derived entirely from a social standpoint. Behaviour therefore, is believed to be influenced by moral beliefs though the impact of these beliefs are limited by both emotional drives and cognitive function (97). Thus, the Triandis model aims to take into account multiple sources of potential variance as even the smallest amount of variance may be socially important and critical to the uptake or continuation of tobacco use amongst Indigenous communities. To elaborate further on the definitions used within the Triandis Model:

Habits (frequency of past behaviours), motivation (degree of desire) and facilitating conditions (present situational constraints) are believed to either enable or hinder the performance of a particular behaviour (such as tobacco use) (98).

Social factors, as per the above model, incorporate norms (the social rules about what should and should not be done), roles (sets of behaviours that are considered appropriate for persons holding particular positions in groups) and self-concept (the perception that a person has of him/herself about goals and behaviours that are appropriate for the person to peruse or ensue) (98).

Affect (the unconscious influence on decision making) is governed by instinctive behavioural responses to particular situations that occur without the individual consciously realising that they are doing it (98). The consequences of a perceived act may include both positive and negative emotional responses as a result of a particular decision, which are assumed distinct and of varying strengths (98).

Another way to consider the various influences to smoke is to consider the tri-level explanation of the Triandis model developed by Egmond and Bruel in 2007 (Figure 2) (99). The first level relates to personal characteristics and incorporates the way past experiences shape attitudes, beliefs and social factors related to behaviour. The second level considers how cognition, effect and the social determinants and personal normative beliefs influence the formation of intentions in regards to a specific behaviour. The final level is intended to explain intentions relating to behaviour, prior experiences and situational conditions predict whether or not an individual will perform a particular behaviour (100).

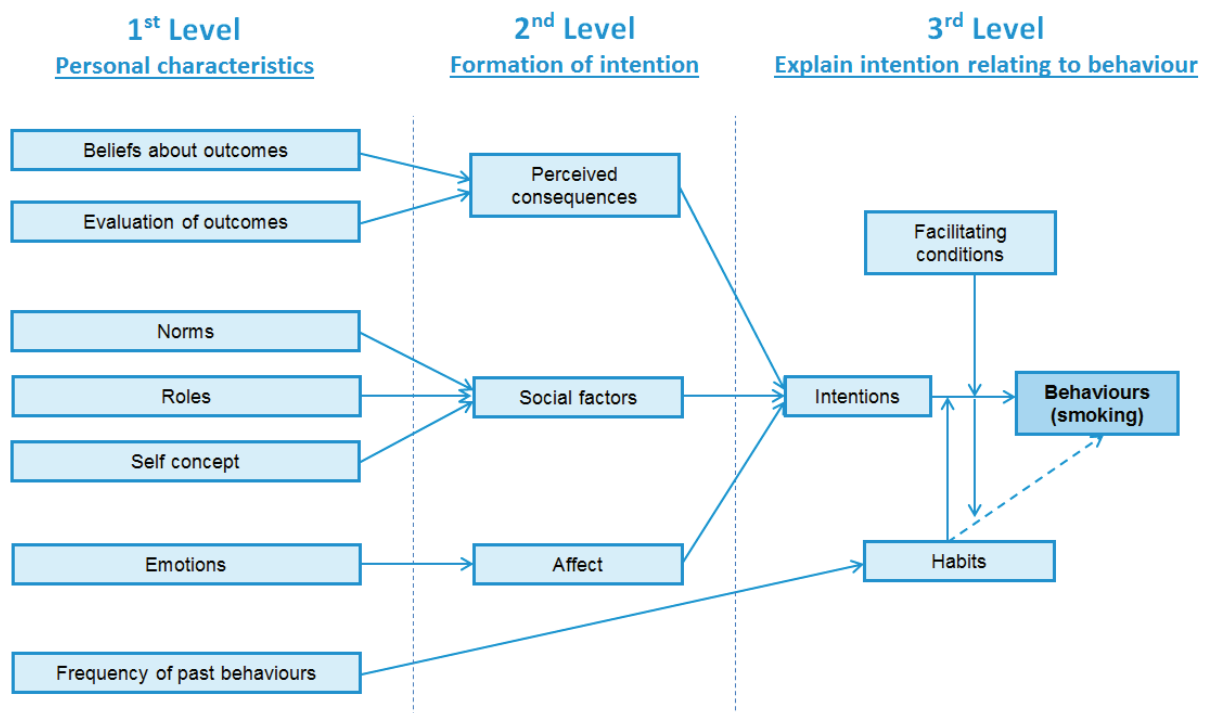


Figure 2: Modified diagrammatic representation of the Triandis model of Interpersonal Behaviour (98, 99)

The Triandis model is primarily used in modern literature to gain a comprehensive understanding of what determines behaviour and what factors cause behaviours in general (98). Thus, the Triandis model offers an ideal framework that may provide explanations and understanding about complex human behaviours, particularly those behaviours that are influenced by social and physical environments such as in the Aboriginal Australian setting.

3.1.5 Sharing information with the community, dissemination of findings and translation of research into practice:

Results from these qualitative and quantitative studies will be composed in a report format and distributed to key personnel, Elders and stakeholders including all consented participants that participated in this research once publication is complete. The report will be written in an easily understood, clear, concise manner encouraging readers to contact the Principal Investigator or study coordinator/s if further elaboration is required, in addition to delivery of the published manuscript/s. An ‘information night’ will also be organised should there be any individuals or groups within local communities who would prefer an oral interpretation of the findings from the report. This will be left to the community and leaders to decide in an effort to allow for community ownership of the outcomes and further consultation. Outcomes have also been extensively presented at appropriate health committees and other sources suggested by community members such as workshops (see conference presentation list above). The final report will be freely available to anyone on request and distributed throughout the Thoracic Society of Australia and New Zealand in published material, presentations, and public forums. In addition the results of the research have and will continue to be disseminated via the media, as evident in media contributions to date (see appendices). Moreover, one of the publications (Chapter 14) was generated as a document designed to inform Government-led policy, translate results into clinical practice improvement initiatives and inform future research projects.

3.1.6 Ethics approvals:

Ethics approvals were obtained from the Aboriginal Health Research Ethics Committee (04-12-472), the South Australian Health Research Ethics Committee (HREC/13/SAH/06), The Queen Elizabeth Hospital Human Research Governance Office (SSA/13/TQEHLMH/44) and the University of Adelaide Research Ethics Committee.

3.2 Survey of Respiratory Specialists and Allied Health Professionals (*related to Chapter 7*)

For the Thoracic Society of Australia and New Zealand (TSANZ) survey data collection, participants who attended the 2013 TSANZ conference in Darwin were informed of the survey prior to oral presentations during special interest group sessions. Only participants attending one of three sessions were provided copies of the survey including Tobacco and Addictive Substances, COPD and Evidence Based Medicine. Audience members were informed about the survey by the panel chair at the beginning of the session and researchers handed out the surveys as audience members were leaving the session. Surveys

included instructions on how to return the form (hand them to the conference administration desk or place them in the box in the main foyer labelled ‘Aboriginal health survey’). Ethics approval was obtained from the Aboriginal Health Council of South Australia as an addendum to the qualitative research application.

3.3 Smoking Termination Opportunity for inPatients (STOP) study *(related to Chapter 13 and Chapter 14)*

The STOP trial is a multi-centre randomised controlled trial of varenicline tartrate (Champix) plus Quitline counselling compared to Quitline counselling alone for smoking cessation. A total of 392 subjects were recruited across three hospitals (196 per arm) with a primary outcome of continuous smoking abstinence at 12 month follow-up. Study methodology is expanded upon in the proceeding sections (results presented in Chapter 13 and Chapter 14).

3.3.1 Sample population:

The STOP trial is a representative sample of daily tobacco users who were admitted to hospital with acute tobacco-related illnesses. Subjects were recruited from the inpatient wards of three hospitals in South Australia, which were chosen due to the high correlation of lung cancer mortality in these areas (see *Figure 3*).

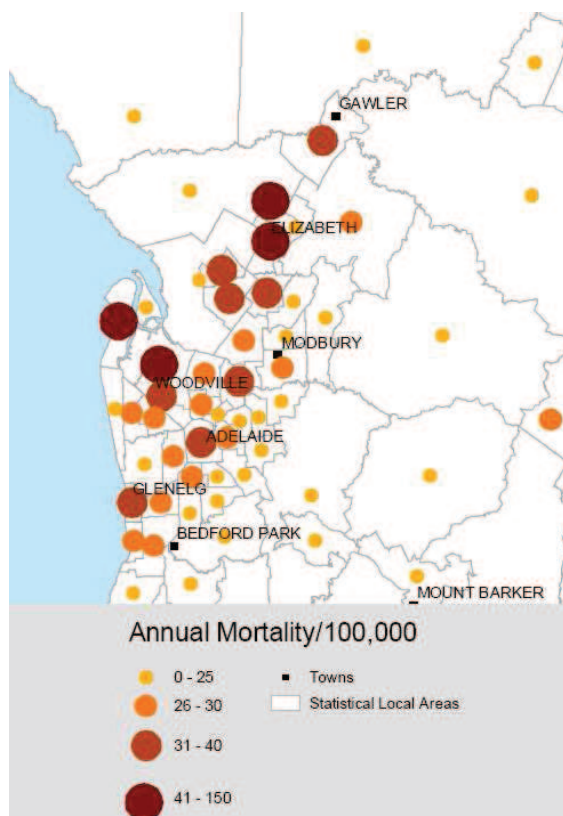


Figure 3: Lung Cancer Mortality in South Australia, 1991-2000 by statistical local areas (101)

The Lyell McEwin Hospital (serving Elizabeth and surrounding suburbs), The Queen Elizabeth Hospital (serving Woodville and surrounding suburbs) and the Royal Adelaide Hospital (central Adelaide) were the three primary recruitment sites. Collectively these three hospitals serve approximately 40,000 admissions per year, of which an estimated 10,500 admissions are active smokers.

3.3.2 Subject recruitment methods:

Subject recruitment occurred through a combination of:

1. Daily review of the patient clinical information system used in South Australian public hospitals 'Exelcare', which records admission diagnosis, and whether or not a patient is a smoker, at the time of admission;
2. Regular encouragement of all health care staff to contact the project officers as soon as they were aware of a recently admitted patient who had been a smoker until admission (or indeed had been noted to smoke early in their admission);
3. Inspection of daily hospital admissions list, for serious tobacco-related illnesses, leading to a comprehensive daily ward round of all such patients.

A combination of the above three strategies were applied across participating units within each of the three hospitals.

3.3.3 Inclusion, exclusion and withdrawal criteria:

Inclusion criteria: Smoker of at least 10 cigarettes a day for at least 1 year prior to admission; inpatient with an anticipated admission > 1 day; willingness to quit; aged between 20 and 75 years; a plan of discharge to go home (as opposed to a rehabilitation centre or palliative care), acute hospital admission with cardiovascular, cerebrovascular, peripheral vascular or airways (asthma and/or chronic obstructive pulmonary) disease (102).

Exclusion criteria: Patient preference to use nicotine replacement therapy; respiratory patients being considered for home oxygen (as nicotine replacement therapy was recommended treatment for these people); patients undergoing procedures such as video/EEG monitoring who do not intend to quit but want craving control; pregnancy; acute or pre-existing psychiatric illness, including depression requiring ongoing medication, past history psychosis or suicidal ideation; renal impairment with creatinine clearance <30ml/min.

Withdrawal criteria: Any adverse event that is considered to be clinically significant, and possibly related to medication; any clinically relevant abnormal findings in clinical, physical examination, and vital signs, which in the opinion of the investigative/medical/nursing/Allied Health staff that the risk is of his/her participation in the study; pregnancy.

3.3.4 Randomisation and blinding:

Randomisation occurred using a random number generator software programme (WINPEPI; published in Epidemiologic Perspectives and Innovations), assigning subjects to a 1:1 ratio. Respiratory staff independent of the study performed randomisation and allocation concealment to either group A (varenicline tartrate plus Quitline counselling) or group B (Quitline counselling alone). Allocation was concealed using opaque sealed envelopes that were open only after the consent forms were signed and baseline data collected. Blinding of participants and outcome assessors was not possible due to the open label study design.

3.3.5 Quit SA counselling:

Following recruitment of an inpatient, the counselling pro-actively and systematically commenced before discharge in every patient. Research staff at the patient's bedside, (which ensures 100% Quitline registration) instigated the initial call to Quitline and then handed the phone to the inpatient, for the initial 10-15 minute counselling session. At the time of discharge, a patient registration fax was sent to Quit SA, including (with the patient's consent) a summary of the patients smoking history, and the cause of the admission, in order to facilitate continuity of counselling support to the patient, and to avoid duplication. Furthermore, Quitline counsellors called each patient an additional seven times (maximum) within the first three months of enrolment, (call approximately 5-minutes) resulting in an estimated total counselling time of approximately 45-50 minutes per subject. STOP research officers were also trained with Quit SA staff and in motivational interviewing techniques in order to understand the 5A-counselling programme, to answer any patient questions, and to provide a consistent and integrated approach.

3.3.6 Primary and secondary outcomes:

Primary outcome: Smoking abstinence at 12 months, measured by continual abstinence, (defined as <5 cigarettes total between week 3 and 12 months) via self-report over phone, and measured objectively by carbon monoxide (CO) breath test at 3 and 12 month visits.

Secondary outcomes: Post enrolment data collection occurred at days 3 and 5, weeks 1, 2, 3 and 4 and months 3, 6 and 12. 7-day point prevalence (self-reported) was measured until 1 month and continual abstinence was measured at 12 months, quantitatively analysed by Bedfont micro Smokerlyser CO breath testing, (CO concentration of >6ppm indicative of

smoking). Follow-up assessments for determination of outcome measures were completely independent from all counselling sessions. Data collection post initial recruitment, (i.e. from day 3 onwards) was collected by a separate research officer from the one recruiting the patient, to reduce risk of bias. The validated Fagerström craving test for nicotine dependence was collected at baseline (103), in addition to 10-point Likert scales for craving, anxiety, motivation and confidence at each follow-up period. Self-reported triggers resulting in relapse were also collected at each follow-up period where the subject reported current smoking and monitoring of adverse events related to medication use, counselling, quitting smoking and their baseline admission to hospital were also collected at each follow-up time point. Inpatient self-reported smoking was also monitored by the project officers whilst patients were still inpatients, which was supplemented by observations from ward staff.

3.3.7 Data collection:

Baseline questionnaire included demographics, baseline co-morbidities, smoking history, levels of confidence, importance and motivation to quit smoking, receptiveness to counselling, medical history, social situation and stresses and level of craving by Fagerström questionnaire. These tools have been widely used and validated and their use facilitates ready comparisons of new findings with the published literature (103, 104).

3.3.8 Adverse event monitoring:

Health outcomes and adverse events such as changes in behaviour, agitation, depressed mood, suicidal ideation and nausea were monitored daily whilst subjects were inpatients by ward and research staff. External GP's were notified of patient participation in a study involving randomisation to either 'varenicline tartrate plus counselling' or counselling alone on discharge. All investigators and research staff were experienced in clinical research trials and the monitoring of adverse events. Questions related to baseline health and changes in health since the previous contact were asked at each time point. If a patient appeared to be experiencing a significant adverse event, researchers requested immediate cessation of study medication as well as follow-up consult with a medical officer. The medical officer who approved patient recruitment and the GP nominated by the recruited subject were immediately informed of new and significant symptoms, with additional follow-up as clinically indicated by research staff and responsible medical officer. Subjects were also provided with 24 hour emergency contact numbers upon enrolment. All adverse events were recorded and reported quarterly to the Chairman of the relevant hospital's

Research Ethics Committee, and serious adverse events were reported in line with hospital protocol. Research staff contact patients post enrolment for data collection and monitoring at days 3 and 5, weeks 1, 2, and 3 as well as months 1, 3, 6 and 12.

3.3.9 Sample size calculation:

A sample size of 196 participants per study arm was estimated to produce a 15% difference (45% vs. 30%) at 52 weeks, using a two group uncorrected chi-squared test with a 0.05 two-sided significance level, based on available literature (105-107) This provided 80% power to detect the difference between groups, with additional adjustments for attrition (20%). Sample size calculations were performed by Professor Adrian Esterman, the Inaugural Chair of Biostatistics for the University of South Australia.

3.3.10 Statistical analyses:

The primary outcome of continuous abstinence in addition to point prevalence and safety data after 52 weeks by treatment arm were undertaken using a two-sided chi-squared test and Mann-Whitney U-test. A log binomial GLM model was used to explore changes in quit rates over time as part of secondary analyses. An independent samples two-tailed t – test comparison determined the significance of any changes in the additional secondary outcome measures of craving, anxiety, motivation and confidence to quit in each study arm. Adjustments were made for differences in baseline data between medical disciplines. The statistical packages STATA version 11 and SPSS version 19 were used and all analyses were based on intention to treat. Participants who withdrew from the study or were lost to follow-up were assumed to be smokers for the remainder of the study, regardless of their smoking status at the last contact period. Missing data from subject questionnaires were excluded from the analyses.

3.3.11 Ethics approvals:

Ethics approvals were obtained from The Queen Elizabeth Hospital and Lyell McEwin Hospital Human Research Ethics Committee (Protocol Number 2008012) and the Royal Adelaide Hospital Ethic Committee (Protocol Number 080520).

Chapter 4.

Interventions for smoking cessation in Indigenous populations

(Literature review and meta-analysis)

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Author contributions:

By signing the Statement of Authorship, each author certifies their stated contribution to the publication is accurate and that permission is granted for the publication to be included in the candidate's thesis.

Name of principal author (candidate)	Kristin Carson		
Contribution to the paper	Conceived the investigation, designed and wrote the protocol, searched grey literature including online clinical trial registries, screened all retrieved literature, identified studies for inclusion, exclusion and as ongoing, extracted data for characteristics and risk of bias, performed all data entry, data analysis (including meta-analyses) and interpretation of results, developed the summary of findings table, wrote the first draft of the manuscript, contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, addressed editorial and peer reviewer comments, made critical revisions and approved final version.		
Signature		Date	17/05/2015

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Contribution to the paper	Screened all retrieved literature, identified studies for inclusion, exclusion and as ongoing, extracted data for risk of bias, contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, addressed editorial and peer reviewer comments, made critical revisions and approved final version.		
Signature		Date	26/05/2015

Name of co-author	Matthew Peters		
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Contribution to the paper	Contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, addressed editorial and peer reviewer comments, made critical revisions, approved final version and supervised process.		
Signature		Date	09/06/2015

Name of co-author	Antony Veale		
Contribution to the paper	Contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, addressed editorial and peer reviewer comments, made critical revisions, approved final version and supervised process.		
Signature		Date	26/06/2015

Name of co-author	Adrian Esterman		
Contribution to the paper	Contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, addressed editorial and peer reviewer comments, made critical revisions, approved final version and supervised process.		
Signature		Date	25/05/2015

Name of co-author	Brian Smith		
Contribution to the paper	Contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, addressed editorial and peer reviewer comments, made critical revisions, approved final version and supervised process (primary supervisor).		
Signature		Date	17/05/2015

Indigenous populations have borne a longstanding disproportionate burden of tobacco related morbidity and mortality in comparison to the non-Indigenous. Tobacco prevalence globally amongst this cohort is often double that of the non-Indigenous. Yet the majority of research is still focused specifically on non-Indigenous cohorts (53-55, 108). Despite the fact that mainstream smoking cessation and tobacco prevention programs have indeed been successful in reducing the overall population burden of tobacco use across the board. The inability of these programs to influence ‘the gap’ between Indigenous and non-Indigenous tobacco users could be related to either content of the intervention or access to appropriate resources. Either way this gap suggests there is a need to culturally-tailor smoking cessation interventions specifically for these populations. However, appraisal of the Cochrane library, one of the highest ranked journals in evidence based medicine research (ranked 11 out of 151 journals in the medicine, general and internal category), was unable to identify a review that specifically examined smoking cessation for Indigenous populations.

The Cochrane Database of Systematic Reviews is frequently used to underpin policy, practice and provide recommendations for future evaluations and research based on a methodologically rigorous systematic appraisal of the available published and unpublished evidence. Cochrane practices not only ensure that a broad cross-section of resources are searched to identify relevant studies for inclusion, it also safeguards the quality of evidence with risk of bias evaluations alongside each study, to identify any possible issues with interpretation of results. Therefore before deciding upon an appropriate method for intervention in this area, it was necessary to perform a Cochrane review to establish an evidence base of current interventions globally and to determine what has been effective, ineffective and build recommendations based on this available data rather than reinventing the wheel.

Only four studies were identified on a global scale as meeting all of the eligibility criteria for this meta-analysis and only one of these was conducted within the Indigenous Australian setting. The ability to draw any reliable conclusions based on the findings from this review are thus limited, though from the available evidence we can conclude that smoking cessation interventions tailored for Indigenous populations can be effective in producing smoking abstinence and that Indigenous people are willing to attempt cessation.

Interventions for smoking cessation in Indigenous populations (Review)

Carson KV, Brinn MP, Peters M, Veale A, Esterman AJ, Smith BJ



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[Intervention Review]

Interventions for smoking cessation in Indigenous populations

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ABSTRACT

Background

Tobacco use in Indigenous populations (people who have inhabited a country for thousands of years) is often double that of the non-Indigenous population. A disproportionate burden of substance-related morbidity and mortality exists as a result.

Objectives

To evaluate the effectiveness of smoking cessation interventions in Indigenous populations and to summarise these approaches for future cessation programmes and research.

Search methods

The Cochrane Tobacco Addiction Group Specialised Register of Trials was searched (April 2011), with additional searches of MEDLINE (May 2011). Online clinical trial databases and publication references were also searched for potential studies.

Selection criteria

We included randomized and non-randomized controlled trials for smoking cessation interventions in Indigenous populations. Interventions could include pharmacotherapies, cognitive and behavioural therapies, alternative therapies, public policy and combination therapies. No attempts were made to re-define Indigenous status for the purpose of including a study in this review.

Data collection and analysis

Data pertaining to methodology, participants, interventions and outcomes were extracted by one reviewer and checked by a second, whilst methodological quality was extracted independently by two reviewers. Studies were assessed by qualitative narrative synthesis and where possible meta-analysis. The review process was examined by an Indigenous (Aboriginal) Australian for applicability, acceptability and content.

Main results

Four studies met all of the eligibility criteria for inclusion within the review. Two used combination therapies consisting of a pharmacotherapy combined with cognitive and behavioural therapies, whilst the remaining two used cognitive and behavioural therapy through counselling, one via text message support and the other delivered via clinic doctors trained in smoking cessation techniques. Smoking cessation data were pooled across all studies producing a statistically and clinically significant effect in favour of the intervention (risk

Interventions for smoking cessation in Indigenous populations (Review)

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ratio 1.43, 95%CI 1.03 to 1.98, $p=0.032$), however following sensitivity analysis a statistically non-significant but clinically significant effect was observed in favour of the intervention (risk ratio 1.33, 95%CI 0.95 to 1.85, $p=NS$) .

Authors' conclusions

A significant health disparity exists, whereby Indigenous populations, a minority, are over-represented in the burden of smoking-related morbidity and mortality. This review highlights the paucity of evidence available to evaluate the effectiveness of smoking cessation interventions, despite the known success of these interventions in non-Indigenous populations. Due to this lack of published investigations, the external validity of this review is limited, as is the ability to draw reliable conclusions from the results. The limited but available evidence reported does indicate that smoking cessation interventions specifically targeted at Indigenous populations can produce smoking abstinence. However this evidence base is not strong with a small number of methodologically sound trials investigating these interventions. More rigorous trials are now required to assist in bridging the gap between tobacco related health disparities in Indigenous and non-Indigenous populations.

PLAIN LANGUAGE SUMMARY

Can smoking cessation interventions targeted at Indigenous populations achieve smoking abstinence?

In Indigenous populations, rates of smoking have not fallen as they have in the wider communities around them and the associated health harms are unacceptable. This review of four studies found that published studies evaluating smoking cessation interventions specifically aiming to reduce and/or stop the use of tobacco in Indigenous people are significantly lacking. The limited evidence reported in this review does indicate some benefit in these interventions to help Indigenous people stop smoking. However, the change in attitudes after one study was negative with fewer people 'ready to quit' after the smoking cessation intervention was completed. Consideration needs to be given to cultural differences and traditions when tailoring interventions for Indigenous people. Modified or innovative interventions and careful outcomes research are needed to improve the usefulness of smoking cessation interventions aimed at Indigenous populations.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

interventions for smoking cessation for Indigenous populations						
Patient or population: Indigenous populations Settings: Intervention: interventions for smoking cessation						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Interventions for smoking cessation				
Smoking abstinence Follow-up: 6 to 12 months	Study population		RR 1.43 (1.03 to 1.98)	1081 (4 studies)	⊕○○○ very low ^{1,2}	
	97 per 1000	139 per 1000 (100 to 193)				
	Low					
	100 per 1000	143 per 1000 (103 to 198)				
Attitudes - readiness to quit Follow-up: 6 months	Study population		RR 1.64 (0.82 to 3.3)	92 (1 study)	⊕○○○ very low ^{1,2}	
	203 per 1000	334 per 1000 (167 to 671)				
	Low					
	200 per 1000	328 per 1000 (164 to 660)				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

¹ There was insufficient sequence generation, allocation concealment and blinding across some studies

² It is possible that due to the nature of these studies some publication bias is occurring with a failure to publish studies that produce no effect

BACKGROUND

Specific definitions for 'Indigenous' vary between regions and populations. These definitions remain highly contested and are not always accepted or used (Nettelton 2007). Such examples include 'Aboriginal Australians' or 'Torres Strait Islanders' for the Indigenous Australian people, 'First Nations' is sometimes used to describe the Indian, Metis, and Inuit populations Indigenous to the United States of America and Canada. 'Native Hawaiians' is used for Hawaii's Indigenous people and 'Tangata Whenua' or 'People

of the land' for the Māori of New Zealand (Cunningham 2003). In an attempt to create consistency, though cognisant of the preferential syntax for populations, the term 'Indigenous' has been chosen to encompass participants within this review as it reflects "the experiences shared by a group of people who have inhabited a country for thousands of years, which often contrast with those of other groups residing in the same country for a few hundred years" (Cunningham 2003). No offence is intended to any group whose preferred descriptor is not used.

The term 'intervention' also has the potential to be misconstrued. The use of the term in the context of this review is "The process of intervening on people, groups, entities or objects in an experimental study. In controlled trials, the word is sometimes used to describe the regimens in all comparison groups, including placebo and no-treatment arms" (Cochrane Glossary 2011). This term is not to be confused with the 'Northern Territory Intervention' of Australia for example, where the Federal Government acquired control of local community land leases for a five year period and removed the permit system that allowed Aboriginal communities to control access of land. No offence is intended by the use of this term.

Indigenous populations bear a disproportionate burden of substance-related morbidity and mortality in comparison to non-Indigenous populations throughout the world. The prevalence of tobacco use amongst Indigenous people is often, in fact, double that of the relevant non-Indigenous population, with estimates of 51-59% in Canada (Health Canada 2003; CEITC 2005), 51% in Australia (ABS 2006; CEITC 2005), 51% in New Zealand (Borman 1999; CEITC 2005) and 44% in the United States for Native Alaskans (First Nations Center 2005; Alaska Department of Health 2006). One report from Canada suggests that 62% of First Nation and Inuit people are smokers, with the greatest smoking prevalence of 74% within their young adults aged 20 to 24 years (CEITC 2005). Similarly, approximately two million American Indians and Native Alaskans live in the United States and combined they have the highest prevalence of tobacco use (32%), among ethnic minorities. Another evaluation of Māori, Indigenous to New Zealand, suggested that tobacco kills nearly 600 Māori prematurely every year (Reid 1991), with the average life expectancy of 70.4 years in males compared to 79.0 years for a

non-Māori and 75.1 years compared to 83 years for Māori and non-Māori women respectively (The Social Report 2010).

Due to cultural and geographic diversity, tobacco use often varies widely between sub-populations and regions. An increased smoking prevalence may be attributed to a comparatively low socioeconomic status (SES) in Indigenous communities, the 'normalisation' of tobacco use (Harvey 2002), racism (Paradies 2006) and early introduction of tobacco as a means of payment for services rendered (Briggs 1996), which may have contributed to a higher prevalence of tobacco use in some communities. Within Indigenous Australian populations, high levels of community acceptance for smoking has been identified as a barrier in cessation initiatives for hospital patients (Harvey 2002) and school students (Lowe 2004), since smoking appears to play a key role in social interaction and relationship building (Briggs 2003). In some cases substandard, overcrowded living conditions further increase tobacco exposure in young people and non-smokers (ABS 2006; DHA 2006). Tobacco cessation interventions which appear effective in one population will not necessarily work in another. Many Indigenous tribes in America consider tobacco as a sacred gift and use it during religious ceremonies and as traditional medicine (MMWR 2007). As a result of this high smoking prevalence, the leading cause of death in these communities is cardiovascular disease (MMWR 2007).

Despite the fact that there is a high prevalence of tobacco smoking in Indigenous populations compared to non-Indigenous populations, most research in smoking intervention has occurred in the latter (Lancaster 2005a; Lancaster 2005b; Rigotti 2007; Rice 2008; Stead 2008; Civljak 2009). The failure of otherwise successful population health and individual treatment strategies to reduce smoking rates in Indigenous settings could be related to either access or content. Public mass media information campaigns may not reach the target audience, may not be linguistically or culturally appropriate, may not be delivered by an appropriate representative or may simply be less effective. Even if smoking is accepted as harmful, it may be relegated behind other concerns such as other substance abuse problems, levels of education and issues relating to the criminal justice system. Treatment services may not reach Indigenous smokers or may be less effective. An alternate possibility is that there is in fact no difference in program reach or efficacy and that the ongoing differences in smoking rates are associated with poverty, unemployment or other aspects of the social context of smoking.

Only methodical research will close this knowledge gap. Systematic consolidation of interventions and sub-components for those in this high-risk populace is warranted, to identify features of any effective programs for Indigenous populations so that they can be pursued (US Dept Health and Human Services 1998) and to identify ineffective programs so that they can be altered or abandoned.

OBJECTIVES

To evaluate the effectiveness of smoking cessation interventions in Indigenous populations and to summarise these approaches for future cessation programmes and research.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCT) or quasi-randomised controlled trials (CCT).

Types of participants

Participants were young people and adults of any age and either gender, who were Indigenous to their country and were active smokers participating in a smoking cessation study. Trial participants were not required to be selected according to their susceptibility to quitting or suitability for particular interventions. Studies aimed at pregnant women were also assessed for inclusion even though this area may be considered highly specialised, since some of the issues may be common to Indigenous people generally. No attempts were made to re-define Indigenous status for the purpose of including a study in this review. When meaningful data were found which referred to an Indigenous subpopulation in a larger study, it was assessed for inclusion in the review.

Types of interventions

We included interventions in five categories:

- 1.) Pharmacotherapies (including nicotine replacement therapies, bupropion and varenicline tartrate).
- 2.) Cognitive and behavioural therapies, (including CBT (Cognitive Behavioural Therapy), counselling, support groups, self-help, seminars, motivational lectures).
- 3.) Alternative therapies (including acupuncture, hypnotherapy, aversion therapy).
- 4.) Public policy (including legislative interventions, media campaigns, community interventions).
- 5.) Combination therapy (including a combination of at least two therapies from the above four categories).

We did not exclude trials with high levels of attrition, however this was documented within the risk of bias tables and discussed.

Controls were assessed as usual practice, no intervention, placebo, co-interventions (e.g. an intervention such as alcohol cessation counselling that occurs in both the intervention and control arm) or reduced intervention. Control participants receiving reduced interventions could be offered brief advice on quitting, but support

had to be of a lower intensity than that given to the intervention participants.

Types of outcome measures

Primary outcomes

The primary outcome was smoking cessation as defined by continuous abstinence and/or the relevant 'point prevalence' as described by the authors, for the longest follow-up point reported in the study (minimum of six months). The strictest definition of sustained abstinence was used (e.g. if results were presented as 'no smoking' or 'smoking < five cigarettes' throughout the study period, the data for the 'no smoking' population was used). Where possible individual study authors performed biochemically validation. Trials reporting less than six-months' follow up were excluded.

The type of 'smoking' as defined for this review refers to the practice where tobacco is burned and the vapours are either tasted or inhaled (e.g. cigarettes, tailor-mades and rollies).

Secondary outcomes

Secondary outcomes considered for this analysis included:

1. Adverse effects of interventions (through relevant reporting scales or narrative synthesis)
2. Mortality
3. Costs of interventions
4. Change in quality of life (e.g. St George Respiratory Questionnaire, SF-36 (Short Form-36), PsyQol (Psychological Quality of Life) or any other generic quality of life tool)
5. Change in pulmonary function (e.g. FEV₁, FVC etc)
6. Change in attitudes (e.g. readiness to quit)
7. Change in knowledge (e.g. health effects of tobacco)
8. Change in exercise tolerance (e.g. six-minute walking distance (6MWD))

Search methods for identification of studies

Electronic searches

We identified potential studies from the Tobacco Addiction specialised Register (April 2011). This was generated through regular searches of The Cochrane Library, EMBASE, MEDLINE, PsycINFO and Science Citation Index for trials of smoking cessation and prevention interventions. No language restrictions were applied. The following free text search terms were used to identify records relevant to the topic:

'Aborig*' OR 'Indigenous*' OR 'Inuit' OR 'Maori' OR 'Native American' OR 'American Indian' OR 'tribe*' OR 'tribal'

Online clinical trial registers were also searched for ongoing and recently completed studies including, Controlled Clinical Trials (www.controlled-trials.com), the National Research Register (www.nrr.nhs.uk), government registries (clinicaltrials.gov), and WHO registries (www.who.int/trialsearch/).

For these searches the topic related terms were combined with the term 'smoking cessation'.

Searching other resources

Reference lists of all included studies and reviews were screened to identify potentially relevant citations. In addition, enquiries regarding other published or unpublished studies known to the authors of the included studies were made.

Data collection and analysis

The entire review process was examined by an Indigenous (Aboriginal) Australian for applicability, acceptability and content.

Selection of studies

From the title, abstract, or descriptors, KC independently reviewed the literature searches to identify potentially relevant trials. All studies that clearly did not meet the inclusion criteria in terms of study design, population or interventions, were excluded. KC extracted the data, which was checked by a second reviewer MB. Both KC and MB independently extracted data for risk of bias in all included studies.

Data extraction and management

KC extracted data for the trials using a standardised data extraction form prior to entry into The Cochrane Collaboration software program Review Manager 5.1. KC also attempted to correspond with authors to obtain any missing or raw data as required.

The following information was extracted:

Methods: country/setting of trial, design, objectives, study site, methods of analysis;

Participants: age, gender, ethnicity, socio-economic status, n-values for eligibility, recruitment and completion, recruitment means;

Interventions: descriptions of interventions and controls, duration, intervention delivery, type/dose/duration of pharmacotherapy or behavioural support, and control group components;

Outcomes: method of outcome collection, pre-specified outcome data, validation, follow-up period, other follow ups and definitions of abstinence, outcome data as defined under '[Types of outcome measures](#)' in this protocol;

Risk of bias: methods of sequence generation, allocation concealment, blinding of participants and outcome assessors, incomplete outcome data, selective outcome reporting, comparability of intervention and control group characteristics at baseline, imbalances in outcome measures between intervention and control at

baseline, protection against contamination, selective recruitment of participants, and other potential threats to validity.

Assessment of risk of bias in included studies

Risk of bias (ROB) was evaluated by two independent reviewers, KC and MB, in line with recommendations made in the Cochrane Handbook of Systematic Review of Interventions ([Higgins 2009](#)). This was on the basis of allocation sequence, allocation concealment, blinding for participants and outcome assessors, incomplete outcome data, selective outcome reporting and other potential threats to validity. Three additional domains were included to assess design-specific threats to validity including: imbalances of outcome measures at baseline; comparability of intervention and control group characteristics at baseline; and protection against contamination ([EPOC 2009](#)). The risk of bias associated with an additional domain of selective recruitment of participants was also assessed. ROB for each domain was assessed as 'low risk', 'high risk' and 'unclear risk' of bias, as per the guidelines from table 8.5.c of the Cochrane Handbook ([Higgins 2009](#)). Conflicts in the assessments were resolved by consensus.

Measures of treatment effect

Where possible, a risk ratio (RR) was provided for the primary outcome of each trial. This was defined as (number of subjects that stopped smoking in the intervention group/ total number randomised to the intervention group) / (number of subjects that stopped smoking in the control group/ total number randomised to the control group). The RR was greater than 1 if more subjects ceased smoking in the intervention group in comparison to the control group. An estimated pooled weight average for RRs was calculated using the Mantel-Hetzel fixed-effect model, with 95% confidence intervals. In all instances an intention-to-treat analysis was assessed. For secondary outcomes the differences in change scores were considered for analysis.

Unit of analysis issues

In the case of cluster controlled trials, analysis was performed at the level of individual whilst adjustments were made to account for clustering effects in the data. For studies that did not include adjustments for clustering, the size of the trial was reduced to the effective sample size ([Rao 1992](#)) using the original sample size from each study, divided by a design effect of 1.2, which is consistent with other smoking cessation intervention trials ([Gail 1992](#)), and as per recommendations in the Cochrane Handbook, section 16.3.4 ([Higgins 2009](#)). We expected trials to use a variety of statistical methods to investigate or compensate for clustering; we recorded whether studies used these and whether the significance of any effect was altered (see [Characteristics of included studies](#)). In the case of multi-arm trials we would have included each pairwise comparison separately, but with shared intervention groups

divided out approximately evenly among the comparators. However, if the intervention groups were deemed similar enough to be pooled, the groups would have been combined using appropriate formulas in the Cochrane Handbook (table 7.7.a for continuous data and chapter 16.5.4 for dichotomous data) (Higgins 2009).

Dealing with missing data

Missing information regarding participants was evaluated on an available case analysis basis as described in chapter 16.2.2 of the Cochrane Handbook (Higgins 2009). Missing standard deviations would have been addressed by imputing data from the studies within the same meta-analysis or from a different meta-analysis as long as these used the same measurement scale, had the same degree of measurement error and the same time periods, (between baseline and final value measurement), as per chapter 16.1.3.2 of the Cochrane Handbook (Higgins 2009). Where statistics essential for analysis were missing (e.g. group means and standard deviations for both groups were not reported) and could not be calculated from other data, attempts were made to contact the authors to obtain data. Loss of participants that occurred prior to performance of baseline measurements were assumed to have no effect on the eventual outcome data of the study. Any losses after the baseline measurement were taken, have been assessed and discussed. Subjects lost to follow up were assumed to be smoking and were included in the denominators for calculating the relative risk, as per standard Tobacco Addiction Group methods.

Assessment of reporting biases

Providing the inclusion of greater than ten included studies, potential reporting biases would have been assessed using a funnel plot. Asymmetry in the plot could have been attributed to publication bias, but may well be due to true heterogeneity, poor methodological design or artefact. In case of asymmetry, we could have included contour lines corresponding to perceived milestones of statistical significance ($p=0.01, 0.05, 0.1$ etc.) to funnel plots, which may help to differentiate between asymmetry due to publication bias from that due to other factors (Higgins 2009). In instances of fewer than ten studies, the reporting biases were extrapolated within the 'other bias' section in the risk of bias tables.

Data synthesis

Qualitative narrative synthesis was performed for all included studies in addition to meta-analysis (see [Measures of treatment effect](#) for details about meta-analysis). Subjective (rather than statistical) methods were used to compare the study outcomes using a standardised template for extraction by one reviewer (KC), which was checked by a second (MB). The narrative synthesis of evidence was reported in a table format separated for the pre-specified primary and secondary outcomes (see: [Types of outcome measures](#)).

Subgroup analysis and investigation of heterogeneity

We attempted to categorise trials according to the subgroups listed in [Types of interventions](#) above. Consideration was given to pooling trials within these subgroups, however insufficient studies did not permit subgroup analysis. Had there been sufficient numbers of included studies we would have attempted to pool trials of different pharmacotherapies, trials of different intensities of behavioural interventions, or different types of population based interventions within subgroups under each category. We considered the addition of further heterogeneity contributed by factors such as baseline smoking status, participant and community characteristics, (e.g. age, physical state, cultural and educational differences), time of measurement of results and varying measurement tools used to assess outcomes. The chi square and I^2 statistic (Higgins 2009) were used to quantify inconsistencies across studies. In groups of trials where meta-analysis is judged potentially appropriate, extracted data were pooled using the fixed-effect model. In the presence of significant heterogeneity (as defined by: $I^2 \geq 60\%$, visual inspection of study data and consideration of study design and methodology), the use of a random-effects model would have been considered. However this would have been considered with caution taking into account the possible influence of smaller studies which could over or under estimate the true treatment effect. To consider instances where meta-analysis may not be judged appropriate, we also used narrative synthesis, treating the studies individually with consideration of their confidence intervals. Providing sufficient numbers of included studies we would have considered reporting the results restricted to the larger, more rigorous studies as suggested in section 10.4.4.1 of the Cochrane Handbook (Higgins 2009). These data were all analysed using Review Manager 5.1. Ideally we aimed to conduct subgroup analyses for each population (e.g. Aboriginal Australian, Native Alaskan etc). Also within each population, we considered that smoking prevalence may vary widely between dispersed community groups, further adding to potential heterogeneity of results. As each Indigenous population is unique and each has specific characteristics (such as remoteness) that could influence the effectiveness of smoking cessation interventions, subgroup analysis would have provided the most relevant results for a particular population. However insufficient studies meeting the inclusion criteria existed for any populations to be analysed as a subgroup.

Subgroup analysis of remote versus urban dwelling and isolated versus integrated populations would also have been considered. Providing sufficient studies existed we would have also performed a subgroup analysis for cessation initiatives in young people (aged <25 years) and pregnant women.

In studies of long duration, we considered that results may be presented for several periods of follow-up including short-term (≤ 26 weeks), medium-term (27 to 52 weeks) and long-term (≥ 53 weeks). Data permitting, extended follow up would also have been collated for studies presenting data over two years.

Sensitivity analysis

Sensitivity analysis was conducted on studies with a high risk of bias for sequence generation and/or allocation concealment and studies with participants with significant co-morbidities.

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#).

RESULTS

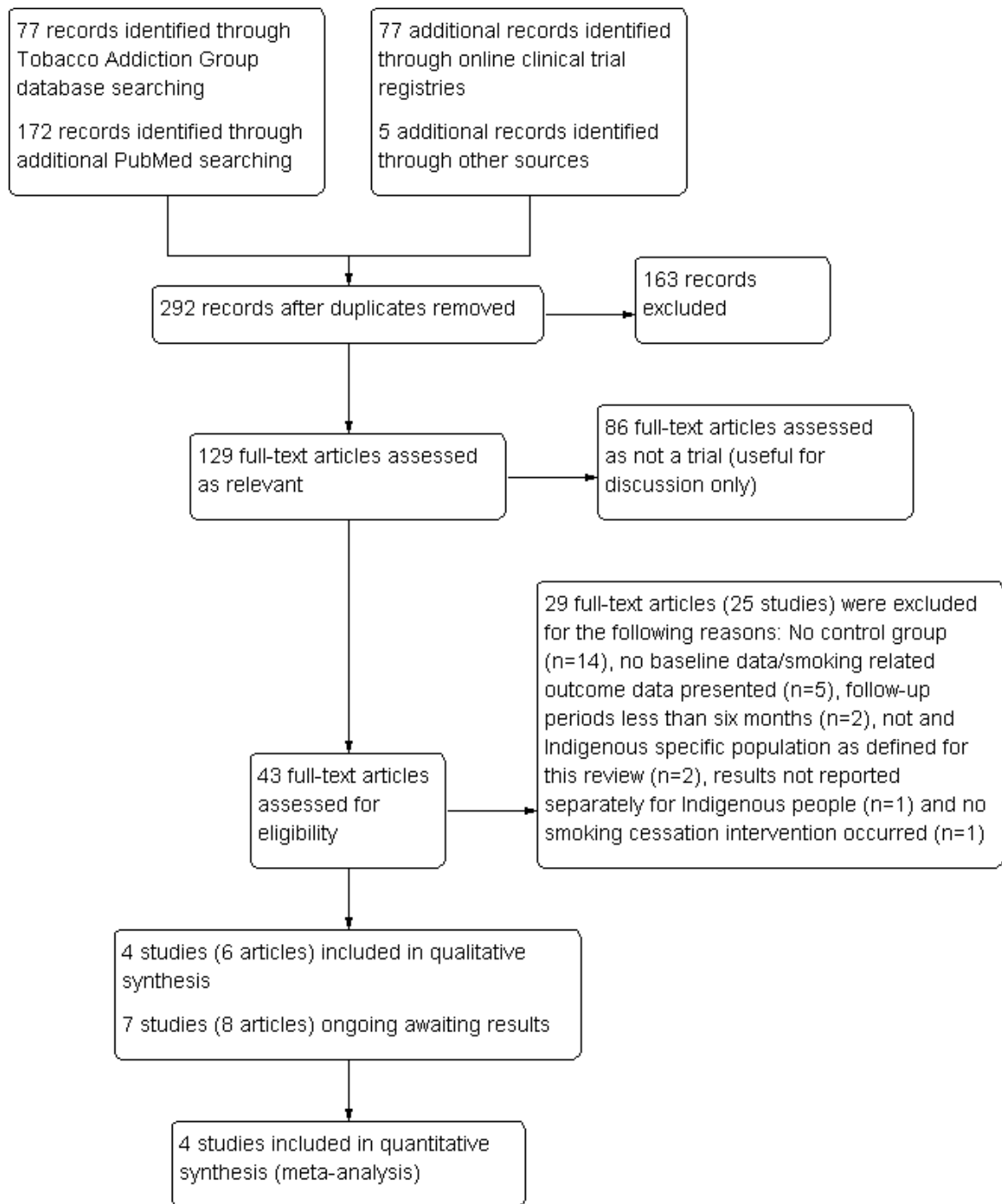
Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#); [Characteristics of ongoing studies](#).

Results of the search

The literature search retrieved 292 references after duplicates were removed, with 43 references identified from this search for retrieval and possible inclusion in the review. Five studies were obtained from the bibliographies of retrieved articles, one of which was later identified as a study for inclusion. From these, four trials (six publications) were identified for inclusion in the review (see [Figure 1](#)), with seven trials identified as potential ongoing studies (eight publications) ([Characteristics of ongoing studies](#)).

Figure 1. Study flow diagram.



Included studies

The four studies included in this review were published between 1997 and 2005. Two were randomised controlled trials ([Bramley 2005a](#); [Holt 2005](#)) and the remaining two studies used a controlled clinical trial design. [Holt 2005](#) and [Ivers 2003](#) investigated pharmacotherapy for smoking cessation (bupropion and nicotine replacement therapy respectively) in addition to some form of counselling. The [Bramley 2005a](#) study used a randomised investigation of smoking cessation services through mobile phone text messaging, whilst the [Johnson 1997](#) study used a 'Doctors Helping Smokers' model where doctors and clinical staff were trained in smoking cessation and counselling techniques. For full details of each trial see [Characteristics of included studies](#).

A total of 1201 subjects were included from these four studies. Two

were based on the Mā ori population Indigenous to New Zealand ([Bramley 2005a](#); [Holt 2005](#)), one on Aboriginal Australians and one on American Indians. Overall follow-up time periods ranged from six to twelve months post baseline data collection, although intermediate data collection also occurred in two studies ([Bramley 2005a](#); [Holt 2005](#)), and ranged from three weeks to nine months ([Holt 2005](#)) post intervention commencement. Intervention durations were seven weeks, ten weeks and six months for the [Holt 2005](#), [Ivers 2003](#) and [Bramley 2005a](#) studies respectively, whilst

the [Johnson 1997](#) study had two days of training for doctors and clinical staff with no data provided on intervention duration received by patients. Sample sizes were medium to large for all studies with 111 participants in the [Ivers 2003](#) study, 134 in the [Holt 2005](#) study, 355 in the [Bramley 2005a](#) study, whilst the [Johnson 1997](#) study had a large total sample size with 601 subjects.

Excluded studies

Twenty-five studies were excluded for the following reasons: no control group (n=14), no baseline data/smoking related outcome data presented (n=5), follow-up periods less than six months (n=2), not and Indigenous specific population as defined for this review (n=2), results not reported separately for Indigenous people (n=1) and no smoking cessation intervention occurred (n=1). See also [Characteristics of excluded studies](#) for more details.

Risk of bias in included studies

The key features for risk of bias in the four included studies are summarised in [Figure 2](#), in addition to the 'risk of bias' tables at the end of each [Characteristics of included studies](#) table. Overall the methodological quality of the studies were good, although each study had at least one category marked as a high risk of bias. Agreement for assessment of study quality were reached by two independent reviewers (KC and MB).

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Imbalance of outcome measures at baseline	Comparability of intervention and control group characteristics at baseline	Protection against contamination	Selective recruitment of participants	Other bias
Bramley 2005a	+	+	-	+	+	+	+	+	?	+	-
Holt 2005	+	?	+	+	+	+	+	+	+	+	-
Ivers 2003	-	-	-	?	+	+	-	-	+	-	-
Johnson 1997	-	-	-	?	-	+	+	+	+	?	-

Sequence generation

Sequence generation was a high risk of bias in two studies which did not randomise subjects (Johnson 1997; Ivers 2003) and low risk of bias for the remaining two studies, which used a central telephone randomisation algorithm (Bramley 2005a) and a computer generated code (Holt 2005).

Allocation concealment (selection bias)

Allocation concealment was unclear in one study (Holt 2005), a high risk of bias in two (Johnson 1997; Ivers 2003) and a low risk of bias for the Bramley 2005a study, which used central telephone randomization with sequence concealment until the intervention was assigned.

Blinding of participants (performance bias)

Due to the nature of the three community level interventions in the Johnson 1997, Bramley 2005a and Ivers 2003 studies it was not possible to blind participants. However the Holt 2005 study design incorporated a double-blind (i.e. participant and outcome assessor) design through the use of placebo pills for the control population.

Blinding of outcome assessors (detection bias)

Both the Bramley 2005a and Holt 2005 studies report blinding of outcome assessors, whilst this category was unclear in the Johnson 1997 and Ivers 2003 studies with no mention of attempted blinding.

Incomplete outcome data (attrition bias)

Three studies adequately addressed incomplete outcome data in their analyses with subjects lost-to-follow up being considered as 'continuing smokers' for outcome data. Secondary analysis models within the Bramley 2005a study also evaluated data with subjects lost-to-follow-up as non-smokers as per their pre-specified analysis plan. The Johnson 1997 study had a high risk of bias, as response rates for subjects in Seattle were significantly lower ($p=0.002$) compared to the other three health centres, resulting in a higher proportion of assumed-to-be-smokers.

Selective reporting (reporting bias)

Selective reporting was not identified in any of the included studies with a low risk of bias for each inclusion.

Imbalance of outcome measures at baseline

Three studies had low risks of bias for imbalances in outcomes measures at baseline with two studies (Johnson 1997; Bramley 2005a) conducting analysis of covariance and another study (Holt 2005) presented all of their baseline data with no imbalances reported. The Ivers 2003 study reported statistically significant differences between intervention and control participants at baseline. There was no mention of statistical adjustments made within the publication to account for these differences.

Comparability of intervention and control group characteristics at baseline

Similar to 'imbalances in outcome measures at baseline', the comparability of intervention and control group characteristics at baseline was a low risk of bias for three studies which reported their data and was found to be similar across groups (Johnson 1997; Bramley 2005a; Holt 2005). The Ivers 2003 study however demonstrated statistically significant differences between intervention and control groups at baseline, with no mention of adjustments incorporated within analysis models.

Protection against contamination

Potential contamination was a low risk of bias in three studies (Johnson 1997; Ivers 2003; Holt 2005) and an unclear risk of bias in one study (Bramley 2005a). For the Bramley 2005a study, author's mention that no restrictions were placed on the use of other smoking cessation strategies. To clarify, they mention that this trial was designed to test the addition of mobile phone-based services to existing practice. No further information was provided regarding any confirmed contamination.

Selective recruitment of participants

Selective recruitment was a low risk of bias in two studies which reported n-values and methods of recruitment across groups, and were deemed similar for intervention and control populations (Bramley 2005a; Holt 2005). However for the Ivers 2003 study subjects could 'self-select' to be in either the intervention or control group, whilst methods of recruitment were unclear for the Johnson 1997 study.

Other bias

All four studies had other biases identified which resulted in a unanimous high risk of bias for this category. The Bramley 2005a study provided incentives of free text messaging for a month in the control population only, which authors believe may have increased

the motivation within the control to report abstinence. It is a possibility that some of the control participants believed that in order to receive the month of free text messaging they were required to report abstinence. As such the control population may have had an advantage over the intervention with increased motivation to quit as a result of the incentive, and may also have reported false abstinence rates (salivary cotinine validation only occurred in a subset of participants). In the [Holt 2005](#) trial the targeted population sample size of n=141 were not collected due to a lack of eligible subjects. Authors also point out concerns over generalisability as the population, through self-selection to participate in a cessation trial, were highly motivated to quit. The pre-specified study design in the [Johnson 1997](#) trial was not possible due to funding limitations. This resulted in an amendment from fourteen study sites to a total of four (two in each arm). Authors also raised some concerns over comparability of each of the four clusters due to significant variations in tribes attending each of the health clinics. Finally the [Ivers 2003](#) study provided no adjustments for potential clustering effects to their data, which was required due to recruitment from three communities. Authors also report that no participant complete a full course of nicotine patches, with the mean number used being five. Only six subjects reported using more than seven patches (full course of patches for this trial would have been 70 patches over a 10-week period). Moreover, validation of smoking was not possible in 18% of intervention subjects and 20% of control subjects.

Effects of interventions

See: [Summary of findings for the main comparison interventions for smoking cessation for Indigenous populations](#)
See also Summary of findings table 1 for the main comparison: Smoking cessation interventions for Indigenous populations.

Smoking behaviour

Four different interventions were available for evaluation of smoking cessation strategies for Indigenous populations. Three interventions produced statistically non-significant but clinically significant effects in favour of the intervention ([Johnson 1997](#); [Bramley 2005a](#); [Holt 2005](#)), whilst one study produced a statistically and clinically significant effect in favour of the intervention ([Ivers 2003](#)), however the sample size was small with six intervention and one control subject reporting abstinence at follow up. Three studies assessed abstinence through point prevalence ([Johnson 1997](#); [Ivers 2003](#); [Bramley 2005a](#)) and the remaining one via continuous abstinence. When combined onto the one forest plot to examine the overall effect, a pooled risk ratio (RR) of 1.43 (95% CI 1.03 to 1.98, p=0.032) is produced in favour of the intervention ([Analysis 1.1](#)). However, due to the substantial methodological limitations including the limited uptake of the intervention found in the [Ivers 2003](#) study (only six subjects used more than seven patches, resulting in only 10% of the recommended treatment course being com-

pleted), a sensitivity analysis was performed excluding this study from the meta-analysis. The remaining three studies when pooled produced a statistically non-significant but clinically significant effect in favour of the intervention (RR 1.33, 95%CI 0.95 to 1.85, p=NS) ([Analysis 1.3](#)). For the purpose of this review the final follow up period reported in each study has been used for the meta-analysis. Data in the [Johnson 1997](#) and [Ivers 2003](#) studies were manually adjusted for potential clustering effects according to the pre-specified methodology as outlined in [Unit of analysis issues](#) under [Methods](#) in this review. The result for both studies were the same pre-cluster adjustment with a statistically non-significant but clinically significant effect in favour of the intervention for the [Johnson 1997](#) study and statistically and clinically significant effect in favour of the intervention for the [Ivers 2003](#) study. For a more detailed description of study outcomes see [Table 1](#) which provides a narrative synthesis of intervention effectiveness.

Adverse events

Adverse events were discussed in two studies with authors in the [Holt 2005](#) study reporting side effects due to bupropion as mild and self-limiting. Subjects in the treatment arm were more likely to experience insomnia (26% versus 9%), over that of the placebo arm. Three subjects reported a rash in the intervention arm and ceased treatment as a consequence. Subjects in the [Ivers 2003](#) study were not blinded, as a result adverse events are only reported for the intervention population. Adverse events included bad dreams (29%), pruritis (21%), nausea (4%), palpitations or shakiness (7%) and tiredness (7%). Seven percent of subjects reported that the patches would not remain stuck to their skin.

Mortality

One subject in the [Ivers 2003](#) evaluation died during the study period of causes unrelated to the use of the nicotine replacement therapy patch.

Costs of interventions

Authors in the [Ivers 2003](#) study evaluated the costs of the intervention (nicotine patches) compared to cigarette smoking. They estimated that a week's supply of nicotine patches cost approximately \$32-35 in addition to freight costs, in comparison to a pack a day smoker which can range between \$46-74. As a result they comment that other factors apart from the costs of nicotine patches appear to prevent smokers from using nicotine replacement therapy as an aid to quitting, which may include a widespread perception that smoking was normal behaviour.

Change in quality of life

No included studies addressed this outcome.

Change in pulmonary function

No included studies addressed this outcome.

Change in Attitudes

One study assessed changes in attitudes through the outcome 'readiness to quit' (Ivers 2003). Using the Fisher's Exact test no significant changes for intervention or control groups were found ($p=1.0$ and 0.21 respectively). There was a potentially negative finding following the intervention, in that 38% of smokers in the intervention group and 29% in the control group were less ready to quit after trying patches than they had been at the baseline visit.

Change in knowledge

No included studies addressed this outcome.

Change in exercise tolerance

No included studies addressed this outcome.

DISCUSSION

Summary of main results

Four completed studies assessed the benefits of smoking cessation interventions for Indigenous populations in 1201 subjects,

(two studies in New Zealand (Mā ori), one in Australia (Aboriginal) and one in the United States of America (American Indian)). Whilst some methodological variations occurred between studies in relation to intervention, delivery, mode of action and duration, they all were aimed at smoking cessation. In pooled analyses, a statistically and clinically significant effect in favour of the intervention was evident for the primary outcome of smoking cessation (RR 1.43, 95%CI 1.03 to 1.98, $p=0.032$), however following sensitivity analysis and removal of one study, a statistically non-significant but clinically significant effect was observed (RR 1.33, 95%CI 0.95 to 1.85, $p=NS$). Only one study examined changes in attitudes potentially demonstrating a negative finding, in that intervention subjects were less ready to quit following the intervention (see also Summary of findings table 1). This may be attributed to the recent failed smoking cessation attempt affecting confidence and motivation, subsequently reverting the subject back through the trans-theoretical model (Prochaska 1988) into the pre-contemplation phase. Adverse events were discussed in two studies with one reporting a statistically significant increase in episodes of insomnia for the intervention arm of bupropion, over that of placebo. The remaining study reported adverse events for the intervention arm only (nicotine patches), with the most

common adverse event being bad dreams experienced in 29% of the intervention population. Costs of interventions were assessed in one study with authors commenting that other factors excluding costs of nicotine patches must prevent smokers from using this cessation aid, as the cost of patches in comparison to the estimated costs of a pack-a-day smoker is lower. One study reported mortality with only one subject dying during the study period, for reasons unrelated to the trial.

Overall completeness and applicability of evidence

In the context of current practice, this review should be used to provide readers with an outline of what interventions have proven effectiveness, and where resources need to be directed for future investigations. However, the limited number of included studies and small samples sizes of these trials does limit the ability to draw reliable conclusions from the results. As such, interpretation of these findings need to be considered with caution. The overall completeness and applicability of the evidence found in this review highlights the paucity of data that exists to evaluate smoking cessation interventions for Indigenous populations around the world. Successful campaigns identified in this review have surveyed and/or conducted pilot investigations in the population being targeted and then tailored an appropriate intervention which meets the requirements of the communities needs. Based on the limited evidence from the available studies, a multi-faceted approach which provides cessation and prevention from various sources simultaneously, in addition to promoting community engagement, appear more likely to be successful in the reduction and cessation of smoking. Importantly, evaluations need to be performed alongside any future smoking cessation programs to ensure the applicability and effectiveness of the intervention not only for the targeted community, but also for the translation of evidence both nationally and internationally. To ensure intervention effectiveness and methodological rigour, future interventions should aim to incorporate the following into the study design:

- Use culturally appropriate interventions tailored for the population being targeted; consider the views and incorporate the suggestions of key members from the population (develop the intervention with community members); provide sufficient intervention exposure, duration and training; where possible involve Indigenous health care workers or project officers for intervention delivery and outcome collection
- Ensure an adequate control group which mirrors the demographic characteristics of the intervention population; consider potential sources of contamination where the intervention may reach the control population and incorporate strategies to minimise this risk
- Data collection (including smoking status) needs to occur pre-intervention and post-intervention in the same cohort of subjects; provide meaningful follow-up periods (i.e. minimum

six-months post-baseline data collection); outcome data and methods of analysis should be pre-specified to reduce *post hoc* amendments and additions which can introduce bias; calculate a target sample size prior to recruitment which has sufficient power to determine intervention effectiveness

Quality of the evidence

A significant health disparity exists whereby Indigenous populations, a minority, are over-represented in the burden of smoking-related morbidity and mortality (Bramley 2005b; ABS 2006; Wood 2008). Despite this, a paucity of evidence using methodologically rigorous evaluations to assess smoking cessation interventions has been identified for the Indigenous population, which has been confirmed by many researchers (Gray 2000; Gohdes 2002; Ivers 2003; Clifford 2009). As a result, the external validity of this review is limited by a lack of published investigations on which to draw a conclusion. Not only is there a lack of evidence examining the different types of interventions (e.g. pharmacological, behavioural etc.), there is also a lack of investigation for the various sub-sets of Indigenous populations (e.g. Native

Alaskan, Mā ori, Aboriginal Australian, American Indian etc.). Of the available data, study quality is a potential issue with some studies in this review being of unclear methodological quality or of a high risk of bias. There are no cost-effectiveness studies for dissemination of smoking cessation interventions, that are specific to Indigenous health-care services and programs. The gap in this evidence has also been identified in other recent studies (Sanson-Fisher 2006; Clifford 2009), and is of concern due to the gap in health disparities between Indigenous and non-Indigenous populations, which are further exacerbated by the delay between intervention research efforts and implementation of cost-effective dissemination strategies (Berwick 2003).

Of note, no methodologically rigorous evaluations alongside governmental policies were identified for this review despite the large monetary investments publicised for Indigenous smoking cessation strategies (Ministry of Health 2004; COAG 2009; SA Department of Health 2010; US Dept of Health and Human Services 2010). These policies (which can include mass media campaigns, access to free nicotine replacement therapies etc.) require considerable resources, however their subsequent efficacy to increase long-term smoking abstinence following implementation is unknown. The use of such resources for programs with unproven effectiveness in the Indigenous context can have a detrimental result, as resources provided for the delivery of ineffective interventions means an opportunity cost for other interventions (Ivers 2004). One concern is that epidemiological studies have reported that tobacco control infrastructures (e.g. outreach smoking cessation clinics or public policy initiatives) vary or are lacking between communities despite the implementation of wide-spread policies (Baezconde-Garbanati 2007; Johnston 2010b). The reasons for

this are not widely understood, though some researchers hypothesise that the historical and cultural role that tobacco plays in these communities in addition to the sovereignty of tribal nations (particularly for American Indians), may result in these policies not being implemented within the communities (Baezconde-Garbanati 2007). Other suggestions relate to the lack of enforcement of existing tobacco legislation, reticence by the community to change the status quo and few non-smoking role models in leadership positions (Johnston 2010b). As such, the next phase in tobacco cessation strategies for Indigenous populations must include accompanying assessments to determine the success of the intervention, efficacy of its implementation and ability for mass-dissemination. This does not necessarily dictate that a heavily funded double-blind randomized controlled trial is required. Rather, an assessment involving descriptive and qualitative data to determine the likely success following the transfer of interventions to the Indigenous setting may suffice (Ivers 2004).

Potential biases in the review process

A potential bias in the review process is exclusion of studies examining Indigenous specific interventions that are of questionable methodological design. This review does sacrifice inclusion of some relevant information, however the trade-off is a meta-analysis of higher quality evidence on which future investigations can be based. Some of the pertinent information from these studies are discussed below under 'Agreements and disagreements with other studies or reviews' though results should be interpreted with caution. One key strength of the review process to address potential biases, is the use of two experienced and independent review authors who assess the study quality. Although this can do little to account for biases which occur in the methodological designs of the included studies.

This review of studies does not take into account the social construct of smoking in Indigenous communities and how this differs from the mainstream dominant culture's views of tobacco use. It is difficult to separate addiction from social determinants of tobacco use, especially for the studies predominantly reporting intervention outcomes. Literature has been published around why Indigenous people smoke, with one publication reporting that Aboriginal and Torres Strait Islander communities nominate many of the same reasons for smoking as non-Indigenous Australians including, a consolation in bad times, an aid to relaxation and as a dependable aspect of daily routines (Carter 2001). Another report funded under the National Tobacco Strategy in Australia also found the most commonly reported reasons for smoking were to alleviate stress, social considerations, alleviate boredom, routine habit, used as a 'time out', and addiction (Lindorff 2002). A close connection between tobacco used and other social behaviours such as alcohol, gambling or having a cup of tea or coffee were also observed (Scollo 2008). Tobacco use is also viewed by some as a 'lesser evil' being an acceptable alternative to other drugs such as

alcohol, cannabis and intravenous drugs (CEITC 2005). This is similar to reports in American Indian communities with smoking described as a way for women in particular to care for themselves in response to multiple stressors and responsibilities including the management of stress, anger and coping with the demands of children work and family (Burgess 2007).

Agreements and disagreements with other studies or reviews

Many studies point out the importance of tobacco use in the cultural and spiritual context of Indigenous populations (Brady 2002; Daley 2006; Daley 2009), such as with American Indian communities and tobacco's role in ceremonial, religious and medicinal functions (Baezconde-Garbanati 2007). Some of these cultural practices include burial offerings, spiritual protection or use as a gift to the Creator, or as a gift to honour someone (Rhoades 2000; Eichner 2010; Daley 2011). For American Indians in particular tobacco use has a long and complicated history, with its early use for ceremonial and therapeutic means, and later cultivation and trade with European settlers (Rhoades 2000; Eichner 2010). On a similar note, historical evolution of tobacco in the Indigenous Australian setting stems from its use as part of government rations, as a means of payment for services (Briggs 1996; Johnston 2010b), and as one report suggests, to pacify and exploit the Indigenous owners of the land (Brady 2002). Tobacco has a deep-rooted history in many Indigenous settings, however it is important to realise that current health inequalities do not exist because of traditional tobacco use, but rather through the abuse of tobacco (Eichner 2005).

A study of American Indians in the Northern Plains found that Indian smokers were more likely to report quit attempts of one or more days in the preceding year, than non-Indians with 67% compared to 43% respectively (Gohdes 2002). However, actual quit ratios in this study were lower among Indians with 43% compared to non-Indians with 65%. Two other recent studies produced similar results with survey data indicating that a large proportion of the population were open to interventions aimed at modifying their smoking behaviour, though no interventions were easily accessible (Clough 2009). Importantly, the authors of the investigation state that expecting smokers to quit on their own without the necessary support is unreasonable and needs to be provided if smoking abstinence is expected (Clough 2011). This indicates that it is not necessarily a lack of motivation preventing abstinence, but rather a lack of means to produce a sustained benefit. Despite the scarcity of methodologically rigorous studies existing for inclusion in this review, some limited information is available for interventions of smoking cessation in Indigenous populations by means of focus groups, surveys, small pilot projects and non-controlled trials, which are described below.

As the aim of this review is to examine the broad construct of tobacco cessation interventions for Indigenous populations world

wide, the information produced is drawn from different Indigenous groups. The constant interchange between these populations may falsely imply that characteristics reported are homogenous to all Indigenous people. Attempts have been made to limit false implications in the review.

Summary of evidence for intervention effectiveness in other published studies:

Pharmacotherapy:

An epidemiological investigation of pharmacotherapy in remote Indigenous Australian communities identified that of 133 participants, 40% (n=53) did not know anything about pharmacotherapies for smoking cessation, 47% (n=62) knew about them but had never used them, leaving only 14% (n=18) who had who had tried some form of pharmacotherapy (Clough 2009). Another survey in the Indigenous Australian community found that 6 out of 25 people had used nicotine replacement therapy and two had been successful in short-term abstinence (Johnston 2010b). Overall however, other published evidence for use of pharmacotherapies in Indigenous settings is low (Thornley 2010), with associated costs and availability being concerns highlighted by health care staff (Johnston 2010b), and lack of information about tobacco dependence by health care providers, a concern identified by some Indigenous people (Burgess 2007). Another obstacle identified in numerous studies is the poor compliance rate with people not returning to clinics to refill prescriptions or reduced supplies when pharmacotherapy was shared with other family members (Ivers 2003; Johnston 2010b). Some studies have identified cultural specific barriers to the use of pharmacotherapy, including lack of trust in conventional medicine related to historic and continuing racism (Burgess 2007), and some participants in the included Ivers 2003 study reported bad dreams or nightmares. This is particularly important for Aboriginal Australians as dreams signify that a person is being 'sung' to, or cursed, which consequently produces reticence for the uptake of pharmacotherapy community wide.

Cognitive and behavioural therapies:

In remote Indigenous communities, brief interventions, advice, support services and counselling for smoking cessation are not routinely available, or are based in regional centres which are under-resourced or inappropriately targeted (Briggs 2003, Ivers 2003, Baker 2006, Clough 2009). Community support and small group counselling sessions have the potential to boost quit rates, however intrinsic and explicit pressures to maintain smoking behaviours exist. Examples of barriers described by Aboriginal Australians attempting to quit in one survey include: being asked to buy cigarettes for family, continued offers of cigarettes by friends and

family and the feeling of isolation and exclusion from social gatherings where people were smoking (Johnston 2010b). One study comparing the relationship between tobacco use and cardiovascular disease in an American Indian population, found that a greater proportion of smokers who had a co-morbid condition such as diabetes, hypertension or renal insufficiency quit smoking, compared to those without a co-morbid condition (Eichner 2010). Another survey in Aboriginal Australians identified that interventions delivered in the primary health care setting were ineffective unless associated with a major health event (Johnston 2010b). In Johnston 2010b, drivers to keep smoking such as social pressures, addiction and stress outweighed motivations to quit.

Alternative therapies:

No evidence was available in any of the published literature for alternative therapies directed specifically at Indigenous populations.

Public policy:

Public policies for smoke-free areas and homes when initiated by individuals, do not appear to produce the associated barriers to implementation seen in some of the other interventions. For example, the alteration in attitudes and display of 'smoke-free' stickers on verandas and houses in an Aboriginal Australian community trial testifies to this (Johnston 2010b). The health protection of children was the argument most often used in support of smoke-free areas for this survey and appeared to generate the most traction in producing a consensus on the tobacco issue. In summary, the survey identified that community implemented public policy which highlights the importance of a 'smoke-free environment' for youth, would likely be an effective motivator for smoking cessation in adults. However, no methodologically rigorous trials supporting this claim have been identified to date.

Increasing the taxes on tobacco as a disincentive to smoke in Indigenous communities need to be considered with caution. One study survey produced an alarming result with subjects prioritising tobacco over food or paying bills for amenities (Johnston 2010b). Nonetheless, when funds were scarce, changes in smoking behaviour did occur with subjects using alternative strategies including asking family for cigarettes, purchasing tobacco from the black market or rolling cigarettes from the tobacco remaining in discarded butts (Johnston 2010b). Another study suggests that taxation of tobacco could have substantial health and economic benefits, however governments and other organisations need to examine such policies in the context of Indigenous populations, with consideration for cultural appropriateness (Wardman 2005). One excluded study assessing the 'Bubblewrap' mass media campaign reported that significantly more subjects recalled awareness of television advertisements over that of radio. This program, though of minimal impact for sustained smoking cessation with

1.5% successfully quitting after two months, did result in a quarter of smokers attempting cessation and over 30% reporting that they had cut down the number of cigarettes consumed to some degree (Boyle 2010). Another similar study piloted in Indigenous Australians found good recall of mainstream anti-tobacco media messages among community members, however both Indigenous and non-Indigenous staff perceived that the marketing campaign needed to be significantly modified to be socially acceptable to an Indigenous audience (Johnston 2010b).

Combination therapies:

The majority of studies falling into the above categories could be classified as combination therapies as they include intervention messages delivered via multiple sources. Examples include when pharmacotherapy is prescribed or delivered via a health care professional as some form of accompanying behavioural intervention is usually provided. On a more expansive note, one study suggested that lifestyle brief interventions need to be coupled with multi-level health strategies, as the potential effectiveness will be limited in the absence of broader strategic objectives aimed at community-identified health priorities such as alcohol and other drug abuse (Harvey 2002). Another study reports similar findings in that the capacity to effectively address the disproportionate burden of tobacco-use is contingent upon the presence of multiple sources of program message delivery, appropriate distribution of funds and resources and an underlying understanding of community strengths, history, values and participation (Baezconde-Garbanati 2007). A third study assessing cancer-related health behaviours among Inuit residents in Canada's north, found that lower health service utilisation and health-related behaviours leading to increased cancer risk (e.g. tobacco use), appear to be due to unobserved factors specific to their unique social-cultural context. As such they also recommend that policy interventions designed to address these problems be specifically targeted for the population and should not be considered in isolation of their broader health, economic and social environment (McDonald 2010). However these multi-level strategies are yet to be tested in the Indigenous population under high methodological design standards and as such no strong evidence is available to confirm that such an approach would be any more or less effective in the context of tobacco control interventions.

Summary of evidence for intervention effectiveness in other systematic reviews:

One systematic review which assessed behavioural smoking cessation interventions for disadvantaged groups devoted one section of the evaluation to Indigenous populations (Bryant 2011). They identified two studies targeted at Indigenous smokers (one of which, Bramley 2005a, was incorporated into this review); however pooled analysis produced no statistically significant effect (RR

1.34, 95%CI 0.91 to 1.96). These findings are almost identical to the pooled estimate of smoking cessation found in this review following sensitivity analysis (RR 1.33, 95%CI 0.85 to 1.85) and both reviews report similar clinical significance. The authors of the Bryant 2011 systematic review also concluded that further research is required that is adequately funded and powered to establish the most effective cessation intervention.

Another systematic evaluation aimed at the review of efforts to increase the uptake of evidence-based interventions in Indigenous-specific health care settings and programs also identified two studies related to smoking for inclusion (Clifford 2009). Authors of the review suggest that the use of outcome measures with demonstrated reliability and validity to quantify the effect of interventions are required to evaluate changes in health service delivery, and would improve methodological rigour by almost 50% in Indigenous dissemination strategies (Clifford 2009).

Similar to conclusions in this meta-analysis, a 2009 review of tobacco interventions in Aboriginal Australians found evidence that nicotine replacement therapy and/or counselling, specifically targeted at individuals may be an effective smoking cessation aid, however results were only reported through narrative synthesis (Power 2009). A review of tobacco interventions conducted by Ivers *et al* in 2003 found a major lack of research evaluating tobacco interventions for Indigenous Australians (Ivers 2003). Although the four included studies reported in that review were not the same as the evidence utilised in this meta-analysis, the message produced concerning the lack of evidence in spite of the significant health disparity is the same.

Smoking cessation in pregnant women:

Rates of smoking in Indigenous pregnant women have been reported as high, as 50 to 65% (Eades 1999; Mohsin 2005; Laws 2006; Laws 2008). It is well known that smoking during pregnancy can have devastating health consequences not only on the mother but also the unborn child (Horta 1997; Horta 2001; Wills 2008). Early research in Indigenous women has associated smoking with an increased risk of sudden infant death syndrome (Bulterys 1990; King 1997). Despite this, only limited evidence currently exists to examine interventions for smoking cessation specifically designed for Indigenous pregnant women (Pullon 2003; Wills 2008; Wood 2008; Panaretto 2009), of which no investigations were of sufficient quality to be included within the analyses of this review. The closest evidence available to assess this sub-group has been identified in one ongoing study protocol (Johnston 2010a), which will assess environmental tobacco smoke exposure on Indigenous pregnant women and their children as a primary outcome.

Challenges to consider:

Some potential implementation barriers for smoking cessation programs were identified in a brief intervention piloted in three

routine clinical practice cites (Harvey 2002). These should be considered when planning future investigations and include: constraints surrounding the intervention training program and embracing the needs of a diverse workforce, issues concerning long-term sustainability and the uptake of changes in clinical practice and the subsequent difficulties associated with introduction of new ideas and technologies into existing practice. Authors of the Harvey 2002 study have proposed solutions for these barriers including: a train-the-trainer program, which involves an education and mentoring program for key Indigenous personnel to become trainers in tobacco interventions themselves, thus creating a functional entity capable of upholding the intervention without support, and another solution is to package continuing education and training in a way which enables staff development officers and trainers in health services to access the package as part of ongoing development and education for new staff (Harvey 2002). Another barrier to implementation for brief intervention is the sense of fatalism among health staff surrounding their ability to effectively produce change (Harvey 2002). A study by Thompson 2010 also suggests that the smoking status of the Indigenous health care worker may be another obstacle preventing them from providing quit support. As such, steps need to be considered to ensure that the attitudes and beliefs of health staff do not adversely affect implementation strategies (Harvey 2002; Johnston 2010b). A factor further complicating tobacco cessation is a reliance on the revenue sales can bring to tribes, or ability to use tobacco as a currency or trade which occurs in some communities (Eichner 2005; Baezconde-Garbanati 2007). It is important when reviewing these barriers, to emphasize that these are complications for interventions and not prohibiting factors (Eichner 2010). The health disparity of Indigenous Australians has been well chronicled. It is now time to ensure that methodologically rigorous investigations are undertaken, to examine the effectiveness of tobacco interventions and reduce the gap in Indigenous health care.

AUTHORS' CONCLUSIONS

Implications for practice

Evidence from this review suggest that Indigenous people are willing to attempt smoking cessation through targeted interventions, providing adequate resources and education are available which are culturally appropriate. Some limited evidence exists to support the use of behavioural interventions through culturally appropriate health messages, delivered via health professionals or through text messaging and the use of pharmacotherapies in the form of nicotine replacement therapy and Zyban (bupropion). However the interpretation of these results and effectiveness of these studies do need to be considered with caution due to the small sample sizes and methodological limitations. Since these studies were completed a new smoking cessation aid specifically targeting the

α -4 β -2 nicotinic receptor has become available (varenicline tartrate), which now requires investigation in the Indigenous population, with close monitoring of adverse events particularly around dreams.

More evidence is needed to clearly ascertain what interventions and components of interventions are the most effective for smoking cessation. Interventions should be of a reasonable duration and intensity to produce an effect with consideration given to process measures for the amount of intervention exposure an individual is actually likely to receive. It is important to consider conducting assessments alongside any future practices to determine if an intervention is truly effective and that investments are appropriately directed. When considering strategies for intervention implementation it is just as important to consider 'who' will deliver the intervention. The Indigenous context must be considered at every aspect of program execution to permit optimal uptake by the community. Incorporating the views and recommendations of the population is likely to enhance the effectiveness of a campaign. Tailoring an intervention based on pilot work or survey data should be considered, to ensure an appropriate intervention which meets the requirements of the target population's specific needs. A multi-faceted approach which provides cessation and prevention from various sources simultaneously and engages the community appear more likely to increase success in the reduction and cessation of smoking.

Implications for research

There is an urgent need for research to assess interventions being funded for use in Indigenous populations, as limited evidence exists for proven intervention effectiveness (e.g. pharmacotherapies (including nicotine replacement therapies, bupropion and varenicline tartrate), cognitive and behavioural therapies (CBTs) (including counselling, support groups, self-help, seminars, motivational lectures), alternative therapies (including acupuncture, hypnotherapy, aversion therapy), public policy (including legislative interventions, media campaigns, community interventions), and combination therapies (including a combination of at least two therapies from the above four categories). Studies aimed at pregnant Indigenous women are especially vital. An assessment

of optimal tobacco cessation initiatives for Indigenous pregnant women and the subsequent effects of tobacco use in utero and post partum need to be urgently evaluated. Researchers need to ensure the appropriateness of the intervention and target requirements specific to the population being tested; provide adequate intervention exposure, duration and training through the use of Indigenous project officers wherever possible to enhance the uptake of cessation messages and select an appropriately matched control population to compare results and collect data at both pre and post intervention at meaningful time points (i.e. follow up of a minimum of six months post-baseline assessment). Most importantly, be explicit and comprehensive when describing the limitations and barriers of implementation, as lessons can be learnt from past experiences which can be translated into new investigations to improve the tobacco related health disparities which currently exist in Indigenous populations globally.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Bramley 2005a

Methods	<p><i>Country:</i> New Zealand</p> <p><i>Design:</i> Randomised Controlled Trial</p> <p><i>Objectives:</i> To determine whether a smoking cessation service using mobile phone text messaging is as effective for Mā ori as non-Mā ori</p> <p><i>Study Site:</i> Done remotely via phone (not location dependent)</p> <p><i>Programme name:</i> STOMP study (STOp smoking by Mobile Phone)</p> <p><i>Methods of analysis:</i> Chi-squared analyses compared proportion quit by treatment group with estimation of relative risk, 95% confidence intervals and two-sided p values; Fagerström and number of cigarettes smoked compared with analysis of covariance; Logistic regression used for baseline effect modifiers and confounders; Participants without follow-up data were assumed smoking in the primary analysis</p> <p><i>Cluster adjustment made:</i> None reported though not necessary for this study as subjects are not clustered within a specific location</p>
Participants	<p><i>Eligible for study (n-value):</i> n=1705 overall population including Non-Mā ori</p> <p><i>Recruited:</i> n=176 for intervention and n=179 for control</p> <p><i>Completed:</i> 6 weeks n=160 for intervention and n=168 for control; 26 weeks n=80 for intervention and n=112 for control</p> <p><i>Age:</i> Median (IQR - Inter-Quartile Range): Intervention 24 (19-33); Control 25 (20-32)</p> <p><i>Gender:</i> Female: Intervention n=132 (75%); Control n=131 (73.2%)</p> <p><i>Ethnicity:</i> Mā ori</p> <p><i>Socio-economic status:</i> Income level <\$15,000: Intervention n=43 (24.4%); Control n=37 (20.7%); \$15-30,000: Intervention n=83 (47.2); Control n=78 (43.6%); >\$30,000: Intervention n=49 (27.8%); Control n=63 (35.2%); Did not answer: Intervention n=1 (0.6%); Control n=1 (0.6%)</p> <p><i>Recruitment means:</i> Mā ori radio station advertising, mailing lists to Mā ori students attending tertiary institutions, advertisements in a Mā ori student magazine, hospital staff e-mail lists, faxes to Mā ori health providers, via Mā ori smoke-free networks and providers; Non-targeted advertising included newspapers, web-sites, magazines and Quitline</p>
Interventions	<p><i>Theoretical basis:</i> No specific theoretical basis mentioned however text messaging as a new communications medium is being used</p> <p><i>Intervention description/s:</i> Smoking cessation service using mobile phone text messaging; Regular, personalised text messages providing smoking cessation advice, support and distraction; Included a database of over 1000 text messages with a list of approximately 140 developed by Mā ori researchers related to the Mā ori language and included general support messages and information on Mā ori customs and traditions to produce an individualised program; A quit day was negotiated and five text messages were sent per day for the week leading up to the quit day in addition to the four weeks following; On the quit day free outgoing text messages also began as a means of distraction and communicating the need for support; Six weeks after randomisation (and coinciding with the end of the free text month) the intervention became less intensive with the</p>

Bramley 2005a (Continued)

	<p>number of messages reduced from five a day to three a week until the 26 week period <i>Control description/s:</i> No smoking-related information though they received one text message per fortnight reminding them to complete follow-up; If follow-up was complete they were rewarded with a free month of text messaging; No restrictions were placed on other smoking cessation strategies by trial participants (i.e. additional mobile phone based services may have existed) <i>Duration of intervention:</i> 26 weeks (6 months) <i>Intervention delivered by:</i> Telecommunications (Vodafone customers only)</p>	
Outcomes	<p><i>Method of outcome collection:</i> Baseline and follow-up data collected by mobile phone or text messaging <i>Pre-specified outcome data:</i> Prevalence of current non-smoking 6 weeks post-randomisation; secondary outcomes included self-reported non-smoking at 12 and 26 weeks <i>Validation:</i> In a sub-set - Salivary cotinine <i>Follow-up period:</i> Six months <i>Number of follow-up periods reported:</i> Three - 6, 12 and 26 weeks <i>Process measures:</i> None reported, however because each patient received the text message directly to their mobile the implementation level would be close to 100% providing the text messages were received</p>	
Notes	<p><i>Definition of point prevalence:</i> Not smoking in the past week</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Central telephone randomisation algorithm used
Allocation concealment (selection bias)	Low risk	Central telephone randomisation with sequence concealment until intervention was assigned
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants were not blinded to the intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Follow-up phone calls were made by staff who were unaware of the treatment allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Patients with missing outcome data were assumed to be smoking; Sensitivity analyses performed to assess impact of missing data; 45% attrition in the intervention group compared to 31% for the control

Bramley 2005a (Continued)

Selective reporting (reporting bias)	Low risk	No selective reporting identified; Authors state that data were analysed following a pre-specified analysis plan
Imbalance of outcome measures at baseline	Low risk	Analysis of covariance occurred
Comparability of intervention and control group characteristics at baseline	Low risk	Baseline characteristics reported and similar for all groups - age, gender, income level and smoking dependence/history
Protection against contamination	Unclear risk	Authors mention no restrictions were placed on the use of other smoking cessation strategies i.e. trial tested the addition of mobile phone-based services to existing practice but no further information provided
Selective recruitment of participants	Low risk	n-values and methods of recruitment described and similar across groups
Other bias	High risk	Incentive of one month free text messaging not offered to the intervention population; authors state some control's may have thought their free text month was dependant on reporting quitting and may have affected the result in favour of control

Holt 2005

Methods	<p><i>Country:</i> New Zealand <i>Design:</i> Randomised controlled trial; double blind, parallel group study <i>Objectives:</i> To determine the effectiveness of bupropion for smoking cessation in Māori <i>Study Site:</i> Wellington and Kapiti regions in New Zealand - single centre study <i>Programme name:</i> Not provided <i>Methods of analysis:</i> For the primary analysis comparisons of smoking status occurred through normal approximation to the binomial distribution and expressed as differences in proportions and risk ratios; Secondary analysis used generalised estimating equations by treatment status and time of observation using an exchangeable correlation structure to model the repeated measures; Adverse effects were calculated using the total number of subjects allocated to a particular intervention as the denominator to calculate proportions, expressed as risk ratios and confidence intervals; Exploratory analysis also occurred with a break point at 26 weeks <i>Cluster adjustment made:</i> Not applicable</p>
Participants	<p><i>Eligible for study (n-value):</i> n=300 attended public information meeting <i>Recruited:</i> 2:1 randomisation occurred (two to bupropion: one to placebo); n=88 intervention; n=46 control</p>

	<p><i>Completed:</i> n=56 intervention; n=22 <i>Age:</i> Mean (SD) years; Intervention: 41.7 (9.2); Control: 38.0 (11.1) <i>Gender:</i> Women/total; Intervention: n=61/88; Control: n=35/46 <i>Ethnicity:</i> Mā ori <i>Socio-economic status:</i> Not provided <i>Recruitment means:</i> Self-recruited from advertising in local media and actively recruited from Mā ori health networks</p>	
Interventions	<p><i>Theoretical basis:</i> Cultural safety, reducing barriers and encouraging access through community based clinics with key involvement of Mā ori health providers <i>Intervention description/s:</i> Bupropion (Zyban) 150mg once daily for 3 days, then 150 mg twice daily for 7 weeks; oral course; Participants received motivational telephone calls 1 day before and 3-days after the target quit date; Follow-up visits for counselling and data collection scheduled for 3 weeks, 7 weeks, 3 months, 6 months and 12 months after the target quit date; Counselling topics tailored to individual participants and included support and advice on motivation to quit, identification of smoking triggers, diet, exercise and role of family, friends, and work colleagues <i>Control description/s:</i> Matching placebo control plus identical counselling and follow-up schedule as the intervention <i>Duration of intervention:</i> 7 week course of bupropion/placebo and eight scheduled counselling sessions <i>Intervention delivered by:</i> A Mā ori research nurse was employed to undertake this study</p>	
Outcomes	<p><i>Method of outcome collection:</i> Telephone calls 1 day before and 3 days after target quit date and scheduled clinic visits for 3 weeks, 7 weeks, 3 months, 6 months, 9 months and 12 months <i>Pre-specified outcome data:</i> Continued abstinence from smoking at 3 and 12 months; continued abstinence from smoking at other time points and adverse events <i>Validation:</i> Exhaled carbon monoxide (Smoke Check, Micro Medical) <i>Follow-up period:</i> Twelve months <i>Number of follow-up periods reported:</i> Six: primary: 3- and 12 months; secondary: 3 weeks, 7 weeks, 6 months and 9 months <i>Process measures:</i> n= 32 subjects lost to follow up by 12 months in the intervention arm and n=24 subjects in the control arm; n=3 subjects in the intervention arm stopped taking the medication due to a rash; No further information provided</p>	
Notes	<p>Definition of continuous abstinence: No cigarettes from the quit data and confirmed with a negative exhaled carbon monoxide measure at each of the clinic visits</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated code
Allocation concealment (selection bias)	Unclear risk	Authors state a "...blinded medication pack was dispensed..." no other information provided

Holt 2005 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Low risk	Double blinding occurred; authors state participants were not aware which treatment had been allocated
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Authors state trial was double-blinded; study team were not aware which treatment had been allocated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Subjects lost to follow up were assumed smoking
Selective reporting (reporting bias)	Low risk	No selective reporting identified
Imbalance of outcome measures at baseline	Low risk	No baseline imbalances were identified
Comparability of intervention and control group characteristics at baseline	Low risk	Baseline characteristics for all groups were similar and reported
Protection against contamination	Low risk	Unlikely that the control group received the intervention
Selective recruitment of participants	Low risk	Methods of recruitment similar however recruitment occurred on a 2:1 ratio for intervention and control respectively
Other bias	High risk	Target pre-specified population n-value of n=141 participants were not collected due to lack of eligible subjects; Concerns over generalisability of results - population self-selected so were also highly motivated

Methods	<p><i>Country:</i> Australia</p> <p><i>Design:</i> Controlled clinical trial; pre/post design; cluster</p> <p><i>Objectives:</i> The first aim of this study was to assess the patterns of use of free nicotine patches when offered to Indigenous people with a brief intervention for smoking cessation. The second aim was to assess changes in smoking behaviour and attitudes six months after access to free nicotine patches and/or a brief intervention for smoking cessation</p> <p><i>Study Site:</i> Participating health clinics</p> <p><i>Programme name:</i> Not specified</p> <p><i>Methods of analysis:</i> Not described; However author's state that 'As a results of self-selection, the treatment groups differed on many baseline parameters... and this precludes any direct comparison of the impact of NRT and brief intervention on smoking behaviour and attitudes.'</p> <p><i>Cluster adjustment made:</i> No</p>
Participants	<p><i>Eligible for study (n-value):</i> n=130 interviewed at baseline</p> <p><i>Recruited:</i> Intervention n=40; Control n=71</p> <p><i>Completed:</i> Intervention n=34; Control n=59</p> <p><i>Age:</i> 30 years or under: Intervention n=13, Control n=43; Over 30 years of age: Intervention n=27, Control n=28</p> <p><i>Gender:</i> Intervention: female n=24, male n=16; Control: female n=27, male n=44</p> <p><i>Ethnicity:</i> Indigenous Australian Aboriginals</p> <p><i>Socio-economic status:</i> Not specified</p> <p><i>Recruitment means:</i> Participants were recruited from a consecutive sample of self-identified Indigenous smokers presenting to participating health centres. The sample included some smokers nominated by a health professional</p>
Interventions	<p><i>Theoretical basis:</i> Brief intervention and advice on cessation plus nicotine patches to assist smoking cessation; no other information provided; Transtheoretical model (stages of change) discussed</p> <p><i>Intervention description/s:</i> Brief intervention for smoking cessation plus six weeks of 21mg nicotine patches, two weeks of 14 mg patches and two weeks of 7 mg patches (total 10 weeks of treatment; patches were to be worn for 24 hours); The brief intervention consisted of: advice on quitting, counselling on cessation, shown a flip-chart about tobacco and provided a pamphlet</p> <p><i>Control description/s:</i> Brief intervention only as described above (no patches)</p> <p><i>Duration of intervention:</i> 10 weeks in total for course of nicotine patches; approximately five minutes in total for brief intervention</p> <p><i>Intervention delivered by:</i> The researcher and a local research assistant explained the study, administered the questionnaire and provided brief interventions for smoking cessation</p>
Outcomes	<p><i>Method of outcome collection:</i> Verbal questionnaire administered by researcher and local research assistant</p> <p><i>Pre-specified outcome data:</i> Number of patches used, changes in smoking behaviour (point prevalence), carbon monoxide breath test, attitudes to smoking, side effects experienced and barriers to using nicotine patches</p> <p><i>Validation:</i> Carbon monoxide (CO) breath test</p> <p><i>Follow-up period:</i> Six months</p> <p><i>Number of follow-up periods reported:</i> One</p>

	<i>Process measures:</i> No participant completed a full course of patches; the mean number of patches used, as reported by participants was five patches (range 0-49 patches); Only six people said that they had used more than seven patches, that is, 10% of the suggested course of treatment	
Notes	<i>Definition of smoking abstinence:</i> Author did not define <i>Other notes:</i> Two of the subjects claiming abstinence in the intervention arm had elevated CO levels (10ppm) and as such were removed from analysis	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Subjects self-selected
Allocation concealment (selection bias)	High risk	No allocation concealment occurred
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding of subjects occurred
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No mention of blinding for outcome assessors
Incomplete outcome data (attrition bias) All outcomes	Low risk	Incomplete outcome data accounted for within text; all subjects lost to follow-up were assumed smoking
Selective reporting (reporting bias)	Low risk	No selective outcome reporting identified
Imbalance of outcome measures at baseline	High risk	Statistically significant differences between intervention and control participants identified at baseline; Statistical analysis not described
Comparability of intervention and control group characteristics at baseline	High risk	Statistically significant differences between intervention and control participants identified at baseline; Statistical analysis not described
Protection against contamination	Low risk	Author's state only "One participant in the brief intervention only group had used patches..."
Selective recruitment of participants	High risk	Subjects self-selected to intervention and control groups

Other bias	High risk	No adjustments made for potential clustering effects for the three communities; No subjects completed a full course of patches with the mean number used being five (out of a potential 70 for a full course); Validation of smoking not possible in 18% of intervention subjects and 20% of control subjects
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Johnson 1997

Methods	<p><i>Country:</i> United States of America</p> <p><i>Design:</i> Controlled clinical trial; nested; cluster</p> <p><i>Objectives:</i> Assessment of feasibility and effectiveness in the delivery of a smoking cessation intervention through health clinics, serving to urban American Indians. A primary study goal was the implementation of a culturally appropriate adaptation to the Doctors Helping Smokers (DHS) model</p> <p><i>Study Site:</i> Four urban Indian health clinics; Seattle Indian Board and Indian Health Board of Minneapolis were the intervention sites and Spokane Urban Indian and Community Health Services and the Milwaukee Indian Health Centres were the comparison sites</p> <p><i>Programme name:</i> GAINS (Give American Indians No-smoking Strategies)</p> <p><i>Methods of analysis:</i> Pearson's chi-square test used to compare proportions of variations between conditions; Student's t-test used to compare group means of continuous variables; baseline differences adjusted for using ANCOVA; Adjusted least-square means reported for comparison of smoking outcomes at follow-up</p> <p><i>Cluster adjustment made:</i> No</p>
Participants	<p><i>Eligible for study (n-value):</i> All subjects presenting for medical appointments were screened for eligibility; No n-values were provided</p> <p><i>Recruited:</i> n=601 total</p> <p><i>Completed:</i> n=476 total; Retention rates at follow-up? Intervention Seattle 69.3%, Minneapolis 83.6%; Control Milwaukee 78.3%, Spokane 85.7%</p> <p><i>Age:</i> Mean: Intervention 35 years, Control 36.3 years</p> <p><i>Gender:</i> Percent female: Intervention 67.9%, Control 59.5% (p=0.030)</p> <p><i>Ethnicity:</i> American Indian</p> <p><i>Socio-economic status:</i> Education (Intervention % vs. Control %): Junior high school or less 6% vs. 7.7%, Some high school 28.4% vs. 29.2%, High school graduate 30.1% vs. 31.2%, Some tech school/tech school graduate 12% vs. 8.4%, Some college 21.4% vs. 20.8%, College graduate 2% vs. 2.7%; Current employment status (Intervention % vs. Control %): Working full-time 19.6% vs. 31.2%, Working part-time 15.4% vs. 12%, Self-employed 1.5% vs. 3.8%, Unemployed for over 1 year 11.3% vs. 10.9%, Unemployed for under 1 year 22.2% vs. 20.7%, Homemaker 22.2% vs. 12%, Student 6% vs. 5.3%, Retired 1.9% vs. 4.1%</p> <p><i>Recruitment means:</i> Urban Indian health clinics</p>

Interventions	<p><i>Theoretical basis:</i> Not specified</p> <p><i>Intervention description/s:</i> Training provided on the Doctors Helping Smokers (DHS) protocol. Two day training sessions were conducted with medical and laboratory staff in each intervention site prior to enrolment; Key personnel were provided with additional instructions on intervention techniques and enrolment procedures; The five major principles of DHS included: screening patient smoking status and labelling charts, use of a smoke card as a reminder to providers, clinical message-giving to discuss smoking cessation, supportive reinforcement by clinic staff, monitoring of quit progress; In addition clinic outreach workers provided counselling in-clinic and supportive telephone calls for smokers attempting cessation</p> <p><i>Control description/s:</i> Training in control sites were focused on instructions for screening techniques of patients and record keeping; No smoking cessation training was offered in the comparison sites however they did receive smoking cessation material for distribution to patients</p> <p><i>Duration of intervention:</i> Not specifically stated though intervention delivered during doctor consult</p> <p><i>Intervention delivered by:</i> Doctors of the health clinics and supportive reinforcement of clinic staff</p>	
Outcomes	<p><i>Method of outcome collection:</i> 20-minute interview administered by trained clinic personnel</p> <p><i>Pre-specified outcome data:</i> Smoking history, smoking-related knowledge and behaviours, quit intentions, alcohol use, demographics, height, weight, blood pressure, waist and hip circumference, total cholesterol and fibrinogen</p> <p><i>Validation:</i> Saliva cotinine analysis</p> <p><i>Follow-up period:</i> Twelve months</p> <p><i>Number of follow-up periods reported:</i> One</p> <p><i>Process measures:</i> Higher proportion of intervention subjects reported attending zero clinic visits during the study period (Seattle 24% and Minneapolis 18.9% vs. Milwaukee 27.5% and Spokane 23.2%); Receipt of study material higher in the intervention sites with more seeing study posters in the clinic (94.5% vs. 85.6%), received study brochures (80.7% vs. 49.7%), received self-help guide (52.8% vs. 23.9%), received phone calls from staff regarding cessation (47.1% vs. 9.4%)</p>	
Notes	<p><i>Definition of smoking abstinence:</i> Smoked even a puff of a cigarette in the past 7-days</p> <p><i>Other notes:</i> \$25 cash incentive provided following completion of the questionnaire</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	No randomisation occurred, sites were selected
Allocation concealment (selection bias)	High risk	Allocation was not concealed they were "selected according to geographic location, tribal diversity of the patient population, availability of in-house primary care providers, and patient utilisation rates."

Johnson 1997 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the intervention it is not possible to blind participants
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No mention of attempted blinding of outcome assessors
Incomplete outcome data (attrition bias) All outcomes	High risk	Response rates were significantly lower in Seattle (p=0.002) resulting in a higher proportion of assumed-to-be-smokers as a result
Selective reporting (reporting bias)	Low risk	No selective reporting identified
Imbalance of outcome measures at baseline	Low risk	Significant baseline differences were controlled as covariates in ANCOVA models including number of cigarettes smoked per day
Comparability of intervention and control group characteristics at baseline	Low risk	Significant baseline differences were controlled as covariates in ANCOVA models including gender, employment status and number of clinic visits
Protection against contamination	Low risk	Unlikely that the control group received the intervention
Selective recruitment of participants	Unclear risk	Insufficient information to permit judgement of yes or no
Other bias	High risk	Pre-specified study design was not possible due to limitations in funding (from 14 sites to 4 sites in total); some concerns over comparability of sites due to tribal variations attending each site

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Boles 2009	Control group not an Indigenous population; Follow-up period <6 months (3 months in total)
Boyle 2010	No baseline data or smoking related outcomes reported

(Continued)

DiGiacomo 2007	No control group
Eichner 2010	Intervention not specifically aimed at smoking cessation; No smoking cessation related intervention occurred
Fu 2010	No control group
Geishirt 2005	No baseline data reported
Glasgow 1995	Unit of analysis is tribe whilst survey is conducted on tribal leaders only; No smoking related outcomes reported
Glover 2005	No control group; Follow-up period <6 months (4 months in total)
Gould 2009	No control group
Graham 2008	Not specifically targeted at Indigenous communities; Insufficient numbers of Indigenous participants for inclusion
Grigg 2008	No control group
GrothMarnat 1996	No control group
Hayward 2007	No control group
Hensel 1995	No control group
Hiscock 2009	No control group; No baseline data reported
Hodge 1995	No control group
Horn 2005	Follow-up period <6 months (3 months in total)
Ivers 2005	No control group
Ivers 2006	No control group for comparison of survey data, only comparison through tobacco vendors
Laugesen 2000	No baseline data collected
Lichtenstein 1995	No smoking related outcome data reported
Panaretto 2009	No control group
Panaretto 2010	No control group
Patten 2010	Follow-up period <6 months (108 days in total)
Whittaker 2011	Results not reported separately for the Indigenous population

Characteristics of ongoing studies [ordered by study ID]

Atkinson 2008

Trial name or title	BOABS Study (Be Our Ally Beat Smoking)
Methods	<p><i>Country:</i> Australia</p> <p><i>Design:</i> Randomised Controlled Trial; Block stratification by study site</p> <p><i>Objective/Aim:</i> Prevention</p> <p><i>Study site:</i> Patients visiting primary health care services</p> <p><i>Other:</i> Sequence generation through Computer-generated randomization table created by computer software; Allocation concealment through research assistant at the trial site required to contact the central administration site, which holds the allocation schedule. They will then allocate subjects to intervention or control group based on the computer-generated randomization schedule</p>
Participants	<p><i>Target sample size:</i> n=360</p> <p><i>Age:</i> 16 years minimum</p> <p><i>Gender:</i> Both males and females</p> <p><i>Ethnicity:</i> Aboriginal and/or Torres Strait Islander</p> <p><i>Inclusion/exclusion criteria:</i> Inclusion criteria: Current smoker, Aboriginal/Torres Strait Islander, regular client of the health service, considering quitting smoking soon (within the next 30 days); Exclusion criteria: Unable to provide informed consent, health condition that would prohibit completion of trial, unlikely to be available for follow up at 12 months</p>
Interventions	<p><i>Intervention description:</i> Multi-dimensional smoking cessation intervention; Individualised smoking cessation plan including regular personal contact and counselling (approximately 12-14 individual sessions per subject) ; In addition, monthly group sessions and support to assist access to existing smoking cessation, health and other services will also be offered</p> <p><i>Control description:</i> Best practice regional clinic based smoking cessation program based on the Kimberley Smoking Cessation Protocol</p> <p><i>Duration of intervention:</i> 12 months</p>
Outcomes	<p><i>Pre-specified outcomes in protocol:</i> 12 month smoking abstinence by urine cotinine levels and self-report; self-report for proportion of subjects reporting reductions in number of cigarettes smoked each week; self-report using health questionnaire of subject health status</p> <p><i>Validation:</i> Urinary cotinine levels</p> <p><i>Follow-up period:</i> 12 months</p> <p><i>Number of intended follow-up periods:</i> Two, 6- and 12 months</p> <p><i>Other:</i> Blinding of outcome assessors to occur</p>
Starting date	08/12/2008
Contact information	<p><i>Primary contact:</i> Dr David Atkinson; PO BOX 1377, Broome, WA 6725, Australia; TEL: +61 8 91936043; FAX: +61 8 91922500; david.atkinson@uwa.edu.au</p> <p><i>Secondary contact:</i> Dr Julia Marley; PO BOX 1377, Broome, WA 6725, Australia; TEL: +61 8 91936043; FAX: +61 8 91922500; julia.marley@uwa.edu.au</p>
Notes	

Choi 2010

Trial name or title	ANBL (All Nations Breath of Life)
Methods	<p><i>Country:</i> United States of America</p> <p><i>Design:</i> Randomized controlled trial</p> <p><i>Objective/Aim:</i> To examine the efficacy of a culturally-tailored smoking cessation program for American Indian/Native Alaskan</p> <p><i>Study site:</i> Two sites in the Midwest (Kansas and Oklahoma)</p>
Participants	<p><i>Target sample size:</i> n=448 smokers with n=28 groups per site, containing n=8 smokers per group</p> <p><i>Age:</i> 18-years and older</p> <p><i>Gender:</i> Both</p> <p><i>Ethnicity:</i> American Indian and Native Alaskan</p> <p><i>Inclusion/exclusion criteria:</i> Inclusion criteria: Age 18 years and older, have a home address and telephone number, willing to participate in all study components, willing to be followed for 6 months, smoked at least 100 cigarettes in their lifetime, current smoker, American Indian or Native Alaskan; Exclusion criteria: Planning to leave the state within next 24 months, pregnant or breast feeding or planning to become pregnant in the next 4 months, medically ineligible after screening</p>
Interventions	<p><i>Intervention description:</i> All subjects will be offered pharmacotherapy (e.g. varenicline, bupropion or nicotine replacement therapy) plus the culturally-tailored ANBL program; The ANBL program consists of in-person group sessions and individual telephone calls</p> <p><i>Control description:</i> All subjects will be offered pharmacotherapy (e.g. varenicline, bupropion or nicotine replacement therapy) plus a non-tailored accompanying program with targeted counselling delivered by non-American Indian counsellors</p> <p><i>Duration of intervention:</i> Not specified</p>
Outcomes	<p><i>Pre-specified outcomes in protocol:</i> Smoking status and continuous abstinence, number of quit attempts, utilisation of smoking cessation pharmacotherapy, number of cigarettes smoked</p> <p><i>Validation:</i> None reported</p> <p><i>Follow-up period:</i> 12 months</p> <p><i>Number of intended follow-up periods:</i> Two, 6- and 12 months</p>
Starting date	September 2010
Contact information	Dr Won Choi, wchoi@kumc.edu , University of Kansas Medical Centre, Kansas City, Kansas, United States, 66160, TEL: 913-588-4742
Notes	

Eades 2009

Trial name or title	Not specified
Methods	<p><i>Country:</i> Australia</p> <p><i>Design:</i> Randomized controlled trial</p> <p><i>Objective/Aim:</i> To test the effect of a multifaceted high intensity intervention that is culturally specific and incorporates advice, support and nicotine replacement therapy for smoking cessation in pregnant Indigenous women; This intervention is designed to improve the extent to which staff in Indigenous primary health care clinics are able to support pregnant women who are smokers to quit during their pregnancy</p>

	<p><i>Study site:</i> Clinics for pregnant women, actual setting not described; Controls seen in usual general practitioner clinical health care setting</p> <p><i>Other:</i> No blinding intended</p>
Participants	<p><i>Target sample size:</i> n=270</p> <p><i>Age:</i> 16-50 years</p> <p><i>Gender:</i> Females only</p> <p><i>Ethnicity:</i> Aboriginal Australians</p> <p><i>Inclusion/exclusion criteria:</i> Inclusion criteria: Pregnant women attending antenatal care before 20 weeks' gestation; Exclusion criteria: Major mental illness or chemical dependency other than tobacco or alcohol</p>
Interventions	<p><i>Intervention description:</i> Multifaceted tailored intervention which includes culturally specific advice and support for Indigenous women; Evidence based communication and nicotine replacement therapy will be used after 2 failed quit attempts (smokers < 25 cigarettes per day can use 2mg gum up to 24 times per day; smokers >25 cigarettes per day can use 4mg gum up to 24 times per day); The gum is prescribed as needed for up to 12 weeks</p> <p><i>Control description:</i> Usual clinical care with brief general practitioner as well as clinic health care provider quit advice</p> <p><i>Duration of intervention:</i> Minimum of 2 visits at the clinic, within 5- and 14 days following the visit at which the subject agrees to quit smoking; Specific duration of advice and support services not described; nicotine replacement therapy prescribed for up to 12 weeks</p>
Outcomes	<p><i>Pre-specified outcomes in protocol:</i> Self-reported and cotinine validated smoking cessation</p> <p><i>Validation:</i> Cotinine validation</p> <p><i>Follow-up period:</i> Baseline recruit must be before 20 weeks gestation; Follow-up between 36 to 40 weeks gestation and 6 months post-partum</p> <p><i>Number of intended follow-up periods:</i> Two, 36 to 40 weeks gestation and 6 months post-partum</p>
Starting date	01/11/2005; Follow up completed
Contact information	Professor Sandra Eades; Baker IDI Heart and Diabetes Institute, 75 Commercial Road, Melbourne, Victoria 2004, Australia; TEL: +61 3 8532 1535; FAX: +61 3 8532 1100; sandra.eades@bakeridi.edu.au
Notes	

Johnston 2010a

Trial name or title	Not specified
Methods	<p><i>Country:</i> Australia and New Zealand</p> <p><i>Design:</i> Randomized controlled trial; Stratification using permuted blocks by country and infant age</p> <p><i>Objective/Aim:</i> To reduce respiratory illness in Indigenous infants</p> <p><i>Study site:</i> Darwin City and the Greater Darwin area in the Northern Territory, Australia and within the Counties Manukau District Health Board region, Manukau City, New Zealand; Indigenous families residing in these two geographical areas were recruited with Indigenous newborn infants as the sampling units</p> <p><i>Other:</i> Allocation concealment will occur using central randomization through a computer with potential participants assigned a unique registration number allocated by a central computer following details submitted on a web-based form; The number will be used to identify each randomized participant once consent is</p>

Johnston 2010a (Continued)

	obtained thus permitting blinding of people assessing the outcomes and analysing the results/data; Sequence generation will occur by computer, stratified for country
Participants	<p><i>Target sample size:</i> n=420</p> <p><i>Age:</i> For mothers/caregivers 16 years or older</p> <p><i>Gender:</i> Mothers/caregivers of infants</p> <p><i>Ethnicity:</i> Aboriginal Australians, Mā ori</p> <p><i>Inclusion/exclusion criteria:</i> Inclusion criteria for mother/caregiver: Indigenous (defined by maternal self-identification), 16 years or older, currently smokes or infant lives in a household with at least one other person smokes (defined as smoking at least weekly), plans to reside permanently with the infant in Darwin or Greater Darwin areas of Australia or within the Counties Manukau District Health Board region, Manukau, New Zealand, signed written consent to participate received, English or Mā ori speaking</p>
Interventions	<p><i>Intervention description:</i> Family-centred tobacco control program aimed at providing education about the health effects of Environmental Tobacco Smoke (ETS) and behavioural ‘coaching’ techniques to help mothers reduce the infant’s exposure to ETS and identify mothers and other household members motivation to quit smoking and deliver culturally appropriate smoking cessation counselling and treatment options (e.g. nicotine replacement therapy) as required</p> <p><i>Control description:</i> Usual care through community health providers including routine visits to maternal and child health providers; checking of developmental progress and well being of the infant; mothers receive messages about smoking cessation and ETS exposure in their homes during visits as part of general health promotion</p> <p><i>Duration of intervention:</i> Three face-to-face home visits conducted over the first three months of the infant’s life</p>
Outcomes	<p><i>Pre-specified outcomes in protocol:</i> Mother/caregiver’s self-report of smoking cessation: defined as not smoking a single cigarette (not even a puff) in the preceding seven days by the mother/caregiver; Prolonged abstinence (e.g. quit for 3 months at 4 months follow up; quit for 9 months and 12 month follow up); Other outcomes relating to infant ETS exposure and health are also included</p> <p><i>Validation:</i> None reported</p> <p><i>Follow-up period:</i> 12 months</p> <p><i>Number of intended follow-up periods:</i> Two; 4 months, and 12 months; Baseline is when infant aged 5 weeks</p>
Starting date	09/11/2009
Contact information	Dr Vanessa Johnston; Menzies School of Health Research; PO BOX 41096, Casuarina, Northern Territory 0811, Australia; TEL: +61 (0)8 8922 7968, FAX: +61 (0)8 8927 5187; vanessa.johnston@menzies.edu.au
Notes	Smoking cessation outcomes as assessed for this review are a secondary outcome of this investigation

Maddison 2010

Trial name or title	Fit2Quit Study
Methods	<p><i>Country:</i> New Zealand</p> <p><i>Design:</i> Randomized controlled trial; Stratified by study centre, sex and ethnicity</p> <p><i>Objective/Aim:</i> To determine the effects of a home and community-based exercise intervention (Fit2Quit) on smoking abstinence at six months follow up when used as an adjunct to usual care, being telephone smoking</p>

Maddison 2010 (Continued)

	<p>cessation counselling and nicotine replacement therapy</p> <p><i>Study site:</i> Callers to Quitline in the greater Auckland and Waikato areas</p> <p><i>Other:</i> Sequence generation through a computer central randomization service</p>
Participants	<p><i>Target sample size:</i> n=1400 (n=700 per arm)</p> <p><i>Age:</i> 18-years or older</p> <p><i>Gender:</i> Both</p> <p><i>Ethnicity:</i></p> <p>At least 25% will be Mā ori</p> <p><i>Inclusion/exclusion criteria:</i> Inclusion criteria: 18 years or older, resident in greater Auckland or Waikato areas of New Zealand interested in quitting, want to be physically active, smoke their first cigarette within 30-minutes of waking, contact via telephone possible, able to provide written informed consent; Exclusion criteria Stroke or heart related condition or severe angina in the last two weeks, enrolled in competing smoking cessation programs, have a medical condition which limits their ability to exercise safely, currently participating in an exercise program or participating in greater than 150 minutes of physical activity per week</p>
Interventions	<p><i>Intervention description:</i> Exercise intervention (prescription and behavioural support) in addition to usual care of telephone support through Quitline and subsidised nicotine replacement therapy prescribed free of charge by the national Quitline</p> <p><i>Control description:</i> Usual care alone (i.e. combination of telephone support and subsidised nicotine replacement therapy prescribed free of charge)</p> <p><i>Duration of intervention:</i> Minimum of 10 contacts (face-to-face) over 6 months for home-based exercise program plus counselling and referral to community-based activities and programs; Goal for individuals to participate in a minimum of 30 minutes of moderate-vigorous aerobic-based exercise</p>
Outcomes	<p><i>Pre-specified outcomes in protocol:</i> Seven-day point prevalence of smoking abstinence validated using salivary cotinine, 6-month continuous abstinence, BMI (body mass index), cardio-respiratory fitness, physical activity levels, cost effectiveness</p> <p><i>Validation:</i> Salivary cotinine</p> <p><i>Follow-up period:</i> 6 months</p> <p><i>Number of intended follow-up periods:</i> Three; 2-, 3- and 6 months</p>
Starting date	01/02/2010
Contact information	<p><i>Primary contact:</i> Dr Ralph Madison, Clinical Trials Research Unit, University of Auckland, Private Bag 92019, Auckland 1142, New Zealand; TEL: +64 9 373 7599 (extension 84718); FAX: +64 9 373 1710; r.maddison@ctr.u.auckland.ac.nz</p> <p><i>Secondary contact:</i> Dr Vaughan Roberts, Clinical Trials Research Unit, University of Auckland, Private Bag 92019, Auckland 1142, New Zealand; v.roberts@ctr.u.auckland.ac.nz</p>
Notes	Mā ori population approximately 25% of overall sample

Smith 2010

Trial name or title	Menominee Smoking Cessation Clinical Trial
Methods	<p><i>Country:</i> United States of America</p> <p><i>Design:</i> Randomized controlled trial</p> <p><i>Objective/Aim:</i> To evaluate the effectiveness of a culturally-tailored smoking cessation treatment for American Indian smokers, compared to a standardised (non-culturally-tailored) evidence-based cessation treatment</p> <p><i>Study site:</i> Menominee Tribal Clinic serving Menominee and other American Indian patients</p>
Participants	<p><i>Target sample size:</i> n=150</p> <p><i>Age:</i> 18 years and older</p> <p><i>Gender:</i> Both</p> <p><i>Ethnicity:</i> American Indians, specifically the Menominee</p> <p><i>Inclusion/exclusion criteria:</i> Inclusion criteria: At least 18 years of age, smoking cigarettes, eligible to receive health care services at the Menominee Tribal Clinic (i.e. must be an enrolled member of a federally-recognised American Indian Tribe), primary care provider is at the Menominee Tribal Clinic, must be medically able and willing to take varenicline; Exclusion criteria: End-stage renal disease with haemodialysis, any prior suicide attempts, current or recent (past 12-month) suicidal ideation, currently pregnant or breastfeeding, unwilling to use appropriate methods of birth control while taking study medication for 1-month after discontinuing study medication, primary care provider determines that the individual should not take varenicline</p>
Interventions	<p><i>Intervention description:</i> 12 weeks open-label varenicline tartrate use plus smoking cessation counselling consisting of four sessions (1 via phone and 3 in person); Counselling consists of standard treatment counselling plus culturally-appropriate treatments such as discussion of the history of sacred/traditional use of tobacco (honouring and respecting native traditions) and how it differs from use of commercial tobacco use (harming health), custom booklet on smoking and smoking cessation tailored to Menominee and other American Indian smokers, participants are encouraged to make their own traditional tobacco pouch (symbol of long life)</p> <p><i>Control description:</i> Same as above for varenicline and number of counselling sessions, however standard treatment counselling is used based on recommendations in the 2008 U.S. Public Health Service Guideline (Treating Use and Dependence); Topics include preparing to quit, nicotine addiction, coping with stressors and challenging situations, coping with withdrawal symptoms, seeking support and relapse prevention</p> <p><i>Duration of intervention:</i> 12 weeks open label varenicline tartrate use, counselling consists of four sessions, one in-person pre-quit counselling, one via a phone call and the remaining two in-person counselling sessions</p>
Outcomes	<p><i>Pre-specified outcomes in protocol:</i> 7-day point prevalence of smoking abstinence, self-reported abstinence and carbon monoxide validated abstinence at 3- and 6-months</p> <p><i>Validation:</i> Exhaled carbon monoxide</p> <p><i>Follow-up period:</i> 6 months</p> <p><i>Number of intended follow-up periods:</i> Two, 3- and 6months</p>
Starting date	February 2010
Contact information	<p><i>Primary contact:</i> Dr Steven Smith, University of Wisconsin, Madison, USA</p> <p><i>Secondary contact:</i> Jodi Fossum, jodif@mtclinic.net , TEL: 715-799-5754</p>
Notes	

Walker 2011

Trial name or title	RELIQ - Reduced Levels of nicotine in cigarettes to Increase Quitting
Methods	<p><i>Country:</i> New Zealand</p> <p><i>Design:</i> Randomised controlled trial; Stratified by gender, ethnicity and level of nicotine dependence</p> <p><i>Objective/Aim:</i> Determine the combined effect of nicotine-free cigarettes with nicotine replacement therapy (immediately post quitting) on long-term quit rates (6-months). Secondary aim is to determine if such an intervention is cost effective and acceptable</p> <p><i>Study site:</i> Recruitment through the national telephone-based Quitline service in New Zealand</p> <p><i>Other:</i> Sequence generation will occur via a computer, with stratification</p>
Participants	<p><i>Target sample size:</i> n=1410</p> <p><i>Age:</i> 18 years or older</p> <p><i>Gender:</i> Both</p> <p><i>Ethnicity:</i> 25% Mā ori</p> <p><i>Inclusion/exclusion criteria:</i> Inclusion criteria: Smokers from throughout New Zealand who want to stop smoking, at least 18-years of age, have their first cigarette within 30-minutes of waking, able to provide verbal consent and have a telephone; Exclusion criteria: Pregnant women and women breastfeeding, current users of nicotine replacement therapy, current client of another smoking cessation program (e.g. Txt2Quit and NRT Online), current user of other pharmacotherapy for smoking cessation, use only non-cigarette tobacco (e.g. pipes, cigars), have had a myocardial infarction within the last two weeks, have had angina, severe cardiac arrhythmia or stroke in acute phase within the last two weeks</p>
Interventions	<p><i>Intervention description:</i> Subjects in the intervention will be asked to stop smoking nicotine-containing cigarettes on a chosen quit day and smoke <i>ad libitum</i> nicotine-free cigarettes for six-weeks; Subjects will also receive nicotine replacement therapy in the form of patches, gum and/or lozenges (as recommended by Quitline) for eight weeks; Plus Quitline counselling</p> <p><i>Control description:</i> Subjects will receive nicotine replacement therapy in the form of patches, gum and/or lozenges (as recommended by Quitline) for eight weeks; Plus Quitline counselling</p> <p><i>Duration of intervention:</i> Intervention and control arms will receive eight weeks of nicotine replacement therapy, whilst the intervention only arm will receive an additional six weeks of nicotine-free cigarettes (Quest 3)</p>
Outcomes	<p><i>Pre-specified outcomes in protocol:</i> Proportion of subjects who stopped smoking in the proceeding 7-days (7-day point prevalence) at the 6 month follow up; continuous abstinence, number of cigarettes currently smoked per day; physical signs and symptoms associated with withdrawal, self-rated chances of quitting, reduced smoking, cost information, use of NRT and non-NRT, adverse events, concomitant medication and alcohol use and abuse</p> <p><i>Validation:</i> None reported</p> <p><i>Follow-up period:</i> 6-months</p> <p><i>Number of intended follow-up periods:</i> Four: 3- and 6 weeks and 3- and 6 months</p> <p><i>Other:</i> Blinding of trial steering committee, management committee and other team members from the Clinical Trials Research Unit (with the exception of the project co-ordinator and Quitline research manager) will remain blinded to treatment allocation</p>
Starting date	01/04/2009
Contact information	Dr Natalie K Walker; Clinical Trials Research Unit, School of Population Health, The University of Auckland, Private Bag 92019, Auckland, 1142, New Zealand; n.walker@ctr.u.auckland.ac.nz

Walker 2011 (Continued)

Notes	Mā ori population approximately 25% of overall sample
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DATA AND ANALYSES

Comparison 1. Intervention versus control

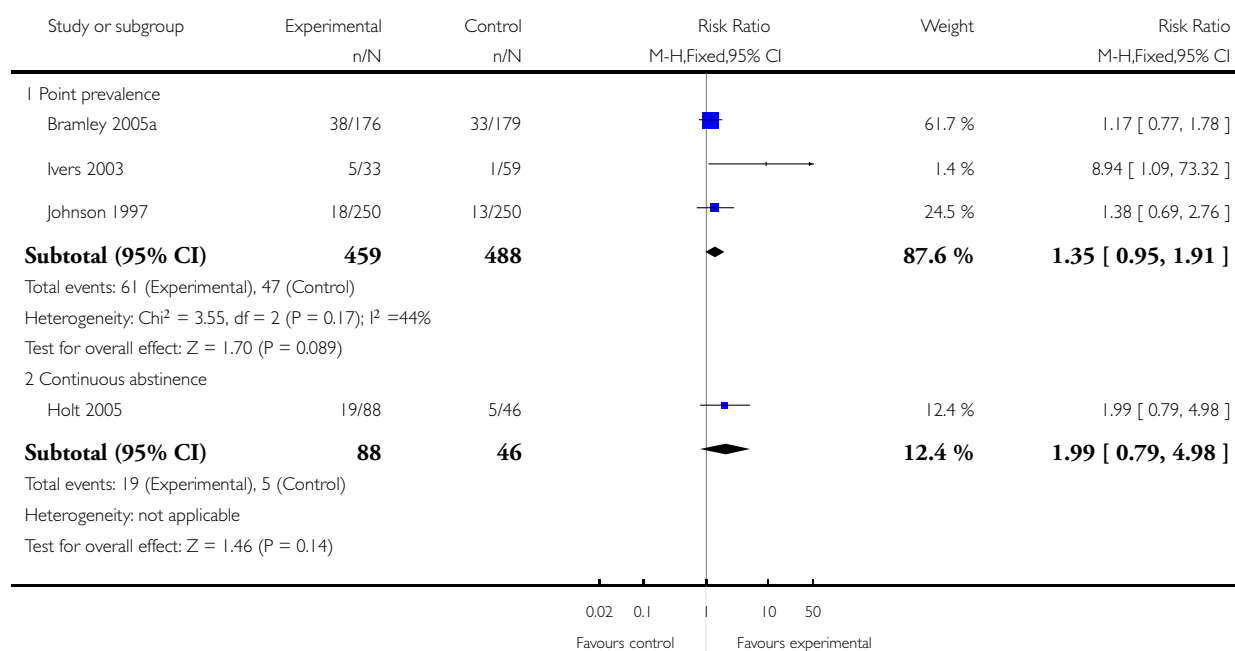
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Smoking cessation	4	1081	Risk Ratio (M-H, Fixed, 95% CI)	1.43 [1.03, 1.98]
1.1 Point prevalence	3	947	Risk Ratio (M-H, Fixed, 95% CI)	1.35 [0.95, 1.91]
1.2 Continuous abstinence	1	134	Risk Ratio (M-H, Fixed, 95% CI)	1.99 [0.79, 4.98]
2 Attitudes - readiness to quit	1	92	Risk Ratio (M-H, Fixed, 95% CI)	1.64 [0.82, 3.30]
3 Smoking cessation - Sensitivity analysis	3	989	Risk Ratio (M-H, Fixed, 95% CI)	1.33 [0.95, 1.85]
3.1 Point prevalence	2	855	Risk Ratio (M-H, Fixed, 95% CI)	1.23 [0.86, 1.76]
3.2 Continuous abstinence	1	134	Risk Ratio (M-H, Fixed, 95% CI)	1.99 [0.79, 4.98]

Analysis 1.1. Comparison 1 Intervention versus control, Outcome 1 Smoking cessation.

Review: Interventions for smoking cessation in Indigenous populations

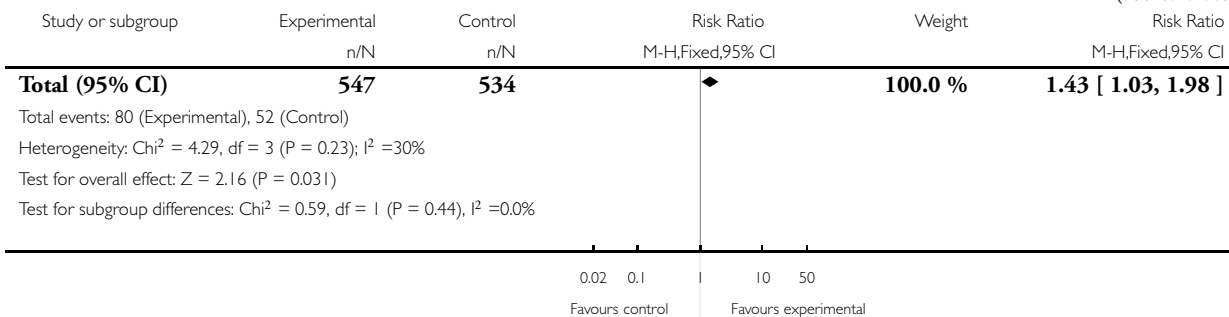
Comparison: 1 Intervention versus control

Outcome: 1 Smoking cessation



(Continued ...)

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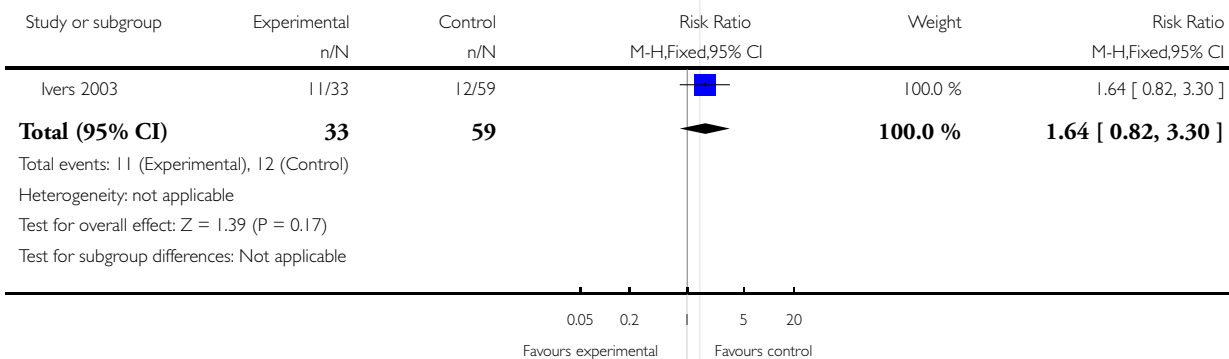


Analysis 1.2. Comparison 1 Intervention versus control, Outcome 2 Attitudes - readiness to quit.

Review: Interventions for smoking cessation in Indigenous populations

Comparison: 1 Intervention versus control

Outcome: 2 Attitudes - readiness to quit

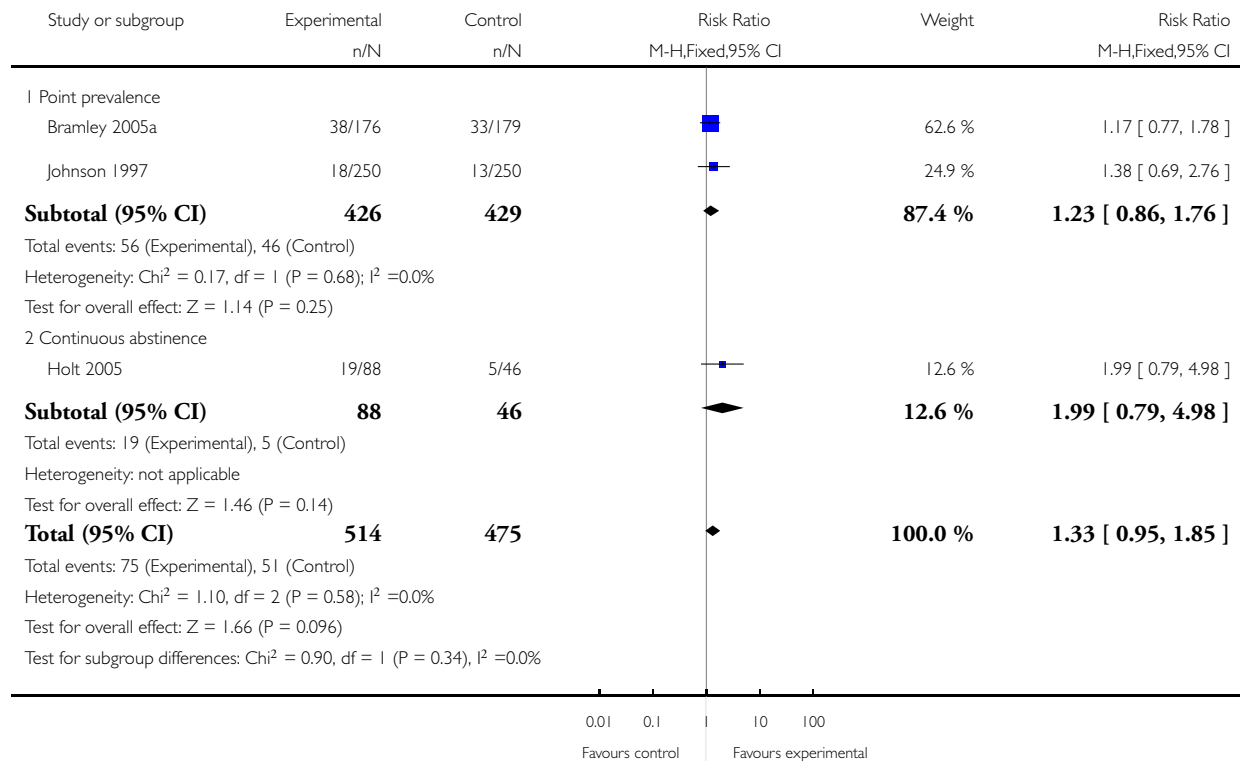


Analysis 1.3. Comparison 1 Intervention versus control, Outcome 3 Smoking cessation - Sensitivity analysis.

Review: Interventions for smoking cessation in Indigenous populations

Comparison: 1 Intervention versus control

Outcome: 3 Smoking cessation - Sensitivity analysis



ADDITIONAL TABLES

Table 1. Narrative synthesis of intervention effectiveness

Study ID/sub-headings:	Detailed synthesis of intervention effectiveness:
Bramley 2005a Smoking behaviour	Point prevalence: Māori participants in the treatment group were more likely to report having stopped smoking at 6 weeks than those in the control group with 26.1% quit compared to 11.2% (RR: 2.34, 95% CI: 1.44 - 3.79); Smoking cessation rates at 12 and 26 weeks reported rates remaining high in the intervention group (21.6%) but increased in the control group (18.4%)
Intermediate outcome data	None reported

Table 1. Narrative synthesis of intervention effectiveness (Continued)

<p>Holt 2005 Smoking behaviour</p>	<p>The rates of continued abstinence in the bupropion vs. placebo groups were 44.3% and 17.4% (risk ratio 2.54 (95%CI 1.30 to 5.00)) at 3 months, and 21.6% and 10.9% (risk ratio 1.99 (95% CI 0.79 to 5.00)) at 12 months for intervention and control groups respectively. Reported risk ratios (95% confidence intervals) for the remaining follow-up periods were: 1.00 (0.84 to 1.20) at 3 days; 1.47 (1.06 to 2.05) at 3 weeks; 1.39 (0.93 to 2.10) at 7 weeks; 2.72 (1.12 to 6.61) at 26 weeks; 2.51 (1.03 to 6.14) at 39 weeks. The model based approach with a break point in the abstinence-time slope at 26 weeks favoured the intervention, with a risk ratio of 2.44 (95%CI 1.22 to 4.88).</p>
<p>Intermediate outcome data</p>	<p>Adverse events: Authors report most side effects as mild and self-limiting; Subjects taking bupropion were more likely to have insomnia (26% vs. 9%; risk ratio 3.0 (95% CI 1.1 to 8.2)) over the placebo arm. Three subjects taking bupropion discontinued use due to a rash</p>
<p>Ivers 2003 Smoking behaviour</p>	<p>Point prevalence: six of those in the nicotine patch group reported they had quit whilst one member of the brief intervention only group had quit. However two participants in the nicotine patch group recorded an elevated CO level (10ppm) and as such there data were not used</p>
<p>Intermediate outcome data</p>	<p>Adverse events: Twenty-nine per cent of subjects using patches experienced bad dreams, 21% pruritis, 4% nausea, 7% palpitations or shakiness and 7% tiredness. 93% said that the patches stayed stuck on all or most of the time; mortality: One subject in the intervention arm died of causes unrelated to the use of patches; Attitudes - readiness to quit: no significant changes in readiness to quit for intervention or control groups (Fishers' Exact p=1.0 and 0.21 respectively) . 38% of smokers in the intervention group and 29% in the control group were less ready to quit after trying patches than they had been at the baseline visit; costs of interventions: nicotine patches costs approximately \$32-35 in addition to freight costs for a week's supply, in comparison a week's supply of cigarettes for a pack a day smoker is \$46-74. It appears that there were other factors apart from the costs of nicotine patches that prevented smokers from using NRT as an aid to quitting, which might have included a widespread perception that smoking was normal behaviour</p>
<p>Johnson 1997 Smoking behaviour</p>	<p>At 1 year follow up 7.1% of intervention subjects reported being abstinent compared to control subjects with 4.9%. However when only the validated quits are included the percentages drop to 6.7% and 6.8% for intervention and control groups respectively. Furthermore when subjects missing from follow up are counted as smokers the point prevalence for validated quits is reduced to 5.3%</p>
<p>Intermediate outcome data</p>	<p>None reported</p>

HISTORY

Protocol first published: Issue 3, 2011

Review first published: Issue 1, 2012

CONTRIBUTIONS OF AUTHORS

Protocol conceived and prepared by Kristin V Carson, reviewed by Brian J Smith, Antony Veale and Adrian J Esterman.

Literature sorting, data extraction, data entry, data analysis and production of the manuscript completed by Kristin V Carson (as part of post-graduate studies at The University of Adelaide)

Second author risk of bias extraction by Malcolm P Brinn

Review of draft manuscript by Matthew Peters, Antony Veale, Adrian J Esterman and Brian J Smith

Supervision of review by Brian J Smith

DECLARATIONS OF INTEREST

No conflicts of interest to report.

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- Respiratory Medicine Unit, The Queen Elizabeth Hospital, Australia.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Risk of bias categories were updated to include four additional fields: imbalances of outcome measures at baseline; comparability of intervention and control group characteristics at baseline; protection against contamination and selective recruitment of participants. In addition, the classification categories for risk of bias have been amended from 'yes', 'no' and 'unclear' to 'high risk', 'low risk' and 'unclear risk'.

The search strategy was amended with removal of the key word 'indig*', which was replaced with 'Indigenous*' as the former was over sensitive.

Examination of the review by an Indigenous (Aboriginal) Australian was added to assess applicability, acceptability and content.

Review Manager software version changed from 5.0 to 5.1

INDEX TERMS

Medical Subject Headings (MeSH)

Australia [ethnology]; Behavior Therapy [methods]; Bupropion [therapeutic use]; Combined Modality Therapy [methods]; Controlled Clinical Trials as Topic; Counseling; Dopamine Uptake Inhibitors [therapeutic use]; Indians, North American [*ethnology]; New Zealand [ethnology]; Oceanic Ancestry Group [*ethnology]; Randomized Controlled Trials as Topic; Smoking [ethnology; *therapy]; Smoking Cessation [ethnology; *methods]; Text Messaging; Tobacco Use Cessation Products; United States [ethnology]

MeSH check words

Humans

Chapter 5.

Interventions for tobacco use prevention in Indigenous youth

(Literature review and meta-analysis)

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Cochrane Database of Systematic Reviews 2012; Issue 8; 1-34

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Author contributions:

By signing the Statement of Authorship, each author certifies their stated contribution to the publication is accurate and that permission is granted for the publication to be included in the candidate's thesis.

Name of principal author (candidate)	Kristin Carson		
Contribution to the paper	Conceived the investigation, designed and wrote the protocol, searched grey literature including online clinical trial registries, screened all retrieved literature, identified studies for inclusion, exclusion and as ongoing, extracted data for characteristics and risk of bias, performed all data entry, data analysis (including meta-analyses) and interpretation of results, developed the summary of findings table, wrote the first draft of the manuscript, contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, addressed editorial and peer reviewer comments, made critical revisions and approved final version.		
Signature		Date	17/05/2015

Name of co-author	Malcolm Brinn		
Contribution to the paper	Screened retrieved literature, identified studies for inclusion, exclusion and as ongoing, extracted data for risk of bias, contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, addressed editorial and peer reviewer comments, made critical revisions and approved final version.		
Signature		Date	26/05/2015

Name of co-author	Nadina Labiszewski		
Contribution to the paper	Attended steering group meetings with other collaborators, performed follow-up of patients, data collection, study maintenance, contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, made critical revisions and approved final version.		
Signature		Date	25/05/2015

Name of co-author	Matthew Peters		
Contribution to the paper	Contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, addressed editorial and peer reviewer comments, made critical revisions, approved final version and supervised process.		
Signature		Date	09/06/2015

Name of co-author	Anne Chang		
Contribution to the paper	Contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, addressed editorial and peer reviewer comments, made critical revisions, approved final version and supervised process.		
Signature		Date	18/05/2015

Name of co-author	Antony Veale		
Contribution to the paper	Contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, addressed editorial and peer reviewer comments, made critical revisions, approved final version and supervised process.		
Signature		Date	26/06/2015

Name of co-author	Adrian Esterman		
Contribution to the paper	Contributed to writing the manuscript, agree with manuscript results and		

	conclusions, jointly developed the arguments and structure for the paper, addressed editorial and peer reviewer comments, made critical revisions, approved final version and supervised process.		
Signature		Date	25/05/2015

Name of co-author	Brian Smith		
Contribution to the paper	Contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, addressed editorial and peer reviewer comments, made critical revisions, approved final version and supervised process (primary supervisor).		
Signature		Date	17/05/2015

As in the case of smoking cessation amongst Indigenous adults discussed in Chapter 4, there were no systematic appraisals of tobacco abuse prevention programs for Indigenous youth when this PhD was conceived. Importantly, Indigenous youth experiment and commence smoking at a much younger age than non-Indigenous youth (36). Peer and Elder influences also hold more weight amongst non-Indigenous youth due to the community approach of raising children (109). Given the high prevalence of tobacco use amongst Indigenous populations, there is potential for youth to emulate these practices as they mature, putting them at greater risk of becoming regular smokers.

Two completed and one ongoing study met all of the eligibility criteria for inclusion at the time of publication. Similar to findings of the tobacco cessation analysis from Chapter 4, the ability to draw reliable conclusions based on this evidence is limited. Based on the available data there was no evidence of an effect on long-term tobacco rates for either of the completed studies. Weekly smoking was significantly lower in the intervention arm of one study directly following completion of the anti-smoking program, yet these results were not maintained by six month follow-up. Knowledge about the health effects of tobacco use was statistically improved at both post-intervention and six months follow-up, but this was not enough to influence smoking behaviour. Interestingly both of the completed studies were quite dated, with publication of the findings from 1987 and 1994.

However, one of the most important yet disturbing findings from this review was the identification of a ‘negative’ result in the ongoing study, with more intervention participants taking up smoking compared to the control participants who received no intervention at all. This suggests that we can’t assume any intervention will be effective. It also highlights the need for appropriate and methodologically rigorous evaluations to occur as part of mandatory practice alongside newly developed programs to make sure that we are not doing more harm than good. Implementation of ineffective trials without evaluation of efficacy also means an opportunity cost, as programs that may be more effective in reducing tobacco use are not being funded due to a reduced pool of resources.

Subsequently, this review stresses that more methodologically rigorous research in the area of tobacco prevention programs for Indigenous youth is needed. The lack of recent published evidence is concerning, especially considering the large amount of funding that has been invested into tobacco prevention programs for youth on a global scale. Yet before another randomised controlled trial of an anti-smoking intervention can take place, qualitative data examining the attitudes, knowledge, perceptions and behaviours preventing uptake of such programs are required.

Interventions for tobacco use prevention in Indigenous youth (Review)

Carson KV, Brinn MP, Labiszewski NA, Peters M, Chang AB, Veale A, Esterman AJ, Smith BJ



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[Intervention Review]

Interventions for tobacco use prevention in Indigenous youth

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ABSTRACT

Background

Tobacco use in Indigenous populations (people who have inhabited a country for thousands of years) is often double that in the non-Indigenous population. Addiction to nicotine usually begins during early adolescence and young people who reach the age of 18 as non-smokers are unlikely to become smokers thereafter. Indigenous youth in particular commence smoking at an early age, and a disproportionate burden of substance-related morbidity and mortality exists as a result.

Objectives

To evaluate the effectiveness of intervention programmes to prevent tobacco use initiation or progression to regular smoking amongst young Indigenous populations and to summarise these approaches for future prevention programmes and research.

Search methods

The Cochrane Tobacco Addiction Group Specialised Register was searched in November 2011, with additional searches run in MEDLINE. Online clinical trial databases and publication references were also searched for potential studies.

Selection criteria

We included randomized and non-randomized controlled trials aiming to prevent tobacco use initiation or progression from experimentation to regular tobacco use in Indigenous youth. Interventions could include school-based initiatives, mass media, multi-component community level interventions, family-based programmes or public policy.

Data collection and analysis

Data pertaining to methodology, participants, interventions and outcomes were extracted by one reviewer and checked by a second, whilst information on risk of bias was extracted independently by a combination of two reviewers. Studies were assessed by qualitative narrative synthesis, as insufficient data were available to conduct a meta-analysis. The review process was examined by an Indigenous (Aboriginal) Australian for applicability, acceptability and content.

Main results

Two studies met all of the eligibility criteria for inclusion within the review and a third was identified as ongoing. The two included studies employed multi-component community-based interventions tailored to the specific cultural aspects of the population and were based in Native American populations (1505 subjects in total). No difference was observed in weekly smoking at 42 months follow-up in the one study assessing this outcome (skills-community group versus control: risk ratio [RR] 0.95, 95% CI 0.78 to 1.14; skills-only group versus control: RR 0.86, 95% CI 0.71 to 1.05). For smokeless tobacco use, no difference was found between the skills-community arm and the control group at 42 weeks (RR 0.93, 95% CI 0.67 to 1.30), though a significant difference was observed between the skills-only arm and the control group (RR 0.57, 95% CI 0.39 to 0.85). Whilst the second study found positive changes for tobacco use in the intervention arm at post test ($p < 0.05$), this was not maintained at six month follow-up (change score -0.11 for intervention and 0.07 for control). Both studies were rated as high or unclear risk of bias in seven or more domains (out of a total of 10).

Authors' conclusions

Based on the available evidence, a conclusion cannot be drawn as to the efficacy of tobacco prevention initiatives tailored for Indigenous youth. This review highlights the paucity of data and the need for more research in this area. Smoking prevalence in Indigenous youth is twice that of the non-Indigenous population, with tobacco experimentation commencing at an early age. As such, a significant health disparity exists where Indigenous populations, a minority, are over-represented in the burden of smoking-related morbidity and mortality. Methodologically rigorous trials are needed to investigate interventions aimed at preventing the uptake of tobacco use amongst Indigenous youth and to assist in bridging the gap between tobacco-related health disparities in Indigenous and non-Indigenous populations.

PLAIN LANGUAGE SUMMARY

Can smoking prevention interventions targeted at Indigenous youth prevent Indigenous youth from starting to smoke or use other tobacco products?

In Indigenous populations, the number of people who smoke has not fallen as it has in the wider communities around them. Young people remain at particular risk of taking up smoking. The associated harms to health are unacceptable. This review found that there is not enough published research evaluating programmes aiming to prevent Indigenous youth from starting to use tobacco. Information from the two included studies in this review (1505 participants in total, in Native American communities) does not allow a conclusion to be drawn as to whether tobacco prevention programmes in Indigenous populations prevent Indigenous youth from smoking or using smokeless tobacco. The review highlights the absence of data and need for more research.

BACKGROUND

Specific definitions for 'Indigenous' vary between regions and populations. These terms remain highly contested and are not always accepted or used (Nettelton 2007). Such examples include 'Australian Aboriginal' or 'Torres Strait Islanders' for the Australian Indigenous, 'First Nations' to describe the Indian populations indigenous to Canada, 'Native Hawaiians' for Hawaii's Indigenous

and 'Tangata Whenua' or 'People of the land' for the Māori of New Zealand (Cunningham 2003). In an attempt to create consistency, though cognisant of the preferential syntax for populations, the term 'Indigenous' has been chosen to encompass participants

within this review as it reflects "the experiences shared by a group of people who have inhabited a country for thousands of years, which often contrast with those of other groups of people who reside in the same country for a few hundred years" (Cunningham 2003). No offence is meant to any group for whom their preferred descriptor is not used.

Description of the condition

Throughout the world, Indigenous populations bear a disproportionate burden of substance-related morbidity and mortality when

compared to non-Indigenous populations. Prevalence of tobacco use amongst the Indigenous population is often double that of the relevant non-Indigenous population, with estimates of 51 to 59 per cent in Canada (Health Canada 2003; CEITC 2005), 47 to 53 per cent in Australia (CEITC 2005; ABS 2009), 45 per cent in New Zealand (Ministry of Health 2009) and 44 per cent in the United States for Alaskan natives (First Nations Center 2005; Alaska Department of Health 2006). In all populations, addiction to nicotine usually begins during early adolescence, with only 10 per cent of new smokers initiating the habit after the age of 18 years (US Dept Health and Human Services 1998). In the recent US Surgeon General's Report, authors state that almost no one in the US will commence smoking after the age of 25, with nearly nine out of 10 smokers initiating tobacco use by the age of 18, and 99 per cent starting by age 26 (Surgeon General's Report 2012). The report also found that if the success in reducing youth tobacco use that was made between 1997 and 2003 had been maintained, there could potentially be three million fewer smokers in the US currently. A similar reduction in tobacco use was also observed in Australian youth between 1996 and 2005, which included a cohort of Indigenous youth (White 2009). Authors report that this reduction in smoking prevalence coincided with a period of increased tobacco control activity, including the funding of local Indigenous tobacco control programmes that were culturally appropriate and tailored for individual communities.

For Indigenous youth there is an added social context to tobacco use. An increased rate of tobacco use in Indigenous youth has been documented in many populations. An Australian report suggests the added social context has resulted in almost half of Indigenous youth aged 14 years and older reporting smoking on a daily basis, compared to approximately 20 per cent in non-Indigenous Australians (AIHW 2002). Despite some reductions in tobacco use following increased tobacco control programmes in Australia, the gap in smoking prevalence between Indigenous and non-Indigenous populations has remained consistent (White 2009). An evaluation of British Columbian youth estimates the prevalence of smoking in their Indigenous population to be 41 per cent for adolescents aged 12 to 18 years and 61 per cent for youth aged 19 to 24 years, whilst non-Indigenous youth have prevalence estimates of 18 per cent and 31 per cent respectively (Reading 1999). A Canadian survey of Indigenous youth reports smoking initiation peaking at 13 years of age (First Nations Center 2005). The First Nations regional longitudinal health survey, conducted in 2002 and 2003, found 38 per cent of youth reporting current smoking, double the rate of that of the relevant non-Indigenous population (Reading 2009). Use of smokeless tobacco, pipe tobacco, roll your own cigarettes and flavoured cigarettes is also reported to be twice as prevalent in Indigenous populations compared to the non-Indigenous (Elton-Marshall 2011).

The 'normalisation' of tobacco use in Indigenous populations has resulted in a disproportionate burden of disease, with subsequent effects on social interactions and relationship building amongst In-

igenous youth. The primary social influences resulting in youth initiation of smoking are relevant for all youth, Indigenous and non-Indigenous alike, and include peer group pressure, positive attitudes toward smoking and the observation of adult smoking. For Indigenous youth this is amplified by the increase in adult smoking prevalence and the normalisation of tobacco use as part of the usual Indigenous landscape (Lindorff 2002; Scollo 2008; Leavy 2010). Parental behaviours and best friend smoking status in particular have been identified as key determinants of smoking among Indigenous adolescents (Scragg 2007). Furthermore, reports suggest that substandard and overcrowded living conditions increase tobacco exposure in young people in Indigenous Australian communities (Johnston 1997; Eades 1999; Ivers 2001; Penman 2006; Johnston 2008). A recent Australian survey of tobacco exposure in Aboriginal and Torres Strait Islander households reported that 21 per cent of children aged 0 to 14 years were exposed to indoor tobacco smoke in 2008, which was a decrease from reports of 29 per cent in 2004 to 2005 (ABS 2011). However, a 2012 report on tobacco use among youth in the US found that rates of decline for cigarette smoking have slowed in the past decade and that rates of decline for smokeless tobacco use have stalled completely (Surgeon General's Report 2012).

Description of the intervention

Interventions considered in this review aim to prevent tobacco use initiation or progression from experimentation to regular tobacco use in Indigenous youth. Tobacco use prevention initiatives targeted at young people are known to prevent the uptake of smoking in youth (Brinn 2010; Carson 2011a). Interventions aiming to prevent youth smoking can include: school-based initiatives that involve classroom lessons (e.g., school-based curriculum delivered by classroom teachers); mass media such as television, radio, billboards or posters (e.g. community or nation-wide media campaigns directed at adolescents or adults through highlighting the health effects of tobacco use); multi-component community level interventions (e.g. combined tobacco use prevention campaigns involving peer role models, school curriculums, anti-smoking messages at local sporting or community events, combined into one intervention); family-based programmes (e.g., anti-smoking messages involving parent and child communication and activities including games, workbooks, discussions or written information); or public policy interventions (e.g. plain packaging of cigarettes or policies for a smoking ban in public places or where children are present, which is enforced by the community). A recent Cochrane review of such interventions in Indigenous populations found evidence of some success in smoking cessation, with significant reductions in tobacco use reported in Indigenous populations (Carson 2012a). However, the review included only four studies and highlighted a paucity of data with which to determine the effectiveness of cessation initiatives specifically tailored to Indigenous populations.

How the intervention might work

Public health programmes have the potential to prevent the uptake of smoking and progression of regular smoking in youth, which may subsequently reduce health inequalities (Hill 2005). A significant amount of social science research has been conducted to establish motivational theories that can address smoking among young people, including the health beliefs model (Stretcher 1997), protection motivation theory (Floyd 2000), social cognitive theory (Bandura 1998), social development model (Fleming 2008) and behavioural change theory (Glanz 2008). Many of these are hinged on interpersonal traits such as self-esteem and self-efficacy as well as social and environmental influences, including peers, family and the school and community environment. Programmes to influence smoking behaviour based exclusively on one theoretical concept alone have been criticised (Bauman 1996; De Vries 2003a), with suggestions that indirect peer pressure may be just as effective in the prevention of smoking. Indeed, the smoking status of parents and peers have been identified as predictors of smoking onset (De Vries 2003b) and as such are believed to be important mediators to target for prevention initiatives. Evidence from other meta-analyses suggest that underpinning a prevention initiative with an established research theory that addresses social and cognitive influences of tobacco use may influence the uptake of smoking by youth (Brinn 2010; Carson 2011a). This has been performed through the provision of 'knowledge' about the health effects of tobacco use and through addressing 'attitudes' toward tobacco and 'perceptions' around peer use and acceptability, combined with support and structured lessons (Carson 2011a).

Why it is important to do this review

Smoking prevalence in the Indigenous population still remains twice that in the non-Indigenous, suggesting that existing mainstream tobacco prevention initiatives are producing little benefit in reducing the uptake of tobacco use amongst this high risk population. Some research has found that smoking prevalence may be decreasing as a result of increased tobacco control activities (White 2009), however more recent reports have found that rates of decline for smoking in the past decade have now slowed (Surgeon General's Report 2012). This 2012 report from the US also found that for each person that dies because of a smoking related illness (more than 1200 per day), at least two youths or young adults are becoming regular smokers (Surgeon General's Report 2012). Indigenous populations bear a disproportionate burden of tobacco-related illnesses in comparison to the non-Indigenous (Reading 2010). As a result, tobacco prevention in youth has been identified as key to reducing long term morbidity and mortality (Fiore 2004). However, a systematic consolidation of interventions and sub-components for those within this high-risk population has not occurred to date. A review of current literature is required to identify features of effective programmes that can be translated

into policy to guide future prevention initiatives and research. As such, this review aims to consolidate this evidence to identify features of any effective programmes for Indigenous populations so that they can be pursued (US Dept Health and Human Services 1998), and to identify ineffective programmes so that they can be altered or abandoned.

OBJECTIVES

To evaluate the effectiveness of intervention programmes to prevent tobacco use initiation or progression to regular smoking amongst young Indigenous populations and to summarise these approaches for future prevention programmes and research.

METHODS

Criteria for considering studies for this review

Types of studies

Randomized controlled trials (RCT) or quasi-randomized controlled trials (CCT).

Types of participants

Young people aged 25 years or less, of either gender, who are members of Indigenous populations, using 'Indigenous' in the sense described earlier, that participated in a study to prevent tobacco use initiation. Interventions could target groups of individuals (e.g. school classes), some of whom had already used tobacco. Trial participants were not required to be selected according to their susceptibility or suitability for particular interventions.

No attempts were made to re-define Indigenous status for the purpose of including a study in this review. If meaningful data was found which referred to an Indigenous subpopulation in a larger study, it was considered for inclusion in this review.

Types of interventions

We included interventions to prevent tobacco use initiation or progression from experimentation to regular tobacco use. Interventions were grouped by type and setting based on the following categories:

1. School only (including class lessons etc.), e.g. school-based curriculum delivered by classroom teachers.
2. Mass media (including television, radio, billboards, posters etc.), e.g. community- or nation-wide media campaigns

highlighting the health effects of tobacco use and directed at adolescents.

3. Multi-component (i.e. more than one) community-based intervention targeting large areas (including school, specialised community groups, health care professionals, mass media etc.), e.g. combined tobacco use prevention campaigns involving peer role models, school curriculums, anti-smoking messages at local sporting or community events, combined into one intervention.

4. Family-based programmes, e.g. anti-smoking messages involving parent and child communication and activities including games, workbooks, discussions or written information.

5. Public policy (including legislative interventions, retailer restrictions etc.), e.g. policy for smoking bans in public places or where children are present, which are enforced by the community.

Controls could be usual practice, no intervention, co-interventions or reduced intervention. Control participants receiving reduced interventions could be offered brief tobacco use prevention advice, but support had to be of a lower intensity than that given to the intervention participants in order to be included.

Types of outcome measures

Primary outcomes

The primary outcome was tobacco use status as defined by self-report or objectively through bio-chemical validation (e.g. saliva thiocyanate levels, alveolar carbon monoxide), at the longest follow-up point reported in the study (minimum of six months). No included studies reported tobacco use prevention data excluding baseline tobacco users (i.e., examining a cohort of only non-smokers at baseline). Had this non-smoking baseline cohort occurred, results would have been reported separately from those including baseline smokers within the reported cohort.

We recorded the definition of smoking or tobacco use used by each study. This could be reported as any smoking/tobacco use since the intervention, or as used within a particular period.

We considered the sustainability of change (whether the effect at longest follow-up is larger or smaller than that at earlier follow-ups) in tobacco use behaviour after the intervention (less than versus longer than one year).

Secondary outcomes

Secondary outcomes that were considered for extraction included:

1. whether the intervention had an effect on intentions to use tobacco, attitudes toward tobacco use, knowledge about tobacco use, decision making, refusal skills, self-efficacy and tobacco use perception/norms;
2. levels of implementation for process measures (e.g. measuring the amount of exposure to the intervention that the participants actually received, including details of

implementation) as given in each included study, for example: cigarette purchases by minors, membership of anti-smoking clubs for young people, media reach and level of exposure to each component of an intervention;

3. costs of interventions.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Tobacco Addiction Group Specialised Register in November 2011. The Specialised Register is generated through regular searches of The Cochrane Library, EMBASE, MEDLINE, PsycINFO and Science Citation Index for trials of tobacco use prevention and cessation interventions. No language restrictions were applied. The following free text search terms were used to identify records relevant to the topic:

- 'aborig*' OR 'Indig*' OR 'inuit' OR 'maori' OR 'native american' OR 'american indian' OR 'tribe*' OR 'tribal', AND
- 'young people' OR 'teen*' OR 'adolesce*' OR 'juveniles' OR 'child*' OR 'boy*' OR 'girl*'

Since the Specialised Register is limited to studies of smoking and other tobacco use behaviour, no smoking related terms were used. We also searched MEDLINE using the search strategy used for the Specialised Register, which combines terms for smoking and terms to identify controlled trials, combined with MeSH terms for Indigenous populations, and age related limits. The MEDLINE search strategy is reported in full in [Appendix 1](#).

Online clinical trial registers were searched for ongoing and recently completed studies. We searched Controlled Clinical Trials (www.controlled-trials.com), the National Research Register (www.nrr.nhs.uk), government registries (clinicaltrials.gov), and WHO registries (www.who.int/trialsearch/).

Searching other resources

We reviewed reference lists of reviews and all included studies to identify potentially relevant citations. In addition, we made enquiries regarding other published or unpublished studies known to the authors of the included studies.

Data collection and analysis

Selection of studies

From the title, abstract, or descriptors, KC independently reviewed the literature searches to identify potentially relevant trials. All studies that clearly did not meet the inclusion criteria in terms of study design, population or interventions, were excluded. KC

extracted the data, which was checked by a second reviewer (MB). Both KC and either NL or MB independently extracted information on risk of bias for all included studies. We did not exclude trials with high levels of attrition, however this was documented within the Risk of Bias tables and discussed.

Data extraction and management

KC extracted data for the trials using a standardised data extraction form prior to entry into The Cochrane Collaboration software programme, Review Manager 5.1.6. KC also corresponded with authors to obtain any missing or raw data as required. Risk of bias for each included study was extracted by two independent authors (KC and either NL or MB).

The following information was extracted:

- Methods: country/setting of trial; design; objectives; study site; methods of participant recruitment; methods of analysis
- Participants: age; gender; ethnicity; socio-economic status; n-values for eligibility, recruitment and completion
- Interventions: descriptions of interventions and controls; duration; intervention delivery; type/duration of behavioural support and control group components
- Outcomes: method of outcome collection; pre-specified outcome data; validation; follow-up period; other follow-ups and definitions of abstinence; outcome data as defined under 'Types of outcome measures' in this review.
- Risk of bias: methods of sequence generation; allocation concealment; blinding; incomplete outcome data; selective outcome reporting; imbalance of outcome measures at baseline; comparability of intervention and control group characteristics at baseline; protection against contamination; selective recruitment of participants and other potential threats to validity.

Assessment of risk of bias in included studies

Information on risk of bias was evaluated by two independent reviewers, KC and either NL or MB, in line with recommendations made in the Cochrane Handbook (Higgins 2011) and additional criteria developed by the Cochrane EPOC Group (EPOC 2009). Risk of bias was assessed based on allocation sequence, allocation concealment, blinding of participants and outcome assessors, incomplete outcome data, selective outcome reporting and other potential threats to validity. Three additional domains recommended by the Cochrane EPOC group were used to assess design-specific threats to validity: imbalance of outcome measures at baseline; comparability of intervention and control group characteristics at baseline and protection against contamination (EPOC 2009). Finally, for cluster study designs, an assessment of risk of bias associated with an additional domain of selective recruitment of participants was performed. Risk of bias for each domain was assessed as low, high or unclear as per the guidelines from table 8.5.d of the Cochrane Handbook (Higgins 2011). Conflicts in

the assessments were resolved through consensus or by referring to a third party (either BS or AV).

Measures of treatment effect

Data was reported through narrative synthesis. Due to the small number of included studies it was not possible to meta-analyse data and make all of the comparisons as detailed in the protocol (Carson 2011b). Methods specified in the protocol but not used due to an insufficient number of studies are detailed in Appendix 2. Where possible, we used a risk ratio (RR) to describe the primary outcome defined as (number of subjects using tobacco in the intervention group/ total number randomized to the intervention group) / (number of subjects using tobacco in the control group/ total number randomized to the control group). An RR less than 1 indicates that the intervention was effective, and more subjects remained non-smokers in the intervention group than in the control group. Data were tabulated using Review Manager 5.1.6.

Unit of analysis issues

In the presence of cluster controlled trials, the analysis has been performed at the level of individual whilst accounting for the clustering in the data. For studies that did not include adjustments for clustering, the size of the trial was reduced to the effective sample size (Rao 1992) using the original sample size from each study, divided by a design effect of 1.2, which is consistent with other tobacco use intervention trials (Gail 1992) and as per recommendations in the Cochrane Handbook, section 16.3.4 (Higgins 2011). Whether or not an author has made adjustments for clustering effects has been reported under 'methods' in the Characteristics of included studies tables.

Dealing with missing data

Missing data regarding participants were evaluated on an available case analysis basis as described in chapter 16.2.2 of the Cochrane Handbook (Higgins 2011). Where statistics essential for analysis were missing (e.g. group means and standard deviations for both groups were not reported) and could not be calculated from other data, we attempted to contact the authors to obtain data. Losses of participants that occurred prior to performance of baseline measurements were assumed to have no effect on the eventual outcome data of the study. We assessed and discussed any losses after the baseline measurement. We considered both differential losses between intervention and control conditions, and differential losses within conditions according to baseline characteristics.

Assessment of reporting biases

Reporting biases in individual studies were extrapolated within the risk of bias tables. Due to the limited number of studies it was not possible to assess reporting biases further.

Sensitivity analysis

Due to the small number of included studies we were not able to conduct sensitivity analyses. Were sufficient data available, sensitivity analyses would have been conducted on studies with a high risk of bias for sequence generation and allocation concealment.

Indigenous engagement in the review process

A recent short report by McDonald 2010 outlines the results of a taskforce conducted between the public health group within the Cochrane Collaboration and Indigenous health researchers, to discuss the issues and challenges of systematic reviews in Indigenous health. It highlights the complexities involved in the synthesis of evidence in such populations, for whom the social determinants of health are important factors underlying health inequalities. An important outcome of this review was to engage Indigenous people, organisations and communities to improve health translation. For this reason, the review was examined by two independent Indigenous representatives for consideration of applicability and content. At least one of these reviewers was an Indigenous researcher

or health care worker.

RESULTS

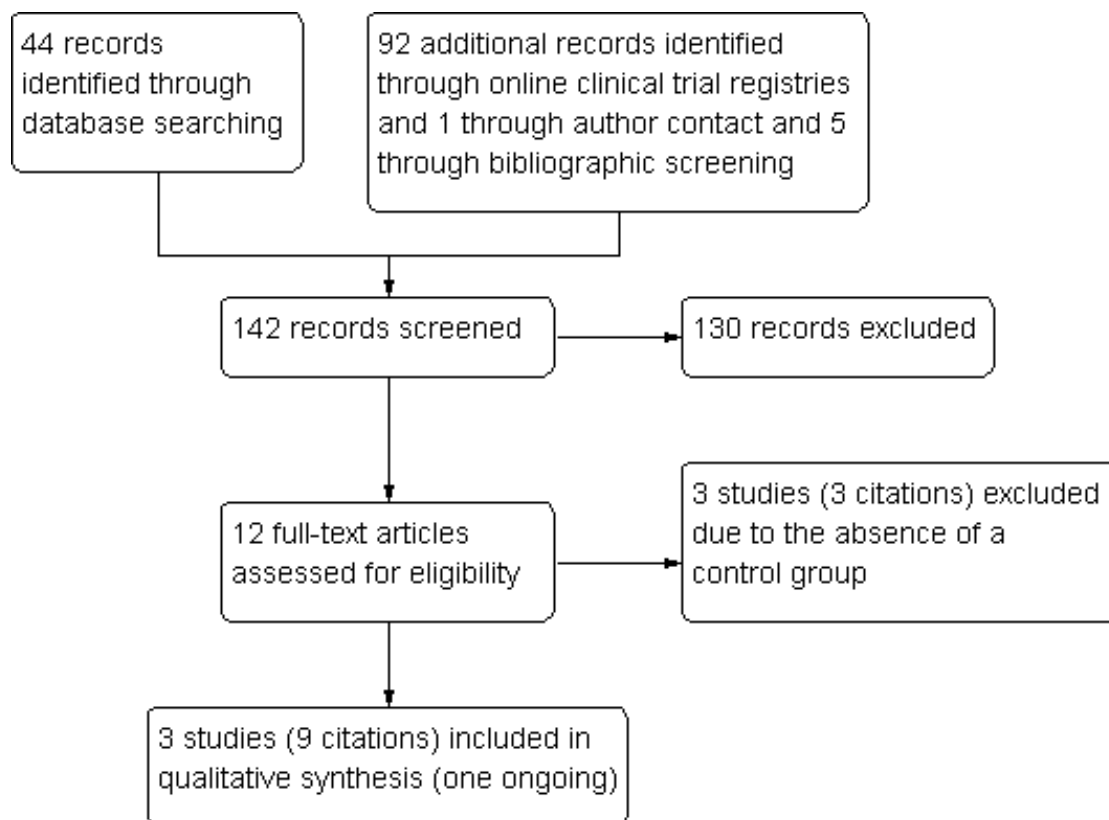
Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#); [Characteristics of ongoing studies](#).

Results of the search

The literature search identified 142 references, of which 92 were obtained from screening electronic clinical trial registries, five through bibliographic screening and one through author contact. Thirteen references were identified from this search for retrieval and possible inclusion in the review, producing a total of two included studies and one ongoing study (nine citations in total) which met all of the inclusion criteria (see [Figure 1](#)).

Figure 1. Study flow diagram.



Included studies

The two studies included in this review were published in 1987 and 1994. They were both randomized controlled trials and used multi-component community-based interventions targeting large areas and involving school forums for message delivery. [Gilchrist 1987](#) had two study arms (three intervention sites, one urban and two rural, and four control sites, one urban and three rural). The intervention in [Gilchrist 1987](#) consisted of a 10-session skills-enhancement programme delivered through school curriculum, group discussions, and invitations to adult from tribal programmes to be guest speakers. This intervention was compared to a test-only control group. The [Schinke 1994](#) study (reservation sites and tribal schools) had three study arms: 'skills-only' (including 15 classroom group interventions and booster sessions six months after initial intervention); 'skills-community' (same as 'skills-only' with the addition of an annual intervention designed to involve the community with various activities in which students modelled the skills they had learned in classrooms to their parents and other community members); and a no intervention control arm. A total of 1505 subjects were included from these two studies and both were based in the Native American population. Follow-up time periods ranged from six months to three and a half years post baseline data collection, although intermediate data collection also occurred, ranging from three months to two years post intervention commencement for the [Gilchrist 1987](#) and [Schinke 1994](#) studies respectively. Intervention durations varied between approximately three and six months, with school-based delivery of between 10 ([Gilchrist 1987](#)) and 15 ([Schinke 1994](#)) classroom sessions. Sample sizes were moderate for both studies with 109 participants in the [Gilchrist 1987](#) study and 1,396 in the [Schinke](#)

[1994](#) study.

In the [Gilchrist 1987](#) study, multiple outcomes were assessed at six month follow-up including drug knowledge scales, attitude scales, interpersonal behaviour tests and amount of alcohol, marijuana, tobacco and inhalants used (if any). Multiple follow-up periods were assessed in [Schinke 1994](#) (6, 12, 24 and 36 months post baseline) for outcomes related to tobacco use (use rates and intentions to use smoked and smokeless tobacco).

For full details of the trials see [Characteristics of included studies](#).

Excluded studies

Three relevant studies were excluded as they did not meet the inclusion criteria as defined for this review due to absence of a control comparison. See [Characteristics of excluded studies](#) for further details.

Ongoing studies

One study was assessed as ongoing at the time of review completion ([Glover 2009](#)). The primary outcome publication for this study was in construction at the time of this review completion; as such, not all trial information was available. For detailed study design information see the [Characteristics of ongoing studies](#) table.

Risk of bias in included studies

The key features for risk of bias in the two included studies are summarised in [Figure 2](#), and are detailed in the 'risk of bias' tables at the end of each [Characteristics of included studies](#) table. Overall, methodological biases were unclear, although each study had at least two categories marked as a high risk of bias.

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Imbalance of outcome measures at baseline	Comparability of intervention and control group characteristics at baseline	Protection against contamination	Selective recruitment of participants	Other bias
Gilchrist 1987	?	?	-	?	-	?	+	?	?	?	
Schinke 1994	+	-	-	?	?	?	+	+	?	?	

Selection bias

Sequence generation was rated as unclear risk in [Gilchrist 1987](#) and low risk in the [Schinke 1994](#) study, which employed a random numbers table using a spreadsheet. Allocation concealment was at high risk of bias in the [Schinke 1994](#) study, with allocation reported as not being concealed, and unclear in [Gilchrist 1987](#). Selective recruitment of participants was unclear for both studies as authors did not report the methods for individual participant recruitment.

Performance and detection bias

Due to the nature of the community level interventions in both studies, it was not possible to blind participants to the interventions. However, it is possible that participants were not aware that they were taking part in a research trial and as such were not aware of their group allocation, i.e. to intervention or control. There was no mention of attempted blinding of outcome assessors in either study.

Attrition bias

Incomplete outcome data was assessed as a high risk of bias in [Gilchrist 1987](#), which reported attrition but did not specify reasons for attrition and did not discuss how missing outcome data was addressed within analyses. [Schinke 1994](#) was unclear for this outcome as insufficient information was provided to permit a judgement.

Reporting bias

Reporting biases were unclear in both studies as there was insufficient information to permit a judgement and neither study had a published clinical trial protocol prior to study commencement.

Baseline measures

Both studies adequately addressed imbalances of outcome measures at baseline. One study reported no imbalances at baseline ([Gilchrist 1987](#)) and the [Schinke 1994](#) study adjusted for differences using an analysis of covariance approach. [Schinke 1994](#) also adjusted for baseline differences in participant characteristics using an analysis of covariance. [Gilchrist 1987](#) did not report sufficient information to judge differences in participant characteristics at baseline.

Protection against contamination

Potential contamination was unclear for both studies. The [Schinke 1994](#) study authors report that the likelihood of contamination between and among intervention and control arms is small, although it could not be completely ruled out. No other biases were identified for either of the included studies.

Effects of interventions

Tobacco use

Two multi-component community-based trials were available for evaluation of tobacco prevention strategies for Indigenous youth. At final follow-up, neither study detected statistically significant changes between intervention and control groups ([Table 1](#)). As the two included studies reported outcomes that were not comparable, we were unable to pool results or compare them side to side.

[Gilchrist 1987](#) detected positive changes in tobacco use at post-test ($p < 0.05$; change score of -0.15 for intervention and -0.01 for control). However, these were not maintained at six month follow-up (change score of -0.11 for intervention and 0.07 for control). In the [Schinke 1994](#) study, no significant differences in weekly smoking between the intervention and control groups were observed at any follow-up. However, weekly tobacco use more than trebled to 35 to 40 per cent over the three and a half year study period. No effect estimates were provided for any 12 month outcomes. At 12 months a non-significant increase in daily smoking, disproportionate to the rest of the sample, was observed in both control conditions and all females. The skills-community condition reported the greatest increase in weekly smoking at 12 months, however smoked tobacco use did rise across the entire sample. During the previous month, an uptake of smoking was shown across all conditions, whilst smokeless tobacco use in the past year increased for skills-community males and skills-only females. Control females showed an increase in smokeless tobacco use, though it was not as high as that observed in the skills-only males. By 42 month follow-up, weekly smoking in the control group had increased over that of the skills-community group and the skills-only group, however the difference was not statistically significant for either group when compared to control (skills-community: RR 0.95, 95% CI 0.78 to 1.14; skills-only: RR 0.86, 95% CI 0.71 to 1.05; [Analysis 1.1](#)). Smokeless tobacco use at the 30 and 42 month follow-ups was lower for subjects in the skills-only arm compared to subjects in the control (at 42 months, RR 0.57, 95% CI 0.39 to 0.85; [Analysis 1.2](#)), whereas the difference between smokeless tobacco use in the skills-community arm when compared to the control arm was not statistically significant at 42 months (RR 0.93, 95% CI 0.67 to 1.30).

Results from the ongoing [Glover 2009](#) study have not been adjusted by ethnicity, and as authors report that more Indigenous youth were present in the intervention arm and Indigenous youth were more likely to take up smoking during the study period, results need to be interpreted with caution. Unpublished results from [Glover 2009](#) detected no difference between intervention and control groups at follow-up for the unmatched cohort (see

[Table 1](#)). Mā ori and Pacific Islander students were more likely to initiate smoking by follow-up compared to other ethnicities

(Mā ori: OR 4.60, 95% CI 3.24 to 6.52; Pacific Islander: OR 2.75, 95% CI 1.92 to 3.82). For the matched cohort (never smokers at baseline that completed both baseline and follow-up assessments), there was a statistically significant difference in favour of the control, with a greater proportion of students in the intervention group having tried smoking by the time of follow-up ($p < 0.001$) ([Glover 2012](#)).

Sustainability of change

Both included studies reported multiple follow-up periods. The interim follow-up for the [Gilchrist 1987](#) study (immediately post intervention, i.e. three months) produced statistically significant changes in tobacco use in favour of the intervention, however these findings were not maintained at final follow-up (six months). For the [Schinke 1994](#) study, there were no significant differences in weekly smoking between the intervention and control groups at any of the reported follow-ups. At the 30 to 42 month follow-ups, smokeless tobacco use was lower for subjects in the skills-only arm compared to subjects in both the control and skills-community arms of the study at 30 month ($p < 0.0001$) and 42 month ($p < 0.001$) follow-ups.

Secondary outcomes

Only the [Gilchrist 1987](#) study reported on participant level outcomes. Attitudes toward drugs and self-esteem were assessed in both intervention and control groups at post-test and six months follow-up. No statistically significant differences were found at post-test or six month follow-up between groups for changes in attitudes toward drugs (intervention change score 0.83, control change score 0.52) or changes in self-esteem (intervention change score 0.47, control change score 0.24). Comparisons of changes in knowledge at both post-test (intervention change score 0.03, control change score -0.01) and six months (intervention change score 0.17, control change score -0.08) follow-up produced a statistically significant benefit in favour of the intervention ($p < 0.01$ for both).

No studies reported process measures for intervention implementation or reported the costs of interventions as an outcome.

DISCUSSION

Summary of main results

Two completed studies in Native American populations assessed the benefits of smoking prevention interventions for Indigenous youth among 1505 participants. Whilst some methodological variations occurred between studies in relation to intervention characteristics, delivery and duration, they both incorporated multi-component community-based interventions aimed at preventing tobacco use in Indigenous youth. No statistically significant differences were observed between intervention and control groups at final follow-up in either study. One study found a statistically significant difference in favour of the intervention for weekly smoking at post-intervention follow-up, but this was not maintained at the six month follow-up. The same study examined secondary outcomes including changes in attitudes, self-esteem and knowledge, and no differences were observed between groups for changes in attitudes toward drugs or changes in self-esteem. However, a statistically significant benefit in favour of the intervention was observed for changes in knowledge at both post-test and six month follow-up. Neither study reported information on process measures or the cost effectiveness of the interventions.

Overall completeness and applicability of evidence

In the context of current practice, this review should provide readers with an outline of what prevention initiatives have been conducted to date, and indicate where resources need to be directed for future investigations. However, this review highlights the paucity of data with which to evaluate tobacco prevention interventions for Indigenous youth from around the world. Only two multi-component community level trials were identified for inclusion in this review, despite the search for multiple intervention types, including prevention programmes as a component of adult initiatives and non-tailored initiatives. Types of prevention interventions that have been examined in non-Indigenous specific populations include school-based ([Thomas 2006](#)), mass media ([Brinn 2010](#)), community level ([Carson 2011a](#)), family-based ([Thomas 2008](#)) and public policy ([Ross 2006](#); [Richardson 2009](#)).

The lack of published trials available for inclusion in this review reflects the need for research to be performed alongside tobacco prevention programmes in Indigenous populations. Significant amounts of government and private funding are being invested into tobacco cessation and prevention programmes ([Ministry of Health 2004](#); [COAG 2009](#); [SA Department of Health 2010](#); [US Dept of Health and Human Services 2010](#)), many of which specifically target Indigenous youth. However, effective evaluation procedures that run alongside them are lacking. These policies (which can include mass media campaigns, access to free nicotine replace-

ment therapies, school-based interventions etc.) require considerable resources. Their subsequent ability to increase long-term smoking abstinence following implementation is, however, unknown. The use of resources for programmes with unproven effectiveness in the Indigenous context can have a harmful result, as resources provided for the delivery of ineffective interventions means an opportunity cost for other interventions (Ivers 2004). Without these accompanying analyses, the true effectiveness of these interventions cannot be ascertained and, importantly, the translation of evidence both nationally and internationally is being hindered as a result. Based on available evidence (through published exploratory qualitative analyses) and the results of the two included studies, the following should be incorporated into the design of future initiatives to ensure intervention effectiveness and methodological rigour:

- Use culturally appropriate interventions tailored for the population being targeted; consider the views and incorporate the suggestions of key members from the population (develop the intervention with community members); provide sufficient intervention exposure, duration and training; where possible involve Indigenous health care workers or project officers for intervention delivery and outcome collection
- Ensure an adequate control group which mirrors the demographic characteristics of the intervention population; consider potential sources of contamination where the intervention may reach the control population and incorporate strategies to minimise this risk
- Collect data (including smoking status) pre-intervention and post-intervention in the same cohort of subjects; provide meaningful follow-up periods (i.e. minimum six months post-baseline data collection); pre-specify outcome data and methods of analysis (publish in an online clinical trial registry such as clinicaltrials.gov to reduce *post hoc* amendments and additions which can introduce bias); calculate a target sample size prior to recruitment which has sufficient power to determine intervention effectiveness.

Dichotomy has been emerging in the uptake of smoking between genders with current reports indicating that smoking behaviour among adolescent girls is increasing over that of boys (Mackay 2006; Warren 2009). At 12 month follow-up in the included Schinke 1994 study, all females reported a disproportionate increase in weekly smoking, though this was not statistically significant. In Schinke 1994, smoking in the previous month was also correlated with a slight increase in smokeless tobacco use in the past year for skills-community males and skills-only females. Control females also demonstrated an increase in smokeless tobacco use, although it was not as high as that observed in the skills-only males. This trend should continue to be examined in future evaluations of prevention initiatives.

Quality of the evidence

Due to the lack of published evidence available with which to evaluate the effectiveness of tobacco use prevention initiatives targeted at Indigenous populations, the external validity of this review is limited, as is the ability to draw any reliable conclusion from the results.

A significant health disparity exists whereby Indigenous populations, a minority, are over-represented in the burden of smoking-related morbidity and mortality (Bramley 2005; ABS 2006; Wood 2008; ABS 2011). Despite the significant health disparity, a paucity of evidence incorporating methodologically rigorous evaluations to assess tobacco prevention and cessation interventions has been identified for the Indigenous population, which has been confirmed by many researchers (Gohdes 2002; Ivers 2003; Clifford 2009). As a result, this review is limited by a lack of published investigations on which to draw a conclusion. Not only is there a lack of evidence examining the different types of interventions (e.g. mass media, school-based, public policy etc.), but there is also a lack of investigation within the various sub-sets of Indigenous

populations (e.g. Native Alaskan, Mā ori, Aboriginal Australian, Native American etc.). Of the available data, risk of bias is a potential issue in this review, with each study having at least seven out of the 10 risk of bias categories assessed as unclear or high risk. No studies evaluated the cost-effectiveness of the prevention initiatives, or assessed any process measures to determine exactly how much of the intervention was received by the population being studied. The gap in this evidence has also been identified in other recent studies (Sanson-Fisher 2006; Clifford 2009), and is of concern due to the health disparities between Indigenous and non-Indigenous populations, which are further exacerbated by the delay between intervention research efforts and implementation of cost-effective dissemination strategies (Berwick 2003).

Potential biases in the review process

A potential bias in the review process is the exclusion of studies examining Indigenous-specific interventions that are of questionable methodological design. This review does sacrifice inclusion of some relevant information, however the trade-off is an analysis of higher quality evidence (and lower risk of bias) on which future investigations can be based. One key strength of the review process to address potential biases is the use of two experienced and independent review authors who assess study risk of bias. However, this can do little to account for biases occurring in the methodological designs of included studies.

This review does not take into account the social construct of smoking in Indigenous communities and how this differs from the mainstream dominant culture's views of tobacco use. It is difficult to separate addiction from social determinants of tobacco use, especially for the studies predominantly reporting intervention outcomes. A theoretical model titled 'the four sided house' (Te

Whare Tapa Wha) was used in the ongoing [Glover 2009](#) study as the model to underpin the prevention initiative. This design was

Indigenous-specific to the Māori and Pacific Islander population being targeted and comprised four interdependent elements (the physical body, the mental realm, family and social relationships and the spiritual realm). In this sense, the prevention initiative was holistic in nature, targeting the 'physical' addiction to nicotine and the attitudes of parents, incorporating spiritual acknowledgement in the processes such as through prayers to open events and meetings, and acknowledging environmental effects proposed by [Glover 2005](#), including the impact of the broader political and economic context such as tobacco industry influences. Although preliminary results of this trial were not statistically significant, the concept is perhaps worthy of further consideration as it incorporates the social constructs of the Indigenous communities as well as broader aspects of tobacco use at the environmental level that are relevant to all youth. Strategies encompassing multiple areas have also been examined in an Aboriginal Canadian context: [McKennitt 2007](#) identifies four aspects of health (physical, mental, emotional and spiritual), and argues that future initiatives should consider a holistic approach coupled with the involvement of Aboriginal healthcare professionals to increase the effectiveness of smoking prevention programmes. The utilisation of healthcare professionals to intervene as part of tobacco interventions has been successfully implemented as part of mainstream smoking cessation programmes ([Carson 2012b](#)). The success of these studies can partly be attributed to the perceptions around healthcare professionals, particularly doctors and dentists, being viewed as influential sources of information ([WHO 2005](#); [Zwar 2009](#)). Moreover, they consult millions of people a year and as such mass dissemination opportunities for intervention messages exist ([Mullins 1999](#); [Richmond 1999](#); [Zwar 2009](#)). Based on the success of these studies for smoking cessation, perhaps healthcare professionals could be utilised for future tobacco prevention interventions among youth.

Agreements and disagreements with other studies or reviews

A review of smoking, nutrition, alcohol and physical activity interventions targeting Indigenous Australians found twenty studies with few employing methodologically rigorous designs and most omitting important details ([Clifford 2011](#)). The authors' conclusions are identical to those found in this review: there is a need for more rigorous evaluations to establish the reliability and validity of any effect. The concept of SNAP (smoking, nutrition, alcohol and physical activity) combines interventions to address each of these issues in a multi-faceted approach and is certainly worthy of further research, since it is often difficult to separate out the use of tobacco, alcohol and other drugs. Moreover, research has found that Indigenous youth in particular are more likely to smoke tobacco, try marijuana and other illicit drugs and engage in binge drinking

in comparison to non-Indigenous youth ([Elton-Marshall 2011](#)). A systematic review of the American National Cancer Institute's adolescent smoking prevention programmes identified five interventions aimed at preventing smoking in youth. They suggested that future programmes should target specific high-risk demographic groups, use professional health educators and/or trained community members and build in methods of updating material to improve the chances of success ([Sherman 2009](#)). Although none of the intervention programmes identified were targeted specifically at Indigenous youth, the implied outcome is that future programmes should target Indigenous populations as they are a high-risk demographic. Moreover, the primary conclusion, that programmes are still needed to address current issues in tobacco control, appears universal.

AUTHORS' CONCLUSIONS

Implications for practice

The findings from this review highlight the paucity of data to evaluate tobacco prevention initiatives in Indigenous youth. More evidence is needed to clearly ascertain what interventions and components of interventions are effective for preventing tobacco use in this population. Based on published qualitative data and recommendations by study authors referenced in this review, pilot work including evaluations such as focus groups should be considered within Indigenous populations prior to intervention delivery to identify potential programmes and components of programmes that are most likely to be effective. This will also produce an assessment of the potential barriers to implementation and facilitators if executed correctly. Interventions should be of a reasonable duration and intensity to produce an effect and should consider process measures for the amount of intervention exposure an individual is likely to receive. It is important to consider conducting assessments alongside any future practices to determine if an intervention is truly effective and investments are appropriately directed. When considering strategies for intervention implementation it is also important to consider 'who' will deliver the intervention.

Implications for research

There is an urgent need for research to assess interventions being funded to prevent tobacco use in Indigenous populations, as there is limited evidence to date for proven intervention effectiveness. This includes classroom lessons, mass media, multi-component community level interventions, family-based programmes and public policy interventions. Based on published qualitative data and recommendations by study authors referenced in this review, researchers should:

- Ensure the appropriateness of these interventions and tailor the programmes to the specific requirements of the population being tested
- Provide adequate intervention exposure, duration and training through the use of Indigenous project officers wherever possible to enhance the uptake of prevention messages and collect process measures to quantify the degree of implementation
- Select an appropriately matched control population to compare results
- Collect data both pre- and post-intervention at meaningful time points (i.e. follow-up of a minimum of six months post-baseline assessment)
- Ensure collected data is pre-specified (through the use of a published online clinical trial registry) and includes meaningful information pre- and post-intervention (such as tobacco use, baseline characteristics (specifically gender differences), existing initiatives underway in the community and secondary outcomes as mentioned in the methods of this review)
- Conduct an evaluation of the cost effectiveness of the intervention using predictive models for disease avoidance
- Be explicit and comprehensive when describing the

limitations and barriers of implementation, as lessons can be learnt from past experiences which can be translated into new investigations.

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- * Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Gilchrist 1987

Methods	<p><i>Country:</i> United States of America</p> <p><i>Design:</i> Randomized controlled trial, cluster, nested</p> <p><i>Objectives:</i> To determine the effectiveness of a skills enhancement model for preventing substance abuse with American Indian adolescents</p> <p><i>Study Site:</i> Reservation and non-reservation settings in the Pacific Northwest; Three intervention sites (one urban and two rural) and four control sites (one urban and three rural)</p> <p><i>Programme name:</i> Not reported</p> <p><i>Methods of analysis:</i> Not reported</p> <p><i>Cluster adjustment made:</i> No</p>
Participants	<p><i>Eligible for study (n-value):</i> Not reported</p> <p><i>Recruited:</i></p> <p>Clusters: n = 3 intervention sites (one urban and two rural); n = 4 control sites (one urban and three rural)</p> <p>Individuals: n = 109</p> <p><i>Completed:</i> n = 39 intervention; n = 58 control</p> <p><i>Age:</i> Intervention mean = 11.22 +1.15; Control mean = 11.46 +1.43</p> <p><i>Gender:</i> Intervention = 52% female; Control = 46% female</p> <p><i>Ethnicity:</i> Native American</p> <p><i>Socio-economic status:</i> Not reported</p> <p><i>Recruitment means:</i> Not reported however intervention occurred in schools</p>
Interventions	<p><i>Theoretical basis:</i> Skills enhancement approaches; SODAS (Stop, Options, Decide, Act/ communication skills, Self-praise) problem solving model</p> <p><i>Intervention description/s:</i> Ten session skills enhancement programme through school curriculum delivered by two people, one a Native American research staff member and the other an Indigenous community leader; Intervention included: discussion of myths concerning Native American drug use, impact of stereotypes on behaviour, provision of health education information through games, handouts, films and posters, group discussions and peer guest speakers sharing personal reasons for rejecting drug use, discussions around SODAS problem solving model, opportunities for skills practice, creation of videotape and adult guest speaker invited from tribal alcohol treatment programme</p> <p><i>Control description/s:</i> Test only control subjects</p> <p><i>Duration of intervention:</i> Ten, 60- minute classroom sessions</p> <p><i>Intervention delivered by:</i> Two person team consisting of one Native American research staff member and one Indigenous community leader (e.g., Native American teachers, school counsellors and alcohol and drug treatment staff members whom subjects knew well and respected; All professional personnel received 10 hours of training about how to deliver the prevention curriculum</p>
Outcomes	<p><i>Method of outcome collection:</i> Not reported</p> <p><i>Pre-specified outcome data:</i> Demographics, drug knowledge scales, attitude scales, inter-personal behaviour tests and if any/amount of alcohol, marijuana, tobacco and inhalants</p>

	used <i>Validation:</i> None reported <i>Follow-up period:</i> Six months <i>Number of follow-up periods reported:</i> Two; post-test and 6 months <i>Process measures:</i> Attendance rates for the intervention condition indicated that 83% of subjects completed the 10 session programme, bulk of remaining subjects attended at least 8 sessions <i>Definition of tobacco use:</i> Not reported	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomization mentioned however methods not described
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the intervention it is not possible to blind participants
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No mention of blinding for outcome assessors
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition reported however reasons not specified and no mention of any missing outcome data or how it was addressed
Selective reporting (reporting bias)	Unclear risk	Baseline outcomes reported and similar between groups
Imbalance of outcome measures at baseline	Low risk	Baseline characteristics reported and similar between groups
Comparability of intervention and control group characteristics at baseline	Unclear risk	Insufficient information to permit judgement of yes or no
Protection against contamination	Unclear risk	Insufficient information to permit judgement of yes or no
Selective recruitment of participants	Unclear risk	Insufficient information to permit judgement of yes or no

Methods	<p><i>Country:</i> United States of America <i>Design:</i> Randomized controlled trial <i>Objectives:</i> To investigate an intervention outcome study of a prevention strategy developed for Native American youth at risk for adopting habitual and lifelong habits of tobacco use <i>Study Site:</i> Fourth and fifth grade youths from both reservation sites and tribal schools; n = 27 tribal or public schools on 10 reservations in 5 states across western United States <i>Programme name:</i> Not reported <i>Methods of analysis:</i> Chi² tests used to detect differences between genders, ANOVA, no correction for intra-class correlation. Scheffe <i>post-hoc</i> multiple comparison tests <i>Cluster adjustment made:</i> No</p>
Participants	<p><i>Eligible for study (n-value):</i> Clusters: n =10 reservations in North and South Dakota; n = 27 tribal and public schools <i>Recruited:</i> Clusters: n =10 reservations in North and South Dakota; n = 27 tribal and public schools Individuals: n =1396 <i>Completed:</i> 18% attrition; Total population only - Individuals: T1 n = 1396; T2 n = 1374; T3 n = 1329; T4 n = 1268; T5 n = 1199 <i>Age:</i> Mean 10 years at baseline <i>Gender:</i> At follow-up 49% female <i>Ethnicity:</i> Native American <i>Socio-economic status:</i> Not reported <i>Recruitment means:</i> Reservation sites and tribal schools</p>
Interventions	<p><i>Theoretical basis:</i> Life skills and social influence models of prevention <i>Intervention description/s:</i> Skills-only: Fifteen classroom group interventions and booster sessions six months after initial intervention; Interventions included material on bicultural competence, tobacco use knowledge, cognitive and behavioural techniques for problem solving, communication and resistance and stress and coping; Interactive classroom work was used with participation in rehearsals of techniques to avoid tobacco use Skills-community: As above plus an annual intervention designed to involve the community including various activities in which students modelled the skills they had learned in classrooms to their parents and other community members; Publications and posters were produced to further educate parents and other community members about the nature and purpose of the intervention; Media was used to enhance participation using traditional Native American legends and puppets to initiate and enhance classroom discussion; Group leaders and group discussions were employed to encourage students to discuss their learning experiences at home and in the community <i>Control description/s:</i> Not described, assumed no intervention control <i>Duration of intervention:</i> Fifteen x 50 minute classroom lessons plus booster sessions at six months <i>Intervention delivered by:</i> Health professionals who had participated in week-long training workshops run by study investigators</p>
Outcomes	<p><i>Method of outcome collection:</i> Questionnaires (no further details) <i>Pre-specified outcome data:</i> Demographics, use rates, intentions to use smoked and smokeless tobacco, plus numerous other structural, environmental, social and psychological factors likely to predict future risk for use of tobacco substances</p>

	<p><i>Validation:</i> Thiocyanate and cotinine were administered to every client at each measurement occasion, only a small proportion analysed; Correlation only 0.53 but no information about levels of misreporting</p> <p><i>Follow-up period:</i> Three years post-intervention (or 3.5-years post recruitment)</p> <p><i>Number of follow-up periods reported:</i> Four after baseline: T1 baseline/ T2 six months/ T3 one year/ T4 two years/ T5 three years</p> <p><i>Process measures:</i> Not reported</p> <p><i>Definition of tobacco use:</i> Weekly: number of cigarettes smoked during the 7 days prior to test administration; Monthly: month prior to test administration; Yearly: Used during the year subsequent to initial follow-up</p>	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomized using a random numbers table on a spreadsheet - data obtained from contact with authors
Allocation concealment (selection bias)	High risk	Allocation was not concealed
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the intervention it is not possible to blind participants
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No mention of attempted blinding for assessors
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information to permit judgement of yes or no; Cotinine measurements collected but not all were tested, however those that were tested were not reported in this paper; Subject survey missing data were removed from analysis
Selective reporting (reporting bias)	Unclear risk	'Post-hoc' analysis for self-reported substance use was conducted to assess differences by study arm using the Scheffe multiple comparison test; It is unclear if this method of testing was pre-determined at the protocol stage
Imbalance of outcome measures at baseline	Low risk	Differences were present between conditions for smokeless tobacco use with control subjects reporting ever use and used in the past month significantly more than

Schinke 1994 (Continued)

		those in the skills-only condition, however ANOVA analysis performed; Students did not differ among the 3-arms for 'subject's use of cigarettes'
Comparability of intervention and control group characteristics at baseline	Low risk	Slight but significant demographic differences were observed between the skills-only condition for both age and gender which were higher compared to the other conditions; Analysis of covariance occurred for imbalances
Protection against contamination	Unclear risk	Authors state the likelihood of contamination between and among intervention and control arms is small; However this can not be ruled out
Selective recruitment of participants	Unclear risk	Eligible individuals prior to recruitment not stated; Methods of recruitment not stated

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Davis 1995	No control group
Dixon 2007	No control group
Vogeltanz-Holm 2009	Not a RCT/CCT intervention of tobacco prevention; No control group

Characteristics of ongoing studies [ordered by study ID]

Glover 2009

Trial name or title	The Keeping Kids Smokefree study
Methods	<p><i>Country:</i> New Zealand</p> <p><i>Design:</i> Controlled Clinical Trial</p> <p><i>Objectives:</i> To investigate whether changing parental smoking behaviour and attitudes via a community-partnership approach with parents, school and local health providers can reduce smoking initiation by 11-13 year olds</p> <p><i>Study Site:</i> Four South Auckland 'intermediate' schools in an urban area of high social deprivation with large numbers of Mā ori and Pacific Islands families</p> <p><i>Methods of analysis:</i> Not reported - raw data obtained</p>

	<i>Cluster adjustment made:</i> Not reported - raw data obtained
Participants	<p><i>Eligible for study (n-value):</i> Not reported</p> <p><i>Recruited:</i> Intervention n = 1938, Control n = 2570</p> <p><i>Completed:</i> 2007: Intervention n = 1320, Control n = 1650; 2008: Intervention n = 1250, Control n = 1575; 2009: Intervention n = 1147, Control n = 1590</p> <p><i>Age:</i> Children aged 11-13 years</p> <p><i>Gender:</i> Intervention 51.1% female, control 51.1% female</p> <p><i>Ethnicity:</i> Mā ori: Intervention 38.9%, Control 19.3%; Pacific Islanders: Intervention 44.0%, Control 44.8%</p> <p><i>Socio-economic status:</i> High social deprivation</p> <p><i>Recruitment means:</i> One school was recruited through a local newspaper article about the proposed study, whilst the remaining three schools were invited to participate by the investigators</p>
Interventions	<p><i>Theoretical basis:</i> An Indigenous model Te Whare Tapa Wha (the four-sided house), comprising the physical body, the mental realm family and social relationships and the spiritual realm</p> <p><i>Intervention description/s:</i> Community level intervention including: non-government tobacco control action organisation, regional public health providers, regional tribal Mā ori health provider organisation, sport and recreation association, schools, parents, local businesses and the New Zealand Health Sponsorship Council. The intervention included:</p> <p>The promotion of smoking cessation to parents and school staff through two 'Quit and Win' contests and material sent to parents identified as smokers throughout the year</p> <p>Promotion of protective parental behaviour to reduce child uptake of smoking through a DVD given to each child titled 'Our Choice, Their Future'</p> <p>Attempts to reduce the social supply of tobacco to minors through controlled purchase operations (CPO) visits every two months and through the display of posters developed by a student with the message 'Don't sell or offer cigarettes to children' and 'Report under 18 sales'</p> <p>A smoke-free art competition with winning pieces displayed on wallet cards for parents, posters for community displays and advertising on buses</p> <p>Communication with parents was conducted through newsletters, personal letters, a web site and face-to-face contact through presentations to school staff, parents and community groups, and showings of the DVD at community libraries during the school holidays</p> <p>Health promotion events included stalls at locally run sports or smoke-free days in the community (e.g. at a local marae: traditional Mā ori meeting place), a family fun day, sponsored school events with prize giveaways, celebrity appearances, class-based fun activities, cultural dance and music performances by students, enrolment with Mā ori cessation support services with quit-cards, distribution of sample nicotine lozenges at events; Intervention staff set up stalls in local shopping malls to promote a 'Quit and Win' contest</p> <p><i>Control description/s:</i> Not reported, assumed no intervention control</p> <p><i>Duration of intervention:</i> Approximately 9 months, commencing at the beginning of each school year and waning mid-term 4</p> <p><i>Intervention delivered by:</i> Study investigators</p>
Outcomes	<p><i>Method of outcome collection:</i> Surveyed in class using self-administered questionnaires</p> <p><i>Pre-specified outcome data:</i> Student smoking, parental smoking, smoking inside homes and cars</p> <p><i>Validation:</i> For children whose parents consented, saliva-cotinine and exhaled carbon monoxide were collected at baseline and follow-up</p> <p><i>Follow-up period:</i> Twelve months</p> <p><i>Number of follow-up periods reported:</i> One at 12 months</p> <p><i>Process measures:</i> None reported</p>

Glover 2009 (Continued)

	<i>Definition of tobacco use:</i> Not reported
Starting date	2007 for baseline surveys
Contact information	Dr Marewa Glover e-mail: m.glover@auckland.ac.nz
Notes	The primary outcome publication for this study was in construction at the time of this review completion, as such not all trial information was available

DATA AND ANALYSES

Comparison 1. Reported tobacco use

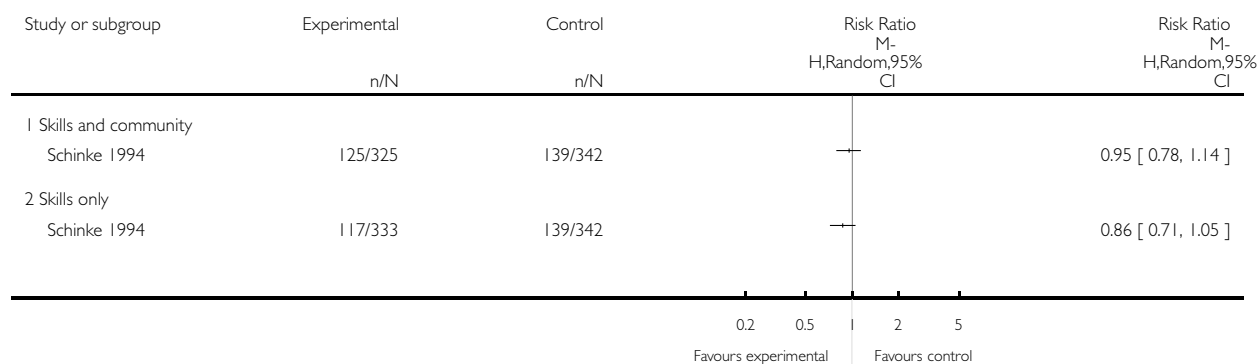
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Smoking - Weekly at 42 months follow-up	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
1.1 Skills and community	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
1.2 Skills only	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
2 Smokeless tobacco use - Weekly at 42 months follow-up	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2.1 Skills and community	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.2 Skills only	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Analysis 1.1. Comparison 1 Reported tobacco use, Outcome 1 Smoking - Weekly at 42 months follow-up.

Review: Interventions for tobacco use prevention in Indigenous youth

Comparison: 1 Reported tobacco use

Outcome: 1 Smoking - Weekly at 42 months follow-up



Analysis 1.2. Comparison 1 Reported tobacco use, Outcome 2 Smokeless tobacco use - Weekly at 42 months follow-up.

Review: Interventions for tobacco use prevention in Indigenous youth

Comparison: 1 Reported tobacco use

Outcome: 2 Smokeless tobacco use - Weekly at 42 months follow-up

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 Skills and community Schinke 1994	54/325	61/342		0.93 [0.67, 1.30]
2 Skills only Schinke 1994	34/333	61/342		0.57 [0.39, 0.85]

0.2 0.5 1 2 5
Favours experimental Favours control

ADDITIONAL TABLES

Table 1. Narrative synthesis of intervention effectiveness

Study ID/sub-headings:	Detailed synthesis of intervention effectiveness:
Gilchrist 1987 Tobacco use	Positive changes in tobacco use found at post-test ($p < 0.05$; change score of -0.15 for intervention and -0.01 for control) were not maintained at 6 months follow-up ($p = \text{NS}$, change score of -0.11 for intervention and 0.07 for control). No intervention effects were observed in subjects' self-identification as tobacco users
Intermediate outcome data	No differences were found in attitudes toward drugs or self-esteem, however a statistically significant difference in favour of the intervention was observed for change in knowledge at both post test and six month follow-up ($p < 0.01$ for both)
Glover 2009 (ongoing study) Tobacco use	Authors report no difference between intervention and control at follow-up (OR 1.30, 95% CI 0.24 to 7.08) as a whole, however Māori (OR 4.60, 95% CI 3.24 to 6.52) and Pacific Islander (OR 2.75, 95% CI 1.92 to 3.82) students were more likely to initiate smoking by follow-up compared to other ethnicities. For the matched cohort (never smokers at baseline that completed both baseline and follow-up assessments), there was a statistically significant difference in favour of the control, with a greater proportion of students in the intervention group having tried smoking by the time of follow-up (21.2% and 14.3% for intervention and control group respectively; $p < 0.001$). However, these results have not been adjusted by ethnicity, and as authors report that more Indigenous youth were present in the intervention arm and Indigenous youth were more likely to take up smoking during the study period, these results need

Table 1. Narrative synthesis of intervention effectiveness (Continued)

	to be interpreted with caution
Intermediate outcome data	None reported.
Schinke 1994 Tobacco use	<p>There were no significant differences in weekly smoking between the intervention and control groups at any follow-up, though all rates more than trebled to 35 to 40% over 3.5-years</p> <p>12 months: Both control conditions and all females reported an increase in daily smoking disproportionate to the rest of the sample at 12 months, however this was not significant. For weekly smoking, the skills-community condition reported the greatest increases, however smoked tobacco use did rise across the entire sample. During the previous month, a slight uptake of smoking was shown across all conditions, whilst smokeless tobacco use in the past year increased for skills-community males and skills-only females. Control females did show a gain in smokeless tobacco use, however it was not as high as that observed in the skills-only males. No effect estimates were provided for 12 month outcomes</p> <p>30-42 months: By 42 month follow-up, weekly smoking in the control group increased over that of the skills-community group, however this was not significant. Smokeless tobacco use was lower for subjects in the skills-only arm compared to subjects in both the control and skills-community arms of the study at 30 months ($p < 0.0001$) and 42 months ($p < 0.001$) follow-ups. Smokeless tobacco at 42 months follow-up has been presented in the meta-analysis for this review, however the p-values are slightly lower though still significant as adjustments for potential clustering effects were incorporated</p>
Intermediate outcome data	None reported.

APPENDICES

Appendix I. MEDLINE search strategy

Database: Ovid MEDLINE(R) without Revisions <1996 to November Week 1 2011>

Search Strategy:

- 1 RANDOMIZED-CONTROLLED-TRIAL.pt. (216874)
- 2 CONTROLLED-CLINICAL-TRIAL.pt. (37532)
- 3 CLINICAL-TRIAL.pt. (263281)
- 4 Meta analysis.pt. (27635)
- 5 exp Clinical Trial/ (444975)
- 6 Random-Allocation/ (37521)
- 7 randomized-controlled trials/ (67037)
- 8 double-blind-method/ (66942)
- 9 single-blind-method/ (12743)
- 10 placebos/ (12010)
- 11 Research-Design/ (42253)
- 12 ((clin\$ adj5 trial\$) or placebo\$ or random\$).ti,ab. (513639)
- 13 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj5 (blind\$ or mask\$)).ti,ab. (65581)

14 (volunteer\$ or prospectiv\$.ti,ab. (329833)
 15 exp Follow-Up-Studies/ (261406)
 16 exp Retrospective-Studies/ (302980)
 17 exp Prospective-Studies/ (226194)
 18 exp Evaluation-Studies/ or Program-Evaluation.mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier] (181432)
 19 exp Cross-Sectional-Studies/ (109522)
 20 exp Behavior-therapy/ (24238)
 21 exp Health-Promotion/ (32843)
 22 exp Community-Health-Services/ (239136)
 23 exp Health-Education/ (67524)
 24 exp Health-Behavior/ (57938)
 25 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 (1932357)
 26 smoking cessation.mp. or exp Smoking Cessation/ (16988)
 27 "Tobacco-Use-Cessation"/ (528)
 28 "Tobacco-Use-Disorder"/ (5409)
 29 Tobacco-Smokeless/ (1419)
 30 exp Tobacco-Smoke-Pollution/ (6325)
 31 exp Tobacco-/ (13526)
 32 exp Nicotine-/ (10034)
 33 ((quit\$ or stop\$ or ceas\$ or giv\$) adj5 smoking).ti,ab. (6274)
 34 exp Smoking/pc, th [Prevention & Control, Therapy] (8520)
 35 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 [A category smoking terms] (48931)
 36 exp Smoking/ not 35 [B category smoking terms] (40119)
 37 1 or 2 or 3 [Likely CT design terms; RCTs, CCTs, Clinical trials] (374329)
 38 35 and 25 [A category smoking+all design terms] (17340)
 39 35 and 37 [A category smoking terms+likely CT design terms] (3184)
 40 (animals not humans).sh. [used with 'not' to exclude animal studies for each subset] (1486040)
 41 ((26 or 27 or 28 or 29) and REVIEW.pt.) not 38 [Set 4: Core smoking related reviews only] (2162)
 42 36 and 25 [B category smoking+all design terms] (17271)
 43 (42 and 37) not 40 [Set 3: B smoking terms, likely CT design terms, human only] (1919)
 44 38 not 39 not 40 [Set 2: A smoking terms, not core CT terms, human only] (13847)
 45 (35 and 37) not 40 [Set 1: A smoking terms, likely CT design terms, human only] (3181)
 46 exp Smoking Cessation/ not (44 or 45) [Smoking cessation only, no design terms] (5583)
 47 indigenous.mp. or Health Services, Indigenous/ or Ethnic Groups/ (30757)
 48 Population Groups/ (1862)
 49 culture/ or minority groups/ (19244)
 50 cultural characteristics/ (7966)
 51 Smoking Cessation/eh [Ethnology] (338)
 52 Smoking/eh [Ethnology] (1342)
 53 47 or 48 or 49 or 50 or 51 or 52 (57199)
 54 45 and 53 (96)
 55 44 and 53 (613)
 56 43 and 53 (24)
 57 54 or 55 or 56 (733)
 58 limit 57 to (humans and ("all child (0 to 18 years)" or "adolescent (13 to 18 years)")) (348)

Appendix 2. Differences between protocol and review

During protocol development we were expecting to identify several types and a considerable number of studies. As such, we described the methods for including and analysing them. The limitations we experienced in applying our protocol are described below:

Measures of treatment effect:

An estimated pooled weighted average for RRs would have been calculated using the Mantel-Hetzel fixed-effect model, with 95% confidence intervals, in the presence of low levels of heterogeneity. Had data been available through a combination of continuous and dichotomous data for the same outcome, we would have combined them using the generic inverse variance (GIV) approach as per section 9.4.6 of the Cochrane Handbook (Higgins 2011) and as outlined in our published protocol (Carson 2011b). We expect secondary outcomes to be presented in different formats, as such we pre-specified that data would be presented as either dichotomous, continuous or combine the two if available in different formats for the same outcome, using GIV. We would have conducted an intention-to-treat analysis, including participants enrolled at baseline, whether or not they receive the intended intervention.

Unit of analysis issues:

As trials were predicted to use a variety of statistical methods to investigate or compensate for clustering, we would have recorded whether studies used these and whether the significance of any effect was altered. Had there been meta-analysable data available for multi-arm trials we would have included each pair-wise comparison separately, but with shared intervention groups divided out approximately evenly among the comparators. However, for those with intervention groups deemed similar enough to be pooled, the groups were combined using appropriate formulas in the Cochrane Handbook (table 7.7.a for continuous data and chapter 16.5.4 for dichotomous data) (Higgins 2011).

Assessment of reporting biases:

Had there been more than ten included studies, potential reporting biases would have been assessed using a funnel plot. Asymmetry in the plot could be attributed to publication bias, but may well be due to true heterogeneity, poor methodological design or artefact. In case of asymmetry, we would have included contour lines corresponding to perceived milestones of statistical significance ($p=0.01$, 0.05 , 0.1 etc.) in funnel plots, which may help to differentiate between asymmetry due to publication bias from that due to other factors (Higgins 2011).

Sub-group analysis and investigations of heterogeneity:

We attempted to categorise trials according to the subgroups listed in [Types of interventions](#) above. However, there were insufficient numbers of included studies available for meta-analysis. Had more studies been available for assessment consideration would have been given to pooling trials within these subgroups, however we would not attempt to pool trials of different intensities of behavioural interventions, or different types of population based interventions. Further heterogeneity could have been contributed by factors such as baseline tobacco use status, participant and community characteristics, (e.g. age, physical state, cultural and educational differences), time of measurement of results and varying measurement tools used to assess outcomes.

The chi square and I^2 statistic, in addition to visual inspection of the data (Higgins 2011), would have been used to quantify inconsistencies across studies. In groups of trials where meta-analysis was judged potentially appropriate, extracted data would have been pooled using the fixed-effect model. In the presence of substantial heterogeneity (based on visual inspection of study data, I^2 statistic, and consideration of study design and methodology), the use of a random-effects model would have been considered. However this would have been performed with caution taking into account the possible influence of smaller studies, which could over or under estimate the true treatment effect.

Ideally we aimed to conduct subgroup analyses for each population (e.g. Australian Aborigines, Alaskan native etc.), however, due to insufficient numbers of included studies this was not possible. Also within each population, tobacco use prevalence was predicted to vary widely between dispersed community groups, further adding to potential heterogeneity of results. As each Indigenous population is unique and each has specific characteristics (such as remoteness) that could influence the effectiveness of tobacco use cessation interventions, subgroup analysis would have provided the most relevant results for a particular population. However, as anticipated, insufficient numbers of studies were available for any populations to be analysed as subgroups. Subgroup analysis of remote versus urban dwelling and isolated versus integrated populations would also have been considered.

We predicted that for studies of long duration, results may be presented for several periods of follow-up including short-term (≤ 26 weeks), medium-term (27 to 52 weeks) and long-term (≥ 53 weeks). Had data permitted, extended follow-up would have also been collated for studies presenting data over two years. For studies with more than one follow-up, we would have considered whether the effect at longest follow-up is larger or smaller than at earlier follow-ups.

HISTORY

Protocol first published: Issue 9, 2011

Review first published: Issue 8, 2012

CONTRIBUTIONS OF AUTHORS

Protocol conceived and prepared by Kristin V Carson, reviewed by Antony Veale, Adrian J Esterman and Brian J Smith.

Literature sorting, data extraction, data entry, data analysis and production of the manuscript completed by Kristin V Carson (as part of post-graduate studies at The University of Adelaide).

Second author risk of bias extraction by Malcolm P Brinn and Nadina A Labiszewski.

Review of draft manuscript by Matthew Peters, Anne Chang, Antony Veale, Adrian J Esterman and Brian J Smith.

Supervision of review by Brian J Smith.

DECLARATIONS OF INTEREST

ABC has received a grant provided by GSK which is unrelated to this topic. She is also the principal investigator on a study examining azithromycin for bronchiolitis in Indigenous children. MJP has received honoraria in relation to attendance at a Smoking Cessation Advisory Board from Pfizer Ltd. No other conflicts of interest are known.

SOURCES OF SUPPORT

Internal sources

- Respirator Medicine Unit, The Queen Elizabeth Hospital, Australia.
- The University of Adelaide, Australia.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

There are a number of differences between the protocol and this review. The changes mainly relate to data analysis and collection, and are a result of the small number and type of included studies (see [Appendix 2](#)). Future updates of the review may need to incorporate these methods if new studies are included.

INDEX TERMS

Medical Subject Headings (MeSH)

*Indians, North American; *Tobacco, Smokeless; Randomized Controlled Trials as Topic; Smoking [epidemiology; ethnology; *prevention & control]

MeSH check words

Adolescent; Humans

Chapter 6.

Barriers and enablers for use of smoking cessation pharmacotherapy for tobacco addiction among Aboriginal and Torres Strait Islander Australians: A mixed method analysis

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Submitted to Tobacco Control 2015

This research was funded by the Respiratory Medicine Department at The Queen Elizabeth Hospital, Adelaide, South Australia

Statement of authorship

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Author contributions:

By signing the Statement of Authorship, each author certifies their stated contribution to the publication is accurate and that permission is granted for the publication to be included in the candidate's thesis.

Name of principal author (candidate)	Kristin Carson		
Contribution to the paper	Conceived the study, established the protocol, performed community consultation, designed the semi-structured interview questions, obtained ethics approval, recruited participants, conducted the interviews, typed the transcripts and organised typing of additional transcripts, performed data analysis, coding using NVIVO and interpretation, wrote the first draft of the manuscript, contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, addressed editorial and peer reviewer comments, made critical revisions and approved final version.		
Signature		Date	17/05/2015

Name of co-author	Kuljit Singh		
Contribution to the paper	Assisted in design of the semi-structured interview questions, performed data analysis, coding using NVIVO and interpretation, contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, made critical revisions and approved final version.		
Signature		Date	17/05/2015

Name of co-author	Harshani Jayasinghe		
Contribution to the paper	Assisted in design of the semi-structured interview questions, performed data analysis, coding using NVIVO and interpretation, contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, made critical revisions and approved final version.		
Signature		Date	25/05/2015

Name of co-author	Gillian Gould		
Contribution to the paper	Assisted in design of the study, contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, made critical revisions and approved final version.		
Signature		Date	24/05/2015

Name of co-author	Matthew Peters		
Contribution to the paper	Assisted in design of the semi-structured interview questions, contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, made critical revisions, approved final version and supervised the process.		
Signature		Date	09/06/2015

Name of co-author	Adrian Esterman		
Contribution to the paper	Assisted in design of the semi-structured interview questions, contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, made critical revisions, approved final version and supervised the process.		
Signature		Date	25/05/2015

Name of co-author	Helen Bradley		
Contribution to the paper	Assisted in design of the qualitative research techniques employed, provided basic instruction for qualitative research methods, agree with manuscript		

	results and conclusions, jointly developed the arguments and structure for the paper, made critical revisions, approved final version and supervised the process.		
Signature		Date	25/05/2015

Name of co-author	Jeffrey Newchurch		
Contribution to the paper	Assisted in design of the semi-structured interview questions, provided input as an Aboriginal Elder to ensure cultural appropriateness, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, made critical revisions and approved final version.		
Signature		Date	27-5-15

Name of co-author	Antony Veale		
Contribution to the paper	Assisted in design of the semi-structured interview questions, provided input related to cultural appropriateness, contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, made critical revisions, approved final version and supervised the process.		
Signature		Date	26/06/2015

Name of co-author	Brian Smith		
Contribution to the paper	Assisted in design of the semi-structured interview questions, contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, made critical revisions, approved final version and supervised the process (primary supervisor).		
Signature		Date	17/05/2015

In Australia, the inability of current mainstream anti-smoking initiatives to close the gap between Indigenous and non-Indigenous tobacco use (38), coupled with the paucity of methodologically rigorous studies uncovered from the two proceeding Cochrane reviews (67, 110), suggests that qualitative research may first be needed before further interventions are planned. Identifying the barriers and enablers to existing smoking cessation pharmacotherapies for tobacco addiction amongst Aboriginal and Torres Strait Islander (TSI) Australians may provide the foundations to establish more effective strategies upon which future initiatives can be built. The most effective means of aided long-term (12 month) quitting is with the use of pharmacotherapy, particularly varenicline tartrate, bupropion hydrochloride and nicotine replacement therapy in that order, as will be discussed in Chapter 10 (111). Although these first-line treatment options have proven beneficial effects in aiding long-term smoking cessation amongst mainstream populations (52, 54), it is not known if these strategies would work in Aboriginal and TSI communities. The one controlled clinical trial identified in the Cochrane review that evaluated nicotine patches amongst Aboriginal smokers in Australia observed poor compliance and no significant effect in smoking cessation between groups at follow-up. An understanding of the reason for the lack of use amongst this cohort is needed. It may be that this type of approach is not appropriate in some Aboriginal communities or that the implementation of these methods has not been appropriate.

A mix of qualitative and quantitative data identified several barriers and facilitators for the uptake of pharmacotherapy from the perspective of health workers, some of which (such as impaired care due to health workers being oversensitive about saying or doing the wrong thing) have not been well described in the existing literature. From the data collected, practical recommendations for current practice, future evaluations and research have been made. In particular, the possibility that a brief training program for health professionals who treat Aboriginal and TSI smokers may provide a cost effective, practical and sustainable means of addressing the broader problem of racism (albeit predominantly unintentional) in health care. However, there is no magic bullet and any approach needs to be tenacious, multifaceted and community owned, directed and evaluated. As such, another opportunity was identified amongst youth, especially considering the previous Cochrane review results reporting the possibility for harm. Utilising social media and web-based technologies, a multifaceted approach with celebrity role models to deliver interventions around smoking, nutrition, alcohol and physical activity combined with addressing other broader social, environmental and cultural factors, may be worth considering.

Title: Barriers and enablers for use of smoking cessation pharmacotherapy for tobacco addiction among Aboriginal and Torres Strait Islander Australians: A mixed method analysis

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Dr Helen Bradley, School of Nursing and Midwifery; The University of South Australia, Adelaide, Australia

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Dr Antony J Veale; Respiratory Medicine; The Queen Elizabeth Hospital; Adelaide, Australia

Prof Brian James Smith; Respiratory Medicine; The Queen Elizabeth Hospital, Adelaide, Australia

Key words/phrases (MeSH terms):

Cessation; Aboriginal health; Primary health care; Tobacco; Addiction

Trial registration number: Clinical Trials identification number (clinicaltrials.gov): NCT01735448

Word count: 5,251

Conflict of interest: KVC has received travel grants from the Thoracic Society of Australia and New Zealand, Healthy Development Adelaide (associated with The University of Adelaide) and the Young Professionals Group (associated with SA Health) to attend national and international conferences related to presentation of this research. She has received financial support and grants from multiple organisations in the past year including the Australian and New Zealand School of Government (to write a policy document about smoking cessation and tobacco prevention in Aboriginal Australians), the National Health and Medical Research Council (to perform a study of training health professionals in smoking cessation amongst health workers treating Aboriginal patients), Cancer Australia (co-funding for the NHMRC project) and the Thoracic Society of Australia and New Zealand (through the Robert Pierce Grant-In-Aid for Indigenous Lung Health to co-fund the NHMRC study). KVC has also received funding from Seeley International for research activities unrelated to this work.

BJS has received grant funding in the past year from the Australian and New Zealand School of Government, the National Health and Medical Research Council, Cancer Australia, the Thoracic Society of Australia and New Zealand and Seeley International, toward supporting several research activities as per detailed descriptions for KVC above.

No other authors have conflicts of interest to declare.

ABSTRACT

Objective Smoking cessation pharmacotherapy and health service utilisation for addressing tobacco addiction are underutilised among Aboriginal and Torres Strait Islander Australians. We examined the barriers and facilitators for use of these smoking cessation options in current practice.

Methods Fifteen in-depth interviews with respiratory doctors and other specialists, general practitioners, health care workers and key community stakeholders (all working with Aboriginal and/or Torres Strait Islander Australians) were conducted between 2013 and 2014. We undertook a thematic analysis of the interview transcripts using the Triandis model of interpersonal behaviour.

Results Tobacco use isn't perceived to be a problem for the majority of smokers in the 'here and now' due to overwhelming concurrent social, familial, financial and health issues. Barriers surrounding the use of current pharmacotherapy such as varenicline tartrate include: poor compliance, the requirement for authority prescribing, availability/access, sharing of the medication and concerns around adverse effects such as psychiatric conditions. Varenicline was reported to be seldom used. Similar concerns were also reported for bupropion and nicotine replacement therapy. In addition, there were reports of vivid or abnormal dreams with these products. Approaching individuals motivated to attempt cessation (e.g., those with tobacco-related illnesses) may improve compliance for smoking cessation pharmacotherapies and improve the number of successful long-term quit attempts. Non-Indigenous doctors may be overestimating the importance for relationship building in Aboriginal communities and underestimating desire for pharmacotherapy compared to key community stakeholders, many of whom were Aboriginal.

Conclusion Pharmacotherapy, particularly varenicline tartrate are grossly underutilised compared to non-Indigenous populations and should be considered as a cessation option particular amongst smokers highly motivated to quit, such as those with tobacco-related illnesses. Doctor perceptions about not using pharmacotherapy may be hindering progress in the clinical management of smoking cessation.

INTRODUCTION

Indigenous populations around the world bear a disproportionate burden of substance-related morbidity and mortality in comparison to non-Indigenous populations, with reported tobacco smoking prevalence estimates of 41% in Australia (21), 41% in New Zealand (22) and 26% in the United States for American Indians and Alaska Natives (23). This is in comparison to 18% (112), 15% (22) and 18% (23) for each country respectively for non-Indigenous peoples. In South Australia (113) and nationwide (114, 115) Indigenous tobacco cessation and tobacco use prevention have been identified as key health priorities because smoking is the number one cause of chronic disease among Aboriginal Australians (48). However, cultural and geographic diversity has created considerable variations of tobacco use within non-Indigenous communities so cessation interventions which appear effective in one community setting will not necessarily work in another. Thus it cannot be assumed that tobacco cessation initiatives that are effective in the non-Indigenous population will translate to the Indigenous setting (67).

Over the past 10 years generalised population level tobacco cessation strategies such as smoke-free policies, taxation and social marketing, have been associated with a reduction in tobacco smoking overall (112), but the prevalence of smoking amongst Indigenous Australians is still more than twice that of non-Indigenous Australians (59, 116-119). Numerous studies demonstrated that smoking cessation pharmacotherapies such as nicotine replacement therapy (NRT) (52), varenicline tartrate (54) and bupropion hydrochloride (54) can be effective in achieving long-term (12-month) continuous abstinence. However, the uptake of such medications by Indigenous Australians has been negligible (66, 120, 121). A 2012 Cochrane systematic review of interventions for smoking cessation amongst Indigenous populations found only four studies worldwide meeting the inclusion/exclusion criteria for the review (67). Although the external validity of the review was limited due to the paucity of evidence, the available data did produce a significant benefit in favour of the culturally-tailored intervention (risk ratio 1.43; 95% confidence interval 1.03 to 1.96; $p=0.032$). This suggests that interventions specifically tailored to Indigenous populations can produce smoking abstinence and may help to reduce the gap between Indigenous and non-Indigenous populations (67).

This paucity of data can be attributed to a number of challenges associated with Indigenous research such as difficulty recruiting participants, inappropriate study design, lack of consultation with key community stakeholders (from here on referred to as key

stakeholders) and Indigenous Elders (67, 69, 122). There are reports from within Aboriginal communities of distrust of research, researchers, government officials and doctors. This might be related to perceptions associated with how often Aboriginal people are portrayed as 'broken' 'helpless' and in need of outside 'expert' assistance in existing research publications (68). Historical abuse of research, non-collaborative and paternalistic and colonising approaches have also contributed to the paucity of empirical evidence (123). Subsequently, adequately resourced randomised controlled trials in the urban Aboriginal setting have failed due to a lack of mutual understanding and engagement resulting in low numbers of willing participants (69). Importantly, authors report that clinic, patient, Aboriginal health worker and General Practitioner (GP) factors, interacting with the study design, contribute to their inability to implement the trial as intended (69). Another smoking cessation study in 2003, which is the only methodologically rigorous trial identified in the Cochrane tobacco cessation meta-analysis coming from Australia, found that no participants completed the full course of nicotine patches (121). An average of five patches were used per person and only six subjects out of 40 reported using more than seven patches (121). These 'failed' studies are of particular concern as the provision of resources for programmes with unproven effectiveness in the Indigenous context can have a harmful result, as resources provided for the delivery of ineffective interventions means an opportunity cost for other potentially effective initiatives (66).

Given the above findings it is a major concern that nation-wide government policies for reducing tobacco are based on limited published scientific evidence, such as that produced by the two Australian studies reported above. Nicotine patches in particular are subsidised by the Australian government for all Aboriginal Australian tobacco users, yet the long-term efficacy of these pharmacotherapies within the Aboriginal setting remains unknown (67). Until new research is conducted that considers the perspectives of Aboriginal people and consults with all key stakeholders, researchers, policy makers and health professionals, a significant gap in tobacco-related disparities, morbidity and mortality will remain (124, 125) and mainstream tobacco cessation and prevention initiatives may continue to be misdirected. Outcomes from these existing studies (67, 69, 126) combined with the known complexity of the Indigenous setting (presence of numerous satellite communities with their own traditions, beliefs and often dialects), suggest that the next phase of evaluation for smoking cessation pharmacotherapies amongst Indigenous Australians should be qualitative in nature (66). For these reasons, we aimed to conduct one-on-one interviews with doctors who treat Aboriginal and Torres Strait Islander patients and key stakeholders

(including Elders, health professionals, researchers and other community leaders) to identify the barriers and facilitators for the use of smoking cessation pharmacotherapies amongst Indigenous Australians, for use in future smoking cessation initiatives and research.

METHODOLOGY

Sample

We conducted in depth one-on-one interviews with doctors (DOC) and key community stakeholders (KCS) until data saturation was reached. Data saturation was determined to have been achieved once no new themes were being identified through coding of the transcripts. Key stakeholders (being researchers, policy makers, male or female Elders or health workers) and doctors (from various disciplines) were identified by the researchers through existing contacts (e.g., Aboriginal Elders and leaders of community groups who supported the research), through healthcare centers (e.g. doctors who were known to consult with Aboriginal and/or Torres Strait Islander patients) and by personal communications and social networks. Potential participants were approached by researchers and provided with a copy of the patient information sheet and consent form for consideration. Inclusion criteria for doctors consisted of: 1) willing to participate and 2) provided clinical care to Aboriginal or Torres Strait Islander people at least one consult per week equivalent over a 12 month period. Inclusion criteria for key stakeholders included 1) willing to participate, 2) currently working/has worked in Aboriginal and/or Torres Strait Islander health as a primary focus of the position, or is a community Elder, or is influential in Aboriginal/Torres Strait Islander health or communities. Subjects who were unable to give informed consent or did not want to participate were excluded.

Purposive selection of participants occurred to ensure diversity of demographic characteristics such as age, gender, specialty, ethnicity and smoking status. Informed consent was obtained from all subjects and all interviews were audio taped and transcribed verbatim to allow analysis of the qualitative data. All subjects had the choice of remaining anonymous or to be acknowledged for participation. Ethics approval was obtained from the Aboriginal Health Research Ethics Committee (04-12-472), the South Australian Health Research Ethics Committee (HREC/13/SAH/06), The Queen Elizabeth Hospital Human Research Governance Office (SSA/13/TQEHLMH/44) and the University of Adelaide Research Ethics Committee.

Procedure

Semi-structured interviews with doctors and key stakeholders were conducted between March 2013 and October 2014. Interview guides were developed following review of the literature, in addition to extensive consultation with over 100 key stakeholders (Aboriginal smokers, ex-smokers and non-smokers, Elders, health workers, doctors, policy makers and researchers identified through community contacts) who have expertise in Aboriginal and/or Torres Strait Islander health. All interviews were conducted by KVC and recorded on two devices before a transcript was typed and validated by each participant. A copy of the two semi-structured interview templates (one for doctors and one for key stakeholders) are available as online supplementary files. Interview duration ranged from 50 minutes to three hours.

Analysis

Qualitative data was analysed using QSR NVivo version 10 by two independent coders under thematic categories based on the Triandis Model of Interpersonal Behaviour (1977) (97), in an attempt to reduce researcher interpretation bias (KVC and either KS or HJ). Quantitative data on demographics, smoking status and 10-point Likert scales assessing attitudes, knowledge, perceptions and beliefs about tobacco use, cessation and prevention were also collected with p-values calculated using an independent samples t-test with Stata version 11. Data are expressed as means and standard deviations (SD) with non-significant results ($\alpha > 0.05$) reported as NS. This quantitative data was used as a means of data triangulation and as a comparison of participant responses to improve reliability and validity. A tag cloud analysis was also conducted for hypothesis generating, giving weight to words in the typed transcripts based on frequency and repetition of use using QSR NVivo version 10.

Theoretical underpinning

Themes were separated by barriers and enablers for the use of smoking cessation pharmacotherapy. The Triandis model belongs to a school of cognitive models and considers intentions and habit as immediate antecedents of behaviour such as with tobacco use (97). According to Triandis, behaviour in any situation can be attributed to intention, habitual response and situational constraints and conditions. Intentions are influenced by social and affective factors (such as peer and Elder tobacco use and the smoking 'norms' within communities) as well as rational deliberations (in order to fit in and make friends or

not be perceived as anti-social, the decision to use tobacco is made). As such no action is either fully deliberative or fully automatic, according to the Triandis model. Likewise, no action is completely autonomous or derived entirely from a social standpoint. Behaviour therefore, is believed to be influenced by an individual's beliefs, though the impact of these beliefs are limited by both emotional drives and cognitive function (97). Thus the Triandis model aims to take into account multiple sources of potential variance as even the smallest amount of variance may be socially important and critical to the uptake or continuation of tobacco use amongst Indigenous communities.

Another way to consider the various influences within the Triandis model is to consider the tri-level explanation developed by Egmond and Bruel in 2007 (99). The first level relates to personal characteristics and incorporates the way past experiences shape attitudes, beliefs and social factors related to behaviour. The second level considers how cognition, affect and the social determinants and personal normative beliefs influence the formation of intentions in regards to a specific behaviour. The final level is intended to explain intentions relating to behaviour, prior experiences and situational conditions predict whether or not an individual will perform a particular behaviour (100) (see Figure 1).

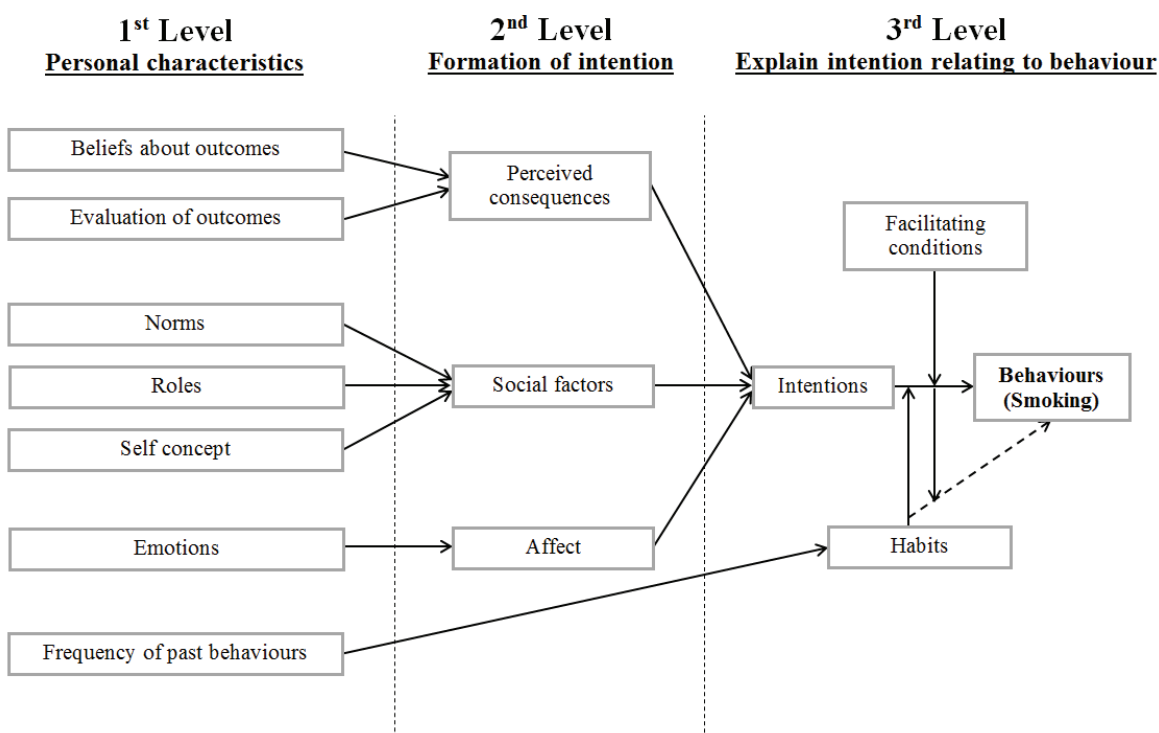


Figure 1: Modified diagrammatic representation of the Triandis model of Interpersonal Behaviour by Egmond and Bruel (98, 99)

The Triandis model is primarily used in modern literature to gain a comprehensive understanding of what determines behaviour and what factors cause behaviours in general (98). Thus the Triandis model offers an ideal framework that may provide explanations and understanding about complex human behaviours, particularly those behaviours that are influenced by social and physical environments such as in the Aboriginal and Torres Strait Islander Australian setting.

RESULTS

A total of 15 participants (from 15 approached) were recruited into the study with data saturation achieved with eight doctors and seven key stakeholders. The characteristics of all participants are reported in *Table 1*.

Table 1: Characteristics of participants

	Age	Gender	Ethnicity	State	Smoking status	Education	Occupation
DOC1	57	M	NI-Australian	SA	Never	PhD	Respiratory Specialist
DOC2	73	M	NI-Australian	QLD	Never	FRACP	Respiratory Specialist
DOC3	55	M	NI-Australian	NSW	Never	FRACP	Respiratory Specialist
DOC4	47	M	NI-Australian	NT	Never	PhD	Respiratory Specialist
DOC5	N/A	F	NI-Australian	NT/QLD	Never	FRACP	Respiratory Paediatrician
DOC6	64	M	NI-Australian	SA	Never	Degree	General Practitioner
DOC7	60	M	NI-Australian	SA	Never	Degree	Psychologist/Medical Practitioner
DOC8	N/A	M	NI-Australian	SA	Never	FRACP	Cardiac Specialist
KCS1	63	M	NI-Australian	SA	Ex-smoker	Honours	Scientist
KCS2	64	F	NI-Australian	SA	Never	PhD	Nurse/midwife/academic
KCS3	45	M	Aboriginal Australian	SA	Never	Year 9	Office work
KCS4	54	M	Aboriginal Australian	SA	Never	Bachelor degree	Private consultant/commissioner (political)
KCS5	55	F	NI-Australian	NSW	Never	Bachelor degree	Researcher/General Practitioner
KCS6	38	M	Aboriginal Australian	SA	Never	Diploma	Manager/sports
KCS7	51	F	NI-Australian	SA	Never	PhD	Academic

DOC= Doctor; KCS= Key Community Stakeholder; N/A= not available; M= Males; F= Females; NI= Non-Indigenous; SA= South Australia; QLD= Queensland; NSW= New

South Wales; NT= Northern Territory; PhD= Doctor of Philosophy; FRACP= Fellow of the Royal Australasian College of Physicians

Barriers to pharmacotherapy:

1st level of Triandis

Tobacco use isn't perceived to be a problem for the majority of smokers in the 'here and now' due to these other concurrent social, familial, financial and health issues (see *Table 2*). Aboriginal and Torres Strait Islander patients were perceived by participants to have a higher prevalence of health issues that need to be addressed compared to the non-Indigenous, including lung disease, mental health problems, heart disease, hypertension and diabetes. However, these issues did not appear to be consistently addressed in the broader context of environmental, social and cultural factors that have an effect on health.

"I think that with a lot of Aboriginals who smoke they're not so worried about what will happen in the long-term with smoking because they're too preoccupied with what might happen to them in the short term." KCS 1

2nd level of Triandis

Barriers surrounding the use of varenicline tartrate (Champix) in particular include: the requirement for authority (Pharmaceutical Benefits Scheme) prescribing, availability, sharing of the medication and concerns around adverse effects such as psychiatric conditions, though for the most part varenicline tartrate is reported to be seldom prescribed. Reports of cultural concerns relating to vivid or abnormal dreams with the use of NRT products were also cited. Both doctors and key stakeholders reported that some Aboriginal and Torres Strait Islander people can perceive vivid dreams as bad omens or as being 'sung to', resulting in people not wanting to try NRT. Moreover, it may only take one member of a community to experience this for the whole community to avoid NRT.

"In terms of NRT well that can be cultural and quite tricky because with all these things you can have dreams... they may think that dead people [ancestors] will be talking to them..." KCS6

3rd level of Triandis

Issues concerning numeracy, literacy and language barriers in particular were raised as a potentially problem that are currently limiting smoking cessation strategies (see *Table*

2). A sense of futility experienced by the health profession and people who are charged with the care of smokers was observed amongst all but one participant. A substantial barrier to successful smoking cessation interventions occurs when health professionals stop offering smoking cessation support because of perceptions that interventions will not be effective.

“...I think that there is probably some nihilism about it...”DOC4; “Sometimes people see an Aboriginal and it has to be an issue rather than just provide the service.” KCS3; “...it’s institutional racism. It’s plain and simple really.” DOC3; “...that people won’t give up anyway so what’s the point.” DOC7

Enablers to pharmacotherapy:

1st level of Triandis

Aboriginal and Torres Strait Islander people who have a tobacco-related health problem were identified by participants as more likely to want to attempt cessation and perceived to be more successful with their attempts and compliance of pharmacotherapies (see *Table 2*). The link between tobacco use and health, social or even family problems cannot always be easily identified. It is important for health professionals and others who are attempting to help smokers quit to actually identify these links and explain how one affects the other. This may in turn make smoking cessation a higher priority as if you can fix this one problem, then it may be possible to address some of the others that are interrelated.

“I think sitting down and talking to them and try to put their health problem in the context of smoking, I think is the best thing.” DOC1

2nd level of Triandis

All participants unanimously highlighted that although smoking cessation pharmacotherapies address bio-chemical addiction they are unlikely to work on their own. As such, a multi-faceted approach is needed that comes from many directions including the community, health care workers, friends, family and Elders (see *Table 2*). Interestingly, peer group pressure was identified as a possible facilitator to help smokers quit. A strong sense of community and having Elders non- or ex-smokers role models may be a useful facilitator in reducing tobacco prevalence as a whole.

“peer group pressure is a very good thing... people look at leaders, their Elders and things like this ... they do look to older people for guidance.” KCS2;

3rd level of Triandis

Although use of medications such as nicotine patches has been inconsistent, they are used within Aboriginal and Torres Strait Islander communities. This suggests that medications for smoking cessation amongst this population do have the potential to be effective providing the right support structures are available (e.g., community, Elders, health professionals, family and friends). However, medications such as varenicline tartrate (Champix) are currently underutilised (see *Table 2*). The computerisation of medical record systems which can keep a better track of health, particularly considering the transient lifestyle of those living in remote communities, could aid implementation of effective smoking cessation strategies and increase pharmacotherapy uptake .

“I think computerisation of medical records is helping but I think there should be more communications with the different systems... If they were all linked up they would help us track patients and what’s happened and that would make a big difference to continuity of care between the health services.” DOC1

Table 2: Sub-themes and quotes identified under the Triandis model

Triandis	Subcategory	Quote
Barriers		
1 st level	Tobacco isn't seen to be a problem	<i>“...that they might develop something bad in 20 or 30 years is a very low priority when they're a victim of domestic violence or if they've got poverty...” DOC1</i>
	One of many issues	<i>“It's one of a pantheon of many problems that need addressing...” DOC 1</i>
	Combined impact of many factors causing health disparities	<i>“I think for Aboriginal people there are a lot of other environmental dust and smoke exposure that probably contributes to the lung disease at least as much as what cigarettes are.” DOC2</i>
2 nd level	Low impact of perceived consequences	<i>“lack of health knowledge about the consequences of smoking, remoteness, addiction and the inability to get effective treatment and I think that actually is point to all women, not only Aboriginal.” KCHS3</i>
	Concerns around using pharmacotherapy	<i>“I think compliance with medication is a big issue in remote Aboriginal communities and I don't think they're particularly compliant with patches or medications like Zyban or varenicline...” DOC3</i>
	Expectations of outcome and poor compliance	<i>“Well I just think that people are not very compliant with medications and to take something every day for three months is just not going to happen...” DOC 5</i>
3 rd level		

	Supervision needed and access difficult	<i>"Champix is a problem. It's a good product but it needs supervision and it needs to be scripted by the doctor, so for the country people this becomes a problem."</i> KCS1
	Habits, addiction and emotions all need to be addressed	<i>"...addiction itself is just a small part of smoking, you have to conquer the other two thirds of it, habit and emotions, and until society recognises it you can't fix it with a simple 30 day or 90 day pill."</i> KCS4
	Poor literacy and language barrier	<i>"...but it's very hard to know, particularly for Pitjantjatjara but they don't really count very well, they only count the one, two, three and then a lot after that..."</i> DOC1
Enablers		
1 st level	Emotions can influence behaviour	<i>"Other than that if they've got lung disease and they've got symptoms then I think it's a bigger priority and you're more likely to in that setting be able to help them find a way to give up."</i> DOC6
	Evaluation of quitting and support through the health system	<i>"...the health service is obviously an important asset and are probably the most regular deliverers of anti-smoking messages."</i> DOC4
	Belief that success is possible	<i>"You have to have a belief that you can make an impact otherwise the people doing it who are smokers, won't actually believe that there is any hope... there has to be people who were smokers who have given up."</i> KCS7
2 nd level	Prevention will reduce smoking consequences	<i>"Stopping new people from smoking is just as important as encouraging new smokers to quit."</i> KCS6
	Utilising existing resources is important	<i>"There are a lot and lots of tobacco resources [for youth tobacco prevention] including the ones that are brought in by Menzies."</i> DOC5
	Cultural competency for non-Indigenous health professionals will aid smoking cessation	<i>"...people either being uneducated about Aboriginal culture and stuff and having not a clue that they are insulting people or that they are being so overtrained with so much information, brow-beaten about this kind of stuff, that they are too self-conscious."</i> KCS3
3 rd level	Facilitating conditions utilising existing resources	<i>"In a controlled community health service where you've got Aboriginal health workers or other people who are able to work as a multi-disciplinary team that's really appropriate."</i> DOC8
	Medication can be effective but are currently underutilised	<i>"I know of patients who have quit smoking and were using patches... but using patches was a bit random...certainly patches do get used."</i> DOC1; <i>"I'm not aware of that being used...I don't recall any of the ones that I know giving up smoking that have ever used Champix."</i> DOC1
	Facilitating conditions of health professional perceptions and behaviours	<i>"...the thing that really resonates is where people stop asking about tobacco because it gets so hard, and so we have to keep coming back to the fact that we have to keep asking."</i> DOC4; <i>"...if we stop asking, we stop giving any opportunity to respond..."</i> DOC2

Tag cloud analysis:

The tag cloud analysis identified several key words in participant responses suggesting possible areas where interventions should be targeted or adapted to incorporate these areas/groups (*see Figure 2*). These primarily include: the use health care systems and linking health problems with tobacco use, tailoring interventions for women and pregnancy in particular, utilising and engaging with communities for new smoking cessation programs, improving the knowledge of not only smoking cessation health problems but also knowledge about strategies that can be used to address chronic tobacco use, prevention of smoking uptake to begin with and the use of sporting role models within interventions.



Figure 2: Tag cloud analysis giving weight to words based on frequency and repetition of use in the typed transcripts

Questionnaire data:

Quantitative data from the questionnaires produced results similar in thought to those reported during the qualitative interviews. There was a strongly held belief that smoking messages should be taught in schools and that tobacco use is more difficult to give up if alcohol and/or other drugs are being concurrently used (*see Table 3*). Interestingly significantly more doctors believed that tobacco use was an important part of relationship building in Aboriginal communities compared to the key stakeholders and more stakeholders believed that pharmacotherapy is the best way to help Aboriginal smokers to quit compared to doctors.

Table 3: Quantitative questionnaire variables separated by the three levels of Triandis identifying participant attitudes, knowledge and beliefs around smoking and cessation

1 st level: Personal characteristics	Doctors		Key stakeholders		p-value
	Mean	SD	Mean	SD	
Tobacco use is an important part of relationship building in Aboriginal communities	8.2	1.92	4.6	3.13	0.02
It is harder to give up smoking if you use alcohol and/or other drugs	9.0	1.41	8.0	1.41	NS
Smoking messages should be taught in schools	9.6	0.55	9.0	1.73	NS
Aboriginal people believe that smoking is bad for their health	7.0	2.00	7.4	1.95	NS
2 nd level: Formation of intention	Doctors		Key stakeholders		p-value
	Mean	SD	Mean	SD	
More resources need to be invested into research to help Aboriginal patients to quit smoking	8.4	1.14	7.4	2.88	NS
Tobacco use is considered a big health problem in Aboriginal communities	7.8	2.77	7.8	2.39	NS
Plain package cigarettes will stop Aboriginal kids from smoking	3.8	2.28	4.4	1.82	NS
Aboriginal people believe that second hand smoke is harmful	4.4	2.07	7.0	2.65	NS
3 rd level: Intention relating to behaviour	Doctors		Key stakeholders		p-value
	Mean	SD	Mean	SD	
There is not enough support to help Aboriginal smokers that want to quit	7	1.58	8.4	1.95	NS
Tobacco cessation pharmacotherapy is the best way to help Aboriginal smokers quit	4.4	1.34	7	1.22	0.04
Healthcare workers shouldn't smoke if they are giving stop smoking advice to patients	9.4	1.34	7.2	2.05	NS
I feel confident that I could help an Aboriginal smoker to give up if I needed to	7.4	2.07	7.4	2.88	NS

DISCUSSION

The 15 participants unanimously believed that pharmacotherapy has an important place in facilitating smoking cessation amongst Aboriginal and Torres Strait Islander people. However, there are still several issues that need to be considered first when attempting smoking cessation. The results support the importance of addressing contextual factors in all strategies aimed at supporting cessation among Aboriginal and Torres Strait Islander populations. In particular tobacco use needs to be considered in the context of a large number of other health issues in addition to social, financial, familial and environmental problems. Key barriers around the use of smoking cessation pharmacotherapy included concerns around a lack of adherence and limited availability for some products particularly in remote locations. These issues around poor access in remote communities and compliance have also been described in other studies conducted in the Aboriginal Australian setting (34). International studies evaluating the effects of colonisation on Indigenous health have frequently identified the reticence and unwillingness of contemporary Indigenous peoples to access health services (127, 128). Reasons can include fear of forced removal of children, racism, shyness, shame, poor self-esteem, lack of confidence and a reluctance to expose particular body parts to non-Indigenous providers, especially if they are of the opposite sex (128), thus limiting the ability of health services to provide optimal care for tobacco use.

Sharing of medications and the fear of developing adverse events were also raised by the majority of participants as important barriers to the wide-spread uptake of pharmacotherapy. A pre-post study of nicotine patch use amongst Indigenous smokers in the Northern Territory resulted in 29% reporting bad dreams, with no participants completing the full course of patches partly due to fear of adverse effects (121). Participants from one community in particular commented that the traditional interpretation of bad dreams or nightmares signified a bad omen and that a person was being 'sung' to or cursed. As a result, authors report that some participants were reticent to use patches.

Champix (varenicline tartrate) was reported to be seldom prescribed despite the fact that it is currently the most efficacious pharmacotherapy for smoking cessation available (111). The reasons for lack of use were generally unknown by key stakeholders and doctors, yet for the most part Champix was often not considered as part of standard clinical practice. Risk of adverse events may be a potential barrier, though recent meta-analyses and trials

evaluating the safety of varenicline have found it to generally be safe and well tolerated (129, 130). Two participants stressed that the risk of developing adverse events were a possible reason for the lack of use and adverse events with smoking cessation pharmacotherapy in general is a concern. Interestingly when examining duration of pharmacotherapy use in the pre-post study by Ivers *et.al*, participants using more than a weeks' worth of nicotine patches did not identify any increase in the likelihood of experiencing an adverse event in comparison to those using seven patches or less (121). The poor uptake of varenicline tartrate reported by participants in our study are similar to other qualitative evaluations conducted (34), suggesting that an opportunity exists for Champix as part of clinical care within the Aboriginal and Torres Strait Islander setting if combined in a comprehensive approach that includes patient education.

Pharmacotherapy enablers included offering medications to smokers, particularly long-term smokers with tobacco-related illnesses, who are already highly motivated to quit. Such an approach has been shown to improve the uptake of varenicline tartrate amongst smokers admitted to hospital with acute tobacco related illnesses (131). International literature, however, has reported the opposite to be true with people likely to quit if offered medication irrespective of motivation (132). Medical clinics and health services are good venues for smoking cessation messages, though a multi-pronged approach is needed with the same anti-smoking messages coming from several different sources simultaneously. A multi-faceted culturally-tailored approach was believed to be the most effective way in aiding smoking cessation with the combined use of pharmacotherapy, counselling, education and other support networks. A systematic review by Gould *et.al*, examined if anti-tobacco media messages should be culturally tailored for Indigenous populations, finding that culturally-targeted messages were preferred though generic messages were just as effective, but did not necessarily lead to quit attempts in Indigenous Australians (61). There was little research however, to directly compare the effect of culturally tailored versus generic messages with similar content in the Indigenous setting. Indeed a qualitative study by Johnston *et.al*. in the remote Indigenous setting also identified that several tobacco control interventions were generally perceived to be acceptable, however, some unmodified Quit programs were perceived to have questionable application in the primary care setting for Indigenous peoples (34).

Unanimously, all participants were of the opinion that prevention should still remain a strong focus going forward. Helping those who are current smokers to quit is important in

reducing health service utilisation, improving quality of life and reducing morbidity and mortality amongst Aboriginal and Torres Strait Islander smokers; it was believed to be more important to prevent tobacco uptake amongst youth in the first place. Another qualitative analysis examining the reasons why Indigenous Australian youth start smoking identified that family and peer influences in particular play a large role. Social influences to smoke were comparable between Indigenous and non-Indigenous youth, though more persuasive in the Indigenous context (62, 133). Focusing on youth to improve education about the healthy lifestyle messages and utilising schools as a delivery mechanism for this are believed to be important strategies to improving utilisation of health care practices and recognising health problems before they progress into more serious illness episodes.

The tag cloud analysis identified that sporting role models may be an important asset when attempting to engage community members and youth in particular in anti-tobacco messages. Again the multi-faceted approach that aims to address other healthy lifestyle, environmental and social concerns should also be combined in a package rather than addressing tobacco alone. One example is the use of the Smoking, Nutrition, Alcohol and Physical activity (SNAP) model (134), which attempts to address these four high priority issues at once. The use of celebrity, Elder and peer role models need to also be incorporated into the package and the use of web-based resources (135) such as social media (136, 137), should also be considered particularly given the large amount of time youth spend engaged in these activities. The constant presence of tobacco use, social pressure and crowded housing shared with other smokers, have also been reported to hinder quit attempts (121). Therefore it is important to address these issues holistically; particularly considering that environmental factors such as environmental smoke, dust and spread of infections within close communities can have a substantial influence on respiratory health as discussed by one doctor in our study.

Quantitative data allowed triangulation of results, improving the reliability and validity of findings as confirmed by the emergence of consistent themes between methods. Interestingly, the quantitative data did reveal that doctors are potentially overestimating the importance for relationship building in Aboriginal and Torres Strait Islander communities compared to key stakeholders and underestimating desire for pharmacotherapy compared to key stakeholders, particular among the Aboriginal participants. However, this information could be interpreted in another way. The stakeholders could be underestimating the importance of relationship building and overestimating the ability of

pharmacotherapy to effectively aid long-term smoking cessation. The majority of participants also reported observing different types of discrimination in the health setting toward Aboriginal and Torres Strait Islander people with most people sitting on either side of 'optimal care'. On the one hand health workers can be ignorant to the roles that culture, community and Aboriginal and/or Torres Strait Islander identify play in health, whilst on the other hand, some healthcare workers may be too sensitive about saying the wrong thing that patient care is compromised. These issues combined indicate that doctor perceptions may be inaccurate, which subsequently could hinder progress in the clinical management of smoking cessation. One solution could be a program designed to train health professionals in smoking cessation strategies that includes a module on cultural awareness training, information about the latest in pharmacotherapeutic options, and skills workshops about how to effectively implement this into standard care (138). An approach such as this would be of minimal cost, aid translation of evidence into practice and provide a sustainable means of upskilling within the community, beyond the duration of the training intervention. However, there is currently no evidence to underpin this approach in the Indigenous Australian context. Evaluation and evidence translation of existing resources that have been developed with community participation from Aboriginal and Torres Strait Islander Australians should be made a priority. Substantial amounts of resources have already been invested into these culturally-tailored programs, yet with the disbandment of the COAG and government budget cuts, these resources are not making it to the front line of clinical care where they are of most value.

Limitations

This analysis contains several limitations including firstly the lack of self-reported Aboriginal and Torres Strait Islander doctors in that group. This does limit the context of the findings to the attitudes, knowledge and behaviours of non-Indigenous doctors. However, in a standard clinical practice setting the large majority of doctors treating Aboriginal and Torres Strait Islander Australians are non-Indigenous themselves. According to the Australian Indigenous Doctors Association there are currently 204 Indigenous doctors (139) with over 80,000 non-Indigenous doctors (140), meaning that the majority of Indigenous people are treated by non-Indigenous doctors. Thus less than a quarter of one percent of doctors are Indigenous and therefore the results are a reflection of real-world practices. Secondly, seven of the eight doctors included in this analysis are specialists, meaning that the population of patients they consult tend to have more severe

underlying illnesses than those seen by general practitioners. As such willingness to quit smoking and approaches taken amongst their cohort of patients is likely to be different to the general population.

Overall, a more responsive and strategic health care system strategy is needed for the 'language of disadvantage' that is adaptive and responsive to people's linguistic, cultural and social needs, irrespective of whether they are Indigenous, from non-English speaking background or a particular socio-economic group (141). It is nevertheless still important to acknowledge Aboriginal and Torres Strait Islander identity as a source of empowerment and to recognise the role of persistent marginalisation in contributing to the high prevalence and initiation of smoking. Perhaps the model of care provided to Indigenous patients should be altered to optimise medical care, with considerations of culture, language and history. Indeed, it is only in recent years that community involvement within the planning and implementation of tobacco cessation initiatives has resulted in the first significant reduction in tobacco use prevalence for many countries (67, 142). However, the diversity of Aboriginal and Torres Strait Islander communities means that a blanket approach is unlikely to be effective. Smoking cessation programs need to be culturally-tailored not only to the individual communities but also the individual smokers.

CONCLUSION

Pharmacotherapy for the most part is underutilised in the Indigenous Australian setting. Under-evaluation of treatment efficacy and safety may contribute to the poor uptake. Although some success has occurred with the use of transdermal nicotine replacement therapy, Champix (varenicline tartrate), which is currently determined to be the most efficacious of the smoking cessation pharmacotherapies, is seldom used by Aboriginal and Torres Strait Islander Australians. Barriers to smoking cessation pharmacotherapies include compliance, availability, sharing of medication and fear of adverse events. Enablers include: improving awareness about the efficacy and safety of available pharmacotherapy, considering interventions in smokers already motivated to quit who may need additional help to aid long-term cessation and taking every opportunity to offer smoking cessation support, which is not currently occurring. From this evidence, multiple opportunities for further research emerge including engaging youth in interactive web-based and social media interventions intended to prevent the uptake of tobacco use to start with and training health professionals in the latest evidence for smoking cessation coupled with a cultural awareness module to increase offers of cessation support for Aboriginal

and/or Torres Strait Islander smokers. Evaluation the safety and efficacy of smoking cessation pharmacotherapy, coupled with other multi-faceted approaches, need to be made a priority. It is important that health professionals always present smoking cessation opportunities to their patients, even if they may perceived it to have little impact, because if we as health professionals stop asking, we stop giving any opportunity for smokers to respond.

Acknowledgements

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Contributions

All authors provided feedback on manuscript drafts and contributed to study development and progress. KVC conceived the study and was responsible for design, participant identification, recruitment, data collection, coding, analysis and producing the first draft of the manuscript. KS and HJ performed coding and data analysis. GG, MP, AE, HB, JN, AV and BS provided input to study design and interpretation of the manuscript. JN ensured cultural relevance of the content and HB ensured appropriate qualitative methods were undertaken. BS, MP, AE and AV were also PhD supervisors for KVC.

Note: References for this study have been listed at the end of the thesis for continuity.

Chapter 7.

A national survey of current practice by Respiratory Specialists and Allied Health Professionals in treating Aboriginal and TSI tobacco use

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Author contributions:

By signing the Statement of Authorship, each author certifies their stated contribution to the publication is accurate and that permission is granted for the publication to be included in the candidate's thesis.

Name of principal author (candidate)	Kristin Carson		
Contribution to the paper	Conceived the study, established the protocol, performed community consultation, designed the questionnaire, obtained ethics approval, recruited participants, performed data analysis, wrote the first draft of the manuscript, contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, made critical revisions and approved final version.		
Signature		Date	17/05/2015

Name of co-author	Kuljit Singh		
Contribution to the paper	Designed the questionnaire, performed data analysis, contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, made critical revisions and approved final version.		
Signature		Date	17/05/2015

Name of co-author	Brian Smith		
Contribution to the paper	Contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, made critical revisions, approved final version and supervised the process.		

Signature		Date	17/05/2015
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Building on the proceeding chapter presenting qualitative research among doctors and key community stakeholders, this brief letter to the editor submitted for publication explores the perceptions of a convenience sample of health professionals who attended the Thoracic Society of Australia and New Zealand annual scientific meeting in Darwin 2013. Demographics including age, number of Indigenous patients treated each year and locations were used to explore the differences between groups. Several significant results were observed including that older health professionals (≥ 40 years) were more likely to offer advice to Aboriginal and Torres Strait Islander (TSI) smokers compared to younger participants. Likewise, older participants were more likely to believe that Aboriginal and TSI people receive the same medical care as non-Indigenous people, compared to the younger health professionals. These differences perhaps point to a lack of experience amongst the younger health professionals that is important to recognise. It also supports the recommendations of the proceeding chapters of this thesis that perhaps a training program for health professionals to improve cultural awareness, provide knowledge about the latest pharmacotherapeutic and behavioural interventions for smoking cessation and provide skills training on how to adequately discuss smoking cessation with a patient are needed. This is particularly important among younger health professionals and highlights that an opportunity exists for mandatory training during undergraduate degrees. Greater involvement from Aboriginal people in developing and delivering training resources for non-Indigenous health professionals is needed, to help the non-Indigenous health professionals gain a better understanding of the cultural reasons for smoking and how to approach the issue of quitting with Aboriginal and TSI smokers.

Several differences were also observed between participant locations from Eastern Australia (Queensland, New South Wales, Australian Capital Territory and Victoria) compared to Central locations (South Australia and Northern Territory). Central locations reported that they were less likely to have enough support to help Aboriginal and TSI smokers who want to quit, less likely to feel that advice from them makes a difference amongst Aboriginal and TSI smokers and less likely to feel that tobacco use is considered to be a big health problem amongst Aboriginal and TSI smokers. These differences point not only to the diversity of communities, but also to the current issues surrounding effective translation of evidence.

Medical Journal of Australia Manuscript submission template

Type of article See Types of articles published by the MJA	Letter (new topics/research/cases)
Title:	A national survey of current practice by Respiratory Specialists and Allied Health Professionals in treating Aboriginal and TSI tobacco use

Abstract	
<p>Articles requiring a descriptive 15-word introductory line are: Editorials, and Perspectives.</p> <p>Articles requiring short (50-word) unstructured abstracts are: Notable cases (abstract should state the general area of relevance, describe the specific nature of the case, and point out the relevance/implications for clinical practice or health policy).</p> <p>Articles requiring 4–6 bullet-point) summaries are: Clinical focus article including narrative review.</p> <p>Articles requiring structured abstracts are: Research reports (use the headings: Objectives, Design, Setting, Participants, Main outcome measures, Results, Conclusions and Trial registration [if applicable]) and Systematic reviews (use the headings: Objective, Study design, Data sources, Study selection, Data extraction, Data synthesis, Conclusions).</p>	
Abstract word count	No abstract required

Text and word count: 350

Research reports should be written in IMRAD format (Introduction, Methods, Results and Discussion).

Case reports should comprise a Clinical record followed by a Discussion.

To the Editor: A recent survey of Respiratory Specialists, nurses and other Allied Health Professionals from across Australia has identified several disparities in perspectives about the clinical care provided to Aboriginal and Torres Strait Islander (TSI) patients. A total of 40 respondents attending the Thoracic Society of Australia and New Zealand conference in Darwin 2013 participated in the survey from across four states and two territories (mean age 40.6 ± 12.5 years; 20 male; 30 were born in Australia). Several characteristics were identified that influenced participant responses, for example, older participants (>40 years) were more likely to report that they would always offer advice to Aboriginal smokers about giving up smoking during consults and felt that Aboriginal people were less likely to receive the same medical care as non-Aboriginal people, in comparison to younger survey participants. Subjects who had less experience treating Indigenous patients (12 times per year or less) were more likely to believe that tobacco use is an important part of relationship building. Opinions also differed by respondents from central Australia (including South Australia and the Northern Territory) compared to those residing in Eastern locations with the latter reporting tobacco use to be a bigger health priority and that advice from them is more likely to make a difference in helping patients to quit. Finally, Respiratory Specialists were more likely to believe that Aboriginal and TSI patients were aware of the health effects caused by tobacco compared to Allied Health Professionals. However, Allied Health Professionals were more likely to believe that tobacco media campaigns do help support quit attempts and that racism is still happening today in general healthcare (see Table 1). All of these responses highlight the wide variation in health care provision caused by the differing opinions, beliefs and attitudes of the health professionals treating Indigenous patients. It was stressed that mandatory training for health professionals in cultural competency and tobacco cessation/prevention skills are needed to address issues of ignorance and the lack of confidence experienced by the very people expected to support Aboriginal and TSI patients to improve their health and help close the gap.

Table 1: Survey responses divided by key characteristics of participants expressed as mean and standard deviation

Survey variable	Mean	SD	n	Mean	SD	n	p-value
	> 40 years of age			< 40 years of age			
“I will always offer advice to Aboriginal and TSI smokers about giving up smoking during consults”	6.89	2.76	19	9.19	1.05	21	0.04
“Aboriginal and TSI people receive the same medical care as non-Indigenous people”	3.95	2.25	19	6.16	3.10	21	0.02
	< 12 Indigenous consults per year			> 12 Indigenous consults per year			
“Tobacco use is an important part of relationship building in Aboriginal and TSI communities”	5.35	1.77	23	6.69	1.66	17	0.02
	Central Australia (SA and NT)			Eastern Australia (QLD, NSW, ACT, Vic)			
“There is not enough support to help Aboriginal and TSI smokers that want to quit”	6.05	2.09	20	8.11	2.00	20	0.0003
“Tobacco use is considered a big health problem in Aboriginal and TSI communities”	7.32	2.11	20	9.22	0.88	20	0.0001
“Advice from me makes a difference amongst Aboriginal and TSI smokers”	4.55	1.93	20	5.71	1.45	20	0.05
	Respiratory Physicians and Advanced Trainees			Allied Health Professionals (e.g. Nurse, pharmacist)			
“Aboriginal and TSI people believe that second-hand smoke is harmful”	5.25	1.71	29	3.91	0.94	11	0.004
“Aboriginal and TSI people believe that smoking is bad for their health”	6.52	1.57	29	5.09	1.70	11	0.03
“The Aboriginal and TSI tobacco media campaigns (TV, posters, radio) don’t make any difference”	5.04	2.23	29	3.55	1.63	11	0.03
“Racism is still happening today in general health care”	7.32	2.16	29	8.91	1.22	11	0.007

All items were assessed on a 10-point Likert scale (1= strongly disagree and 10= strongly agree) with p-values calculated using a two-sample t-test assuming unequal variance.

Chapter 8.

Smoking cessation and tobacco prevention in Indigenous populations

Kristin V Carson^{1,2}, Harshani Jayasinghe^{1,2}, Brian J Smith^{1,2}, Jeffrey Newchurch¹, Malcolm P Brinn¹, Antony J Veale¹, Matthew J Peters³, Adrian J Esterman⁴, Kuljit Singh⁵ and the Thoracic Society of Australia and New Zealand Indigenous Lung Health Working Party

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Author contributions:

By signing the Statement of Authorship, each author certifies their stated contribution to the publication is accurate and that permission is granted for the publication to be included in the candidate's thesis.

Name of principal author (candidate)	Kristin Carson		
Contribution to the paper	Commissioned to write the review, researched the content, designed the protocol, designed the literature search, screened all retrieved literature, identified studies for inclusion, exclusion and as ongoing, extracted data for characteristics and risk of bias, performed all data entry, data analysis and interpretation of results, developed the summary tables for each sub-section, entered all data, wrote the first draft of the manuscript, contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, addressed editorial and peer reviewer comments, made critical revisions and approved final version.		
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Name of co-author	Harshani Jayasinghe		
Contribution to the paper	Researched the content, screened all retrieved literature, identified studies for inclusion, exclusion and as ongoing, extracted data for characteristics and risk of bias, performed data entry for Australian studies, contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, addressed editorial and peer reviewer comments, made critical revisions and approved final version.		
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Signature		Date	17/05/2015

Name of co-author	Members of the Thoracic Society of Australia and New Zealand Indigenous Lung Health Working Party (Kristin Carson signed on behalf of the working party as the Chairperson of this group)		
Contribution to the paper	Contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, addressed editorial and peer reviewer comments, made critical revisions and approved final version.		
Signature		Date	17/05/2015

This commissioned policy document by the Australian and New Zealand School of Government was supplemented with a \$10,000.00 grant to complete the investigation. It provides the first in depth systematic summary of all studies for tobacco cessation and prevention for Indigenous Australian populations in particular including searches of grey literature, pre/post studies and observational studies. Systematic appraisals of evidence in New Zealand, Canada and the United States of America are also provided, as successful strategies identified in the international literature might be extrapolated and tailored into the Indigenous Australian context.

Other than the present findings, the only evidence derived from national searches of existing Aboriginal and TSI research is through the Centre for Excellence in Indigenous Tobacco Control (CEITC) online repository (143), yet at the end of 2014 this was shut down due to a lack of resources available to support the initiative. Furthermore, the repository had only provided a summary of the existing studies individually and did not compare or extrapolate on the findings. Another limitation of current evidence to date is that other than individual published studies, there is no empirical evidence base upon which public policy decisions can be made.

Key findings from this study include the identification of several components of effective interventions, which build on the concepts raised in previous chapters of this thesis. In particular, a multifaceted approach that simultaneously addresses the behavioural, biochemical and psychological aspects of addiction are required rather than a singular approach of simply providing medication or referral to Quitline resources. Importantly, pharmacotherapy was effective among the included studies when used in combination with culturally tailored behavioural interventions and health professional support. Successful interventions were more likely to include greater treatment intensity and duration than unsuccessful programs, which often had lower intensity and shorter durations. No investigations were available to support the use of emerging and new therapeutic options such as electronic cigarettes and the use of social media, whilst little evidence was presented to evaluate the efficacy of pharmacotherapies such as varenicline tartrate or bupropion hydrochloride. The concluding recommendations from this policy document support that of previous chapters suggesting that the next phase investigation should centre on evidence translation and more methodologically rigorous research studies. This is necessary to identify less-successful components of current smoking cessation and tobacco abuse prevention programs so that they can be excluded from future initiatives.

Smoking cessation and tobacco prevention in Indigenous populations

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Abstract

This article systematically reviews 91 smoking cessation and tobacco prevention studies tailored for Indigenous populations around the world, with a particular focus on Aboriginal and Torres Strait Islander populations in Australia. We identified several components of effective interventions, including the use of multifaceted programs that simultaneously address the behavioural, psychological and biochemical aspects of addiction, using resources culturally tailored for the needs of individual Indigenous populations. Pharmacotherapy for smoking cessation was effective when combined with culturally tailored behavioural interventions and health professional support, though it is generally underused in clinical practice. From a policy perspective, interventions of greater intensity, with more components, were more likely to be effective than those of lower intensity and shorter duration. For any new policy it is important to consider community capacity building, development of knowledge, and sustainability of the policy beyond guided implementation. Future research should address how the intervention can be supported into standard practice, policy, or translation into the front-line of clinical care. Investigations are also required to determine the efficacy of emerging therapies (such as e-cigarettes and the use of social media to tackle youth smoking), and under-researched interventions that hold promise based on non-Indigenous studies, such as the use of Champix. We conclude that more methodologically rigorous investigations are required to determine components of the less-successful interventions to aid future policy, practice and research initiatives.

Tobacco prevalence among Indigenous populations is substantially higher compared to the corresponding non-Indigenous people across countries. Current estimates of tobacco use include 46–59 percent for First Nation and Canadian Inuits compared to 16 percent for non-Indigenous Canadians (Health Canada 2014; Propel Centre for Population Health Impact 2014), 39 percent in New Zealand Māoris compared to 15 percent (New Zealand Government 2013), 22 percent for American Indian and Alaska Natives compared to 18 percent (Centers for Disease Control and Prevention 2014) and 42 percent for Aboriginal and Torres Strait Islander (TSI) people compared to 16 percent (Australian Bureau of Statistics 2013, 2014b). These values also vary among population sub-groups. For example, in some remote Australian communities the tobacco prevalence estimate is as high as 83 percent (MacLaren et al. 2010). Smoking is also higher among Indigenous Australian pregnant women with up to 65 percent reported to be using tobacco (Carson et al. 2013) and children aged 15–24 years with 39 percent smoking daily (Australian Bureau of Statistics 2011). As a result, a significant disparity in morbidity and premature mortality between these two groups ensues, with Indigenous people bearing the higher burden. This disparity is often referred to as ‘the gap’ (Knibbs and Sly 2014; Russell 2013).

Population-wide interventions targeted at adult smokers (Cahill et al. 2013; Stead and Lancaster 2012) and young people (Brinn et al. 2010; Carson et al. 2011) are known to help smokers quit and prevent the uptake of tobacco use. However, these broad population-level standardised interventions appear to have had little impact on altering the tobacco prevalence *gap* between Indigenous and non-Indigenous. The most recent statistics from the Australian Aboriginal and TSI Health Survey found a decrease in daily smoking rates over the past decade for Aboriginal and TSI Australians, which was comparable to the decrease observed for the non-Indigenous. Results from these surveys, however, show that the gap between daily smoking rates has remained similar, with 27 percentage points in 2011 and 25 percentage points in 2012–13 (Australian Bureau of Statistics 2014a). Moreover, outcomes from some drug prevention programs aimed at youth suggest the possibility that an inappropriate match between program and participant characteristics may actually lead to an increase in the problem behaviour (Dixon et al. 2007). Culturally tailored interventions have shown some success for smoking cessation in adult Indigenous populations (Carson et al. 2012a) and among youth (Carson et al. 2012b), however, these reviews are limited due to a paucity of published data. Considering the ongoing disparities within this high-risk populace and the known benefits a reduction in tobacco prevalence would yield, systematic consolidation of interventions designed specifically for Indigenous people is warranted.

Aims and methods

The aim of this review is to evaluate the current literature for tobacco cessation and prevention interventions for Indigenous populations worldwide. This will allow identification of effective programs that can be translated into policy, in order to guide future cessation and prevention initiatives and research. It will also help to identify ineffective programs so that they can be altered or abandoned.

Study search strategy

We performed a systematic literature search of academic databases, comprising The Cochrane Library, EMBASE, MEDLINE, PsycINFO, and Science Citation Index, on 15 August 2014. We searched for trials of smoking cessation and prevention interventions. The following free text search terms were used to identify records relevant to the topic: (Aborig*

OR Indigenous* OR Inuit OR Maori OR Native American OR American Indian OR tribe* OR tribal) AND (tobacco OR smok*). No language restrictions were applied.

Online clinical trial registers were also searched for ongoing and recently completed studies: the meta-register of Controlled Clinical Trials (www.controlled-trials.com/mrct); ISRCTN Register International; Action Medical Research (UK); NIH ClinicalTrials.gov; The Wellcome Trust (UK); UK Trials; and government registries (www.clinicaltrials.gov). These sources were searched using the following search strategy (Aborig* OR Indig* OR Inuit OR Maori OR Native American OR American Indian OR tribe OR tribal) AND (tobacco OR smok*).

World Health Organization registries were searched (www.who.int/trialsearch/) using the following search strategy: (Indigenous OR Aboriginal OR Torres Strait Islander OR Inuit OR American Indian OR Native American OR Maori OR Tribe OR Tribal) AND (smoking or tobacco).

We conducted an additional search of grey literature that included contact with a tobacco representative from the Cancer Council from each state or territory within Australia to identify government reports meeting the inclusion criteria for this review. Reference lists of included published studies were also searched for identification of relevant studies.

Study inclusion criteria

Randomised controlled trials, controlled clinical trials, pre and post-studies, government reports, and consultation reports were included. Participants were people who are Indigenous to their country, being 'the experiences shared by a group of people who have inhabited a country for thousands of years, which often contrast with those of other groups of people who reside in the same country for a few hundred years' (Cunningham and Stanley 2003), and were youth who were yet to become regular smokers or youth and adults who were active smokers participating in a smoking cessation initiative. Trial participants were not required to be selected according to their susceptibility to quitting or suitability for particular interventions. No attempts were made to redefine Indigenous status for the purpose of including a study in this review. When meaningful data were found which referred to an Indigenous subpopulation in a larger study (minimum 20 percent of study population), they was assessed for inclusion in this review.

We included interventions in five categories:

1. Pharmacotherapies: nicotine replacement therapies, bupropion and varenicline tartrate.
2. Cognitive and behavioural therapies: cognitive and behavioural therapy, counselling, support groups, self-help, seminars, and motivational lectures.
3. Alternative therapies: acupuncture, hypnotherapy, and aversion therapy.
4. Public policy: legislative interventions, media campaigns, and community interventions.
5. Combination therapy: a combination of at least two therapies from the above four categories.

Analysis methods

From the title, abstract, or descriptors, two reviewers independently screened the retrieved citations to identify potentially relevant trials (KC and either HJ, MB or KS). All data were independently extracted by two reviewers into standardised data-extraction forms. All studies that did not meet the inclusion criteria for study design, population, or interventions were excluded. All outcome data were analysed using narrative synthesis. Risk of bias for each included study was assessed using the report by Tooth et al. (2005), in addition to standard Cochrane risk of bias grading criteria. We assessed biases using classifications of 'low risk of bias' when data for a criterion were reported, 'high risk of bias' when data were not reported,

and ‘unclear risk of bias’ when the criteria were not relevant to the study or not reported in the article. Review Manager Version 5.2 software was used to generate the risk of bias graphs.

What kind of research is available?

Four main types of research were available for assessment, including randomised controlled trials, controlled clinical trials, pre-post studies, and government reports. From the pre-specified search strategy a total of 1442 citations were retrieved: 1176 from the academic literature search, 206 from online clinical trial registries and 60 from screening bibliographies, contact with the Cancer Councils of Australia, and author contact. A total of 91 studies met all of the inclusion-exclusion criteria within the review. Twenty-five studies presented completed results for tobacco cessation interventions and nine for tobacco prevention in youth. Four protocols were identified for ongoing tobacco cessation studies, and the remaining 53 studies were government policy and community intervention programs across Australia.

Overall methodological assessment of the included studies

Methodological rigour among the 91 identified studies was limited due to several flaws in study design. In particular, a lack of randomised and non-randomised controlled study designs reduces the quality of the evidence supplied in pre-post studies and those government reports where intervention data are reported without a comparator population. Difficulties with recruitment were also observed where pre-specified sample sizes were not met and only small numbers of participants were recruited, generating concerns about the generalisability of the recruited sample compared to those who did not want to participate. Substantial attrition in final follow-up samples was also common, which gives rise to questions about the comprehensiveness and generalisability of the follow-up data reported (i.e. differences in the characteristics of those participants who withdrew from the study compared to those who continued through to follow-up). Between-study variability of interventions (by type and duration) and populations (by health and socio-economic demographics, cultural identity and practices and beliefs of the different Indigenous populations), can also impact on the applicability and generalisability of the results.

Moreover, considering that the included studies were conducted between 1987 and 2014, substantial variations will have occurred in practices, environment, population and policy during this time. Outcome measures used to define success also differ between studies in the following ways, all with differing levels of validity:

- the type of outcome used (e.g. continuous smoking abstinence, point prevalence, overall acceptability of the intervention);
- the time of follow-up (e.g. four weeks compared to 12 months);
- the people who collected the outcome data (e.g. Indigenous health workers, research assistants, doctors etc.); and
- how data collection was performed (e.g. face-to-face, self-reported, biological validation of findings, online assessment etc.).

There is also a distinct difference between statistical significance and practical (or clinical) significance. Statistical significance cannot be achieved when there is no comparator group for the cohort receiving the intervention (either via a distinct control population or change from baseline assessments etc.) and is unlikely to be achieved when there is insufficient

power to detect an effect for the intervention (due to the small sample size). For the majority of studies, examining the practical significance of an intervention where authors report a benefit for participants through qualitative assessments (text summaries of ‘good’ or ‘bad’ findings) needs to be taken into account. However, there are also complications when considering information produced from these types of assessments, as there is no way to confirm validity or generalisability of the findings. Authors can also provide an overall comment that is not comprehensive and only reflects one aspect of the study, giving the reader a skewed perception of the intervention’s effectiveness. There is also the potential for selective reporting of results where negative findings are not reported.

We begin by reviewing the major policy developments in Australia, New Zealand, and comparable countries, and the evidence about their respective effectiveness. We then move on to discuss specific themes that arise.

Major policy developments among countries

Nationwide, Australia has implemented many successful tobacco control policies, including tax increases on tobacco products; smoking bans in public places; plain packaging legislation; tougher restrictions on tobacco sales to minors; subsidised nicotine replacement therapy; enhanced regulatory bodies for tobacco content; media campaigns; and many other policies that have shown efficacy in reducing tobacco prevalence on a national level (Australian Government Preventive Health Taskforce 2009).

Although tobacco taxation is believed to be an essential component of these comprehensive tobacco control strategies, there is a lack of evidence about the impact of increasing tobacco cigarette prices on smoking behaviour in heavy/long-term smokers and Aboriginal people (Bader et al. 2011). Evaluations of the impact and perceptions of tax increases in remote Aboriginal Australian communities found wide confidence intervals around the estimated reduction in consumption (2.2% average reduction; 95% *ci* –5 to 10), indicating that the tax increase could have either been associated or *not* associated with a reduction in consumption of tobacco products (Thomas et al. 2013). Although future excise rises are supported, they need to be carefully monitored in the Indigenous context (Thomas et al. 2013). Tax increases on tobacco products are known to be highly effective in reducing smoking among youth, young adults and people of low socio-economic status (Bader et al. 2011).

Since 2008 the Australian Government has funded the ‘Tackling Indigenous Smoking’ measure under the Council of Australian Governments (COAG) National Partnership Agreement on Closing the Gap in Indigenous Health Outcomes (Australian Indigenous Healthinfonet 2012). Under this initiative a regional tobacco coordinator and tobacco action workers are employed and trained in quit smoking measures across all states and territories. This has occurred in conjunction with national media campaign ‘Break the Chain’ (Australian Government 2013), which was found to be a success and resonated well with the target audience. The key messages about ‘Breaking the Chain’ and the harms of tobacco use were reported to have been conveyed and well received, by encouraging Indigenous tobacco users to decrease their smoking while encouraging recent quitters to refrain from re-starting the habit.

In 2014 the Australian government announced funding cuts of \$130 million over five years to the Indigenous Tackling Smoking budget, which is essentially more than a third of the program’s annual funding (Dingle 2014). Indigenous leader Dr Tom Calma, who is the inaugural National Coordinator for the Tackling Indigenous Smoking campaign, has warned that cuts to the program will contribute to the early deaths of Aboriginal smokers (Dingle

2014). Cuts to the Indigenous Tackling Smoking programs are said to occur by not replacing people who are currently employed in various programs once they resign (Speaker Mclucas 2014), leaving questions over the nation's ability to successfully reduce smoking rates within the timeline originally outlined in COAG (Dingle 2014).

The team had to be fully funded, had to be functional, and so the chances of reaching that 2018 target is near impossible now. The logic is that a reduction in information will mean that there will be people who don't receive that information to make an informed choice, and that will contribute to their early demise.

However, substantial amounts of resources and programs have already been developed with community consultation and involvement as part of the COAG funding stream, as reported in Table 2 of this review. Considerable inroads have already occurred for culturally tailored tobacco cessation and prevention programs that have the potential to reduce the tobacco prevalence gap among Indigenous Australian populations. Therefore it is important that the next line of community initiatives and research programs consider the work already undertaken and determine the optimal approach in translating this existing work into the frontline of clinical practice and public policy across Australia. It may also be also pertinent for future programs to consider 'disadvantaged populations' as a whole rather than just focusing on Indigenous people (Gould et al. 2012). This may help to reduce the perception of being specifically targeted with a need for intervention and address a broader 'language of disadvantage' regardless of ethnicity, while also optimising cost effectiveness (Paul et al. 2013).

New Zealand has pioneered many tobacco control measures since the release of their first National Drug Policy, including banning smoking from enclosed workplaces, subsidised nicotine replacement therapy, tax increases on tobacco products, and plain packaging of cigarettes (Trainor and Cancer Control Council of New Zealand 2011). However, there has been some difficulty reported with implementation failures in the use of two New Zealand laws to control the tobacco industry (Thomson and Wilson 2005). Two case studies have identified four occasions over a 14 year period where New Zealand agencies did not enforce consumer protection law, although breaches by the tobacco industry did occur in relation to statements on the relative safety of second-hand smoke. The second case study presents the tobacco industry's failure to provide information on tobacco additives, with the government inadequately enforcing the law and undertaking appropriate political processes for a period of 13 years (Thomson and Wilson 2005). In both instances the financial and opportunity costs of taking legal action, political difficulties, and the fragmented nature of government structures were believed to be responsible for the breaches. In 2011, the New Zealand government publicly adopted the smoke-free 2025 goal, following a landmark Parliamentary enquiry by the Māori Affairs committee. Under this strategy the government has set the long-term goal of reducing smoking prevalence and tobacco availability to minimal levels, essentially resulting in New Zealand becoming a smoke-free nation by 2025 (Ministry of Health 2014). There have also been calls to completely ban cigarettes within 10 years, with one national New Zealand survey between 2007 and 2009 finding that 46 percent of the survey population ($n = 2,299$) supported complete banning, suggesting that most smokers will support stronger government action to control the tobacco industry (Edwards et al. 2013).

In the USA, 2009 legislation providing the United States Food and Drug Administration authority to regulate tobacco products and tobacco advertising has also helped to curtail much of the advertising toward youth (CDC and US Department of Health and Human Services 2012). However, a 2012 report by the Surgeon General has found that for the first time following the Tobacco Masters Settlement Agreement in 1998, the declines observed in youth cigarette smoking have now stalled, and smokeless tobacco use among youth is on the rise. Importantly, the latest research shows that concurrent use of multiple tobacco products is

common among youth, with smokeless tobacco use becoming more popular (CDC and US Department of Health and Human Services 2012). A 2014 report released by the Surgeon General has revealed that the percentage of US middle and high school students that are using electronic cigarettes has more than doubled between 2011 and 2012. Considering the lack of formal regulation and safety concerns around these products, investigations into the use of electronic cigarettes are urgently needed (CDC and US Department of Health and Human Services 2014).

These tobacco prevalence estimates and increase in multiple tobacco product usage are of great concern, particularly considering that none of the five randomised controlled trials evaluating tobacco prevention programs among Indigenous youth in the US showed statistically significant benefits in favour of the intervention at final follow-up, when compared to the control population. Davis et al. (1995) found a statistically significant reduction in smoking in favour of the intervention for boys ($p = 0.02$) and Pueblo students ($p < 0.01$), but not girls or Navajo students.

A number of policy tools have been effectively implemented for tobacco control among Indigenous populations, though these are not mandatory or enforced on a national level. Taxation is currently an underused tool in the US, as access to cheaper cigarettes on Indian reservations is associated with higher tobacco use rates, particularly among youth (Satter et al. 2012). Community control and restrictions of sales do not routinely occur, with active enforcement of tobacco sales-laws and restricting self-service outlets in areas accessible to youth (for example vending machines and counter-top cigarette displays in stores) not standard across Indian reservations. Likewise, smoking bans and restrictions in public places, control of tobacco industry advertising and tobacco education and cessation treatment strategies are not standardised across the US (Satter et al. 2012).

Successes in tobacco control have more than halved smoking prevalence rates since the first Surgeon General's Report released in 1964. Indeed the collective view of smoking has since been transformed from an accepted national pastime to a discouraged threat to individual and public health. The 2009 Family Smoking Prevention and Tobacco Control Act has allowed the government greater authority over tobacco product regulation, and the provision of user fees to be paid by tobacco manufacturers that can support sustained public education media campaigns designed for youth prevention and cessation. Moreover, the 2010 Affordable Care Act has supported initiatives and effective community-based programs and public education campaigns promoting prevention and helping people to quit, as well as expanding access to smoking cessation services with requirements for the majority of insurance companies to cover cessation treatments (CDC and US Department of Health and Human Services 2014).

The Canadian government has implemented several policies in attempts to reduce the tobacco burden, including raising the price of tobacco; complete prohibition on sales of tobacco in certain places; stringent legislation around manufacturing; policies for smoke-free public places and transport; preventing sales to minors; and treatment of people with addictions (Orisatoki 2013). However, some difficulty has been reported in implementing these policy initiatives, with some First Nations feeling that non-Aboriginal governments do not have the right to dictate private behaviours, and therefore ordinary community members are unlikely to accept such regulations (Orisatoki 2013). However, some places within Canada have enforced certain legislation, including Smoke-Free Ontario in 2006, which prohibited smoking in workplaces, enclosed public spaces, and motor vehicles when a minor under the age of 16 is present; banned the public display of tobacco products; and prohibited youth-targeted products such as flavoured cigarillos (Ontario Ministry of Health and Long-Term Care 2011). This action has reportedly greatly reduced tobacco use and lowered health risks to non-smokers in Ontario (Ontario Ministry of Health and Long-Term Care 2011).

Major policy issues from the evidence base

Looking at the overall evidence base for tobacco cessation, the 25 completed tobacco cessation studies were published between 1997 and 2014, with a total of 9254 participants. Eight were conducted in the American Indian and/or Alaska Native populations, eight in New Zealand Māori peoples, eight in Aboriginal and/or Torres Strait Islander Australians, and one in an Aboriginal Canadian population. Ten were randomised controlled trials, five were controlled clinical trials, and the remaining ten were pre and post-studies. Table 1 provides a summary of the characteristics of each study and results for the 25 completed tobacco cessation trials.

Of the 15 randomised and non-randomised controlled trials only two reported statistically significant reductions in tobacco rates at final follow-up compared to the control population (Holt et al. 2005; Walker et al. 2012). Holt et al. (2005) conducted the only controlled trial that examined the efficacy of the smoking cessation pharmacotherapy bupropion hydrochloride (Zyban). They conclude that an eight week course of bupropion, supplemented with counselling, is an effective smoking cessation treatment in the Māori population. The smoking participants in this study were self-selected highly motivated subjects, limiting the generalisability of the findings to a non-motivated cohort. However, authors highlight that motivated smokers may be the preferable target population for pharmacological interventions. Walker et al. (2012) only included a 25 percent subpopulation of Māori subjects, with results not reported separately for the Māori participants. Thus, the true effect on the Indigenous population in this study evaluating very low nicotine content cigarettes as an adjunct to Quitline counselling is not known. Similar to the successful Holt et al. study, authors of this trial recognise that the study population of Quitline callers were highly motivated and more ready to quit in comparison to the standard population of tobacco users.

Overall, methodological quality was determined to be reasonable for the 25 completed tobacco cessation studies, as per the detailed risk of bias assessment shown in Figure 1. A summary risk of bias assessment presented as a percentage across each bias category is shown in Figure 2.

Quit rates at final follow-up for the remaining ten pre and post-studies ranged from 0 percent (Patten et al. 2010) to 30 percent (Gould et al. 2009). Patten et al. (2010) employed a small sample of 35 subjects, while Gould et al. (2009) used a total sample of only 15 as a pilot to an ongoing trial called 'Give up the smokes'.

The overall mean quit rate at final follow-up for the intervention arm of the 25 tobacco cessation studies was 18.29 percent (excluding the Grigg et al. 2008 and Hearn et al. 2011 studies, which did not report quit rates). Final follow-up ranging from three months to 12 months (average final follow-up occurred at six months). The intervention resulted in reduced levels of smoking at follow-up in 12 of the 15 controlled trials, with the control population producing better smoking abstinence results in three studies (Maddison et al. 2014; Patten et al. 2010; Whittaker et al. 2011). Interestingly, these three studies were all conducted between 2010 and 2014, two of which only included sub-populations of Māori tobacco users in a larger cohort of New Zealand subjects, while the third study included a sample size of only 35 as part of a feasibility study (Patten et al. 2010). Authors of the latter study report that the low enrolment rate reflects that the program was not feasible or acceptable by the study population of Alaska Native pregnant women. Both intervention and control arms of this study included brief face-to-face counselling at the first antenatal visit, with provision of written materials. The intervention group also received four telephone calls, a video highlighting personal stories, and a cessation guide.

Australian community intervention programs

An additional 53 Australian government policy and community intervention programs were identified. Eight focused on youth, of which two looked specifically at tobacco prevention (Kickett 2009; Yarran 2010), with the remaining six examining smoking cessation and prevention among youth (Day 2007; Johnston et al. 2013; Minniecon 2005; Ryan 2010; Shah et al. 2013; Tasmanian Aboriginal Centre Inc. 2012, 2014). A total of 27 studies focused just on adults, and the remaining 18 studies included both adults and youth. Twenty-three studies in total examined both prevention and cessation intervention outcomes, 28 just examined cessation, and as mentioned above, two focused only on tobacco prevention. Five studies were specifically tailored for Indigenous pregnant women (Chamberlain 2008; Murphy 2009; Passey 2009; Passey et al. 2009; Quit SA 2011; Rumbalara Aboriginal Co-Operative 2012). One study, 'Break the Chain', was a nation-wide media campaign targeting recent quitters between 16 and 40 years of age, which commenced in 2011 and is ongoing. Eight studies were conducted in the Northern Territory, five in Queensland, 12 in New South Wales, one in the Australian Capital Territory, three in Victoria, two in Tasmania, nine in South Australia and 11 in Western Australia. Thirty-seven of the 53 projects were reported to be complete, yet only 26 provided published results, with the eleven outstanding studies found to have no published results available despite the reported completion.

Characteristics and findings for these 53 studies are reported in Table 2. In summary, primary intervention components included 35 studies using the media; 33 incorporating some form of counselling; 32 involving health care workers or health services; 16 including pharmacotherapy (all using NRT, and one (Lynch 2005) also using varenicline tartrate and bupropion hydrochloride); 15 including Elder and/or peer role models; 10 using school-based intervention delivery methods; five incorporating government and community policies; while four studies examined only qualitative techniques. Of the 26 completed studies with published results, two showed no evidence of any effect, six examined only qualitative outcome variables, and the remaining 18 provided some descriptions relating to successful intervention delivery mechanisms or overall satisfaction with the intervention from participants. However, only one of these 18 studies provided quantitative data on smoking cessation outcomes (Lynch 2005). Lynch (2005) produced 444 quit attempts by 328 people, 24 percent of which were reported to be ex-smokers for a minimum of six months, with an intervention that incorporated community programs, trained health professional assistance with one-on-one monitoring, provision of pharmacotherapies including NRT, varenicline tartrate and bupropion hydrochloride, and 'healthy start' programs with a maternal infant health focus and school 'keeping well' program, in addition to provision of information at correctional facilities. This was the only Australian government and community study identified that examined a smoking cessation pharmacotherapy other than NRT.

A study by Heydari et al (2014) that reviewed smoking cessation tools in the general population from the years 2000-2012 indicated that NRT, varenicline tartrate, and education training for quit attempts were the most commonly advised cessation aids, while electronic cigarettes and non-nicotine based medicines were the least advised methods (Heydari 2014). The most common forms of NRT used among Aboriginal Australian populations are patches, gum and lozenges, while other smoking cessation pharmacotherapies such as varenicline tartrate and bupropion hydrochloride, though known to be more effective in the general population (Carson et al. 2013), are often underused and under-prescribed in the Indigenous setting.

Four ongoing tobacco cessation studies were identified with protocols published between 2011 and 2014, three being randomised controlled trials and one a pre-post study. The characteristics of the four cessation studies are reported in Table 3.

Tobacco cessation studies among pregnant women

Women who smoke during pregnancy can have complications with premature delivery, and can potentially have babies with complications such as low birth weight, Sudden Infant Death Syndrome (SIDS) and respiratory conditions such as asthma (Li et al. 2013). Furthermore, children born to mothers who smoke during pregnancy have an increased risk of developing Type 2 diabetes and coronary heart disease, and being obese later in life. Although almost all these women know that smoking during pregnancy is not good for their baby, it can be hard to break an addictive lifetime habit, especially if everyone around them continues to smoke (Passey et al. 2013). Among Indigenous pregnant women these concerns are amplified due to the increased prevalence of tobacco use in this population, and the high incidence of negative health outcomes on the mother and baby that already occur due to compounding environmental, social, familial and other factors. Only two of the 25 completed cessation trials were designed for pregnant women (Eades et al. 2012; Patten et al. 2010). Five additional studies were identified among Australian government policy initiatives and community projects, though two of these were ongoing (Passey 2009; Passey et al. 2009; Rumbalara Aboriginal Co-Operative 2012), and the remaining three studies showed some positive effects related to the intervention, though no quantitative smoking abstinence data were provided (Chamberlain 2008; Murphy 2009; Quit SA 2011).

Neither of the two completed cessation trials produced results in favour of the pregnancy tobacco cessation program. Indeed Eades et al. (2012) found no statistically significant difference between intervention smoking rates (11 percent) compared to the control population smoking rates (5 percent) at final follow-up. Patten et al. (2010) had a small sample size ($n=35$) and favoured the control population, with 6 percent of control subjects and 0 percent of intervention subjects reporting abstinence at final follow-up.

Thus, there is a paucity of successful smoking cessation options identified from this review for pregnant women, though the use of counselling and support services are recommended, and reports by some expert committees as per the Australian General Practice smoking cessation guidelines do recommend the use of NRT in certain circumstances (Australian Government Department of Health and Ageing 2004). Long-term abstinence post-partum remains an issue, particularly among Indigenous women, that needs greater attention. Passey et al. (2013) explored the views of Indigenous Australian pregnant women and antenatal care providers, finding that both current smokers and providers thought that the most effective strategy was 'involving family'. Other programs have also found that smoking interventions targeting Indigenous Australians should incorporate family-based components because of the importance and closeness of family ties in Aboriginal populations (Gould et al. 2014; Gould et al. 2013; Johnston and Thomas 2008).

Another strategy that also ranked highly in the Passey et al. (2013) study was the role of 'health professionals'. Many studies have highlighted that advice and support from doctors, nurses and health staff plays a role in aiding and supporting quit attempts. However, speaking to pregnant women about their smoking can sometimes be considered a difficult subject, and one that some health professionals and Aboriginal Health Workers avoid completely. Evaluations indicate that they avoid the topic as they do not want to judge the pregnant woman, fear that they may put extra stress on the woman during pregnancy, and fear that women may not return for follow-up appointments if they have not managed to quit between visits (Passey et al. 2013). However, Passey et al. (2013) found that women believed support from health professionals was likely to be helpful, and was perceived to be effective at aiding quit attempts. A better understanding is needed of the behaviours, attitudes and knowledge of Indigenous pregnant women who are smokers, ex-smokers and non-smokers, as well as those of health professionals who treat these women. Qualitative investigations to date suggest that anti-tobacco messages need to relate to and be tailored to Indigenous women's experiences,

with a focus on quitting processes and support efficacy (including individual, group and family involvement), and should capitalise on the positive changes occurring (Gould et al. 2013; Gould et al. 2012).

Evidence base for tobacco prevention in youth

We identified nine completed studies that evaluate tobacco prevention programs in Indigenous youth, published between 1987 and 2011, with a total of 10,498 subjects. Six were randomised controlled trials – five from the United States of America (USA) and one from Canada – with two controlled clinical trials from New Zealand and one from Australia, and the remaining pre-post study coming from Canada. All nine studies used school forums for message delivery, and three also included wider multi-component community-based initiatives, including mass media campaigns. Follow-up time periods ranged from six months to five years after baseline data collection, with intermediate data collection also occurring in three studies. The characteristics and findings from these studies are summarised in Table 4.

Overall, methodological quality was determined to be reasonable, though a detailed risk of bias assessment for each included and completed tobacco prevention study is available in Figure 3, with a summary as a percentage across each bias category presented in Figure 4.

At final follow-up, five of the controlled studies produced no statistically significant changes between intervention and control groups. One additional study had a sample size too small to allow direct comparison (Mckennitt and Currie 2012), and another was a pre-post study (Baydala et al. 2009), which showed improved post-test responses for the majority of participant questionnaires. For the remaining two studies, one found a benefit for the intervention in two sub-populations, but not for the sample as a whole (Davis et al. 1995) and another study produced results in favour of the control (Glover et al. 2009). For the Davis et al. (1995) trial a statistically significant reduction in smoking in favour of the intervention was observed for boys ($p = 0.02$) and Pueblo students ($p < 0.01$), but not girls or Navajo students. However, for the other Davis trial (Davis and Cunningham-Sabo 1999), a (non-statistically significant) trend was observed in favour of the control, with 38 percent of subjects in the intervention arm reporting tobacco use compared to 25 percent in the control. Intervention subjects were also more likely to report smoking within 24 hours of each test and smoking prior to the post-test for those who had self-reported as non-smokers at baseline. Positive changes in tobacco use were found at post-test ($p < 0.05$; change score of -0.15 for intervention and -0.01 for control) for the Gilchrest et al. (1987) study, however, these were not maintained at six months follow-up (change score of -0.11 for intervention and 0.07 for control). Although no statistically significant differences were observed between intervention and control groups at follow-up for the Glover et.al. (2009) study (OR 1.30; 95% *ci* 0.24–7.08), Māori (OR 4.60; 95% *ci* 3.24–6.52) and Pacific Islander (OR 2.75; 95% *ci* 1.92–3.82) students were more likely to initiate smoking by follow-up compared to other ethnicities. In the matched cohort (never-smokers at baseline that completed both pre and post-intervention assessments) a statistically significant difference was observed in favour of the control group, with 21 percent of intervention subjects trying tobacco use compared to 14 percent in the control group ($p < 0.001$), however, these results were not adjusted for baseline differences and need to be interpreted with caution.

Some discussion is warranted highlighting possible explanations for the studies producing outcomes in favour of the control. Tobacco prevention initiatives for youth generally target audiences between the ages of 12 and 18 years, however the age of onset for tobacco use among Indigenous youth is often earlier (Australian Institute of Health and Welfare 2002; First Nations Center 2005). As such, perhaps younger cohorts need to be considered for intervention delivery. Tailoring interventions to the specific population is also important, as findings from some studies have indicated limited generalisability of culturally grounded

drug prevention programs for certain youth ethnic groups, with the possibility that an inappropriate match between the initiative and the participant characteristics may actually lead to an *increase* in the problem behaviour (Dixon et al. 2007). Such characteristics could include age, gender, and lack of consideration around traditional smoking. Likewise the approach of some initiatives could be encouraging young people to smoke through acts of rebellion, especially if community role models, siblings and/or peers continue to smoke as part of the community 'norm' (Scragg and Laugesen 2007). For these reasons, future initiatives need to incorporate secondary outcome measures related to attitudes, perceptions and intentions around the individual's tobacco use, and perceptions around peer or sibling tobacco use.

Evidence from other meta-analyses suggest that underpinning a smoking prevention initiative with an established research theorem that addresses social and cognitive influences of tobacco use may influence the uptake of smoking by youth (Brinn et al. 2010; Carson et al. 2011). A recent Cochrane review assessing interventions for tobacco use prevention for Indigenous youth has presented similar data with inconclusive findings, however due to the strict inclusion criteria for Cochrane meta-analyses, only two of the nine studies we identified for this review were assessed (Carson et al. 2012b). Although this review, like the Cochrane review, highlights the limited evidence to support tailored tobacco prevention initiatives for Indigenous populations, there is encouraging evidence supporting tailored interventions for smoking cessation in Indigenous settings (Carson et al. 2012a; Elton-Marshall et al. 2011). For this reason, well-conducted and culturally tailored tobacco prevention interventions should not be discounted just yet, as a lack of methodological rigour may be partly responsible for our inconclusive findings. Consideration should be given to evaluations within Indigenous populations prior to intervention delivery. These will assist researchers and policy makers alike to identify potential programs and components of programs that are most likely to be effective. They will also allow identification of cultural implications for tobacco use, which need to be incorporated into any initiative (Taulii et al. 2010). No ongoing studies were identified for tobacco prevention for Indigenous youth.

Discussion

This review of 91 studies has identified culturally tailored Indigenous tobacco cessation and prevention studies from across four countries and thus a diverse range of Indigenous peoples. An intervention that may work well in one country will not always be transferable into another. This is due to differences in the origin of tobacco use within each population, cultural significance surrounding tobacco use, access to products, local policies, traditions, and other factors (Carson et al. 2012a). However, it may still be possible from a policy and practice perspective to extrapolate results from one setting into another, providing they have been appropriately adapted to the target population. Definition of success for the intervention varied substantially between studies. In those where a clear research study design was implemented, such as a randomised controlled trial or a pre-post study, efficacy of the intervention was clearer. However, in studies where no comparator group is reported, sample sizes are not provided, and there is no mention of any clear quantitative or qualitative outcomes related to the cessation or prevention of tobacco, it is difficult to draw any reliable conclusions.

From the available evidence as reported in the tables, we can determine some of the elements from successful interventions that can inform policy and program design. These include:

- multi-faceted interventions that take into account various aspects of tobacco use at once such as biochemical addiction, habit, cultural reasons for smoking and stressors, and psychological reasons for smoking;
- interventions carried out among people who are already highly motivated to quit smoking, such as those with acute illnesses, who have family members with tobacco-related illnesses, or who want to quit for their children;
- use of pharmacotherapy, particularly Champix (varenicline tartrate), Zyban (bupropion hydrochloride), and nicotine patches;
- use of incentives (e.g. Quit and Win competitions);
- programs that train health professionals in smoking cessation and motivational interviewing techniques;
- behavioural support services that take into account cultural practices, traditions and language; and
- interventions involving health professionals in addition to community.

It is more difficult to confidently say that a program is ‘not effective’ and unsuccessful, as opposed to there being ‘no evidence of any effect’. Indeed, in many cases the sample sizes are too small and/or attrition too great to confidently confirm that the results of the study are a true indication of what would happen in the real-world population. Thus, defining aspects of programs that are ineffective is not possible due to the unreliability of the existing sample pool. Other barriers to accurate reporting of results are selective recruitment of participants, lack of methodological rigour in study design, follow-up, outcome measures, method of data collection, duration of the intervention, and who the intervention is delivered by.

Emphasising that some of these studies produced results in favour of the control population is important, and highlights the fact that not every intervention is a good intervention. Consideration needs to be given to attitudes, perceptions and motivations within populations and among individuals who are continuing to smoke or intending to smoke, as in some cases it may be better to not intervene at all than risk a negative community-wide response. In light of this, future studies need to consider not only the number needed to treat, but also the number needed to harm.

Emerging issues in tobacco prevention

Electronic cigarettes

None of the 91 identified studies, completed or ongoing, evaluated interventions using electronic cigarettes (e-cigarettes). E-cigarettes, first introduced in China approximately 10 years ago (Kelly and Asal 2014), are devices that mimic certain components of a real cigarette. They are battery operated and allow users to inhale vapour comprised of substances that include nicotine, propylene glycol, and other flavours (Gallus et al. 2014; Kelly and Asal 2014). They have been marketed as a smoking cessation tool or as an alternative ‘safer’ form of smoking for those who are not able to quit. People and organisations supporting their use say that the device reinforces smoking behaviours, while being a safer alternative to traditional smoking. Many of the chemical products contained within cigarettes, and the by-products that are released from tobacco burning, are the primary factors contributing to respiratory and other health problems. These are not present with e-cigarettes. However, there has been very little research surrounding the use of these devices to facilitate smoking cessation, with some studies reporting that they can cause symptoms such as nausea, headaches, coughing, and throat and lung irritations (Gallus et al. 2014). Neither the World Health Organization nor the Food and Drug Authority have approved the use of e-cigarettes,

and both have warned that they should be approached with caution as there have not been enough clinically based studies analysing the vapour within the device or safety following long-term exposure. The emerging popularity of these devices in mainstream culture, particularly in the USA, makes e-cigarettes a potential smoking cessation tool worthy of further investigation in Indigenous and mainstream settings (Bullen et al. 2010).

Training health professionals in smoking cessation and tobacco prevention

Smokers rarely plan quit attempts (Larabie 2005), though according to the most recent National Aboriginal and TSI Social Survey, nearly two-thirds of current daily smokers had indeed tried to quit or reduce smoking in the 12 months prior to interview, with general health concerns being the primary reason (Australian Bureau of Statistics 2011). Collaborating with health services provides an opportunistic and unique environment in which to deliver smoking cessation programs, as health professionals consult countless people each year and are perceived to be influential sources of information for smoking cessation (Zwar et al. 2009). Reviews and meta-analyses have consistently shown that individual counselling from smoking cessation specialists increase the chances of successful abstinence compared to less intensive support (Carson et al. 2012c; Fiore et al. 2008; Lancaster and Stead 2008). Indeed even training of short duration (a one-off session of 2–3 hours) can have substantial implications for quit attempts among patients of health professionals long-term (Carson et al. 2012c).

However, one Australian study conducted in urban Aboriginal medical services failed due to clinic, patient, Aboriginal health worker and GP factors that interacted with the study design and ultimately resulted in the inability to implement the trial as planned (Sibthorpe et al. 2002). Moreover, many of the healthcare workers and some doctors on the frontline are reporting that they do not believe they have the skills or ability to offer smoking cessation/prevention initiatives to patients. Perhaps more importantly, some admit to the attitude of ‘even if I did, it’s not going to work so why bother’ (Carson et al. 2013b; Carson et al. 2012c). The research base from this review has demonstrated that early collaboration and engagement with Indigenous community members is imperative to successful implementation of initiatives and programs within communities (Carson et al. 2012a; Sibthorpe et al. 2002). Indeed, a review of tobacco use and misuse among Aboriginals in Canada identified that health professionals play a critical role in reducing tobacco use through health intervention programs (Orisatoki 2013). For Aboriginal health professionals in particular, the likelihood of engagement with Aboriginal patients is increased compared to non-Aboriginal health professionals. Moreover, Aboriginal healthcare professionals are often viewed as role models within these communities (Orisatoki 2013). Given this evidence, health professionals should be considered as an opportunistic vehicle to deliver sustainable and culturally-adapted tobacco strategies.

Conclusions

Although we are seeing reductions in smoking rates across Australia (Australian Institute of Health and Welfare 2014) and other countries (Health Canada 2014; New Zealand Government 2013), for many these changes are not coming fast enough. This review of 91 studies found some evidence to support the use of culturally-tailored smoking cessation and tobacco prevention interventions among Indigenous populations. Based on the evidence produced we can confidently say that multi-faceted interventions that take into account various aspects of tobacco use at once such as biochemical addiction, habit, cultural reasons for smoking, and stressors and psychological reasons for smoking, are effective. Another key

characteristic of the successful programs includes recruitment of sample populations that are already highly motivated to quit smoking. Therefore these interventions act more as a support mechanism than a tool to change an individual's attitude from one of pre-contemplation to action. Research and clinical practice evaluations are needed that examine strategies and interventions to aid this transition, so that appropriate community-wide policies and programs can be implemented. We know from epidemiological studies that pharmacotherapy is currently underused in the Indigenous context, despite successful quit attempts observed among studies using smoking cessation medications identified in this review. Use of Champix (varenicline tartrate), Zyban (bupropion hydrochloride), and nicotine patches in particular, have produced statistically and clinically significant benefits in long-term smoking cessation among Indigenous participants. Incentive schemes such as Quit and Win competitions, programs that train health professionals in smoking cessation and motivational interviewing techniques and those including behavioural support services that take into account cultural practices, traditions and language, are also components identified in the successful interventions.

Identifying characteristics of the unsuccessful programs is more difficult, as there is a distinct difference between an intervention not being effective and one which shows no evidence of any effect. Indeed in many cases the sample sizes are too small and/or attrition too great to confidently confirm that an intervention will not work. However, programs that have a longer intervention duration, with greater intervention intensity and more multi-faceted components were more likely to be successful than those of shorter duration and with fewer components (e.g. intervention included medication, culturally-tailored written resources, smoking-bans at community events, counselling with health worker, community-wide program and incentive scheme).

It is also important to note that alongside these studies there are always other tobacco prevention and smoking cessation initiatives that are occurring simultaneously and are not being reported by study authors, which is likely to have an impact on the success of an intervention. As per the discussion above relating to existing major policy developments, some countries will have policies that are enforced throughout the entire nation, whilst other countries do not employ that policy at all, or it is only enforced throughout certain regions. For example, in Australia and New Zealand taxes on cigarette sales are enforced across the entire country, whilst in the USA cigarette taxes are not enforced on Indian reservations. These existing policy differences will have an impact on the generalisability of the findings between countries and even between communities within a country. Another factor to consider is to note when nation-wide policy changes were implemented, and determine whether any occurred during the evaluation of one of the included studies. This is particularly relevant for those studies that do not have a control or comparator group, as any changes observed will relate to all smoking cessation and tobacco prevention initiatives that are occurring at a population level, *as well as* the study intervention level. This compounding of intervention factors means that the true effect of any given intervention program may be overestimated in some cases due to the implementation of plain packaging of cigarettes, increased tax on tobacco, or another policy initiative occurring during the course of the study evaluation period.

Studies that investigate programs tailored for pregnant women are also required. This is a high risk population where interventions are sometimes viewed as being controversial due to the fear of placing extra stress on the pregnant woman. Among Indigenous pregnant women this concern is amplified by the increased prevalence of tobacco use and the high incidence of stress and negative health outcomes already occurring on mothers and babies in this population. However, the benefits of smoking cessation on the health of the mother and baby cannot be overstated. Several studies have examined the role of counselling and group

support in addition to NRT products for cessation, with good short-term results for the duration of the pregnancy. A pragmatic guide for smoking cessation counselling and NRT use specifically among Aboriginal and TSI Australian smokers (Gould et al. 2014) recommended include the use of NRT in pregnancy, which experts believe to be safer than continued smoking. Although an initial quit attempt without pharmacotherapy is suggested, women should be offered an accelerated course of NRT within a few days of continued smoking after the initial quit attempt. This includes oral forms and then the use of patches or combined oral and patch therapy, which should be continued for a minimum of 12 weeks and provided post-partum (Gould et al. 2014). Long-term cessation, however, is not often sustained and further research is required to help new mothers to remain smoke-free. Health professionals, Aboriginal Health Workers, and Aboriginal Education Officers play a significant role in addressing the role of smoking in pregnant Aboriginal women. Adequate and effective training needs to be a priority so that professionals feel that they have the right set of skills and confidence to aid tobacco cessation among this cohort.

Training health professionals who see Indigenous patients in general smoking cessation techniques is one promising area that requires more investigation. The benefit of conducting an investigation in this setting is that implementation of the intervention will simultaneously build community capacity by training health professionals in skills and providing them with knowledge that will be sustainable beyond the life of the project. These are important factors to consider when performing research in the Indigenous context and developing appropriate policy responses.

Future programs need to consider the role of social media in tobacco prevention and cessation interventions, particularly considering that tobacco companies are already using these resources for their own advertising purposes. E-cigarettes are also an area of emerging popularity, despite the lack of evidence about their efficacy. The concern is that young people in particular are being actively marketed to by the tobacco companies who own these products, particularly with the production of flavoured e-cigarettes. The general public perception being encouraged by tobacco companies is that e-cigarettes are the 'safe' alternative to cigarettes, but without methodologically rigorous clinical investigations to support these claims, this cannot be verified and thus cannot be recommended as an effective cessation aid or alternative for smoking cigarettes.

Preventing youth from starting smoking remains the most effective strategy in controlling the tobacco epidemic. Moreover, considering that only one completed study was identified on tobacco prevention in Australia, action is required in this area. Future programs need to consider the appropriateness of these tobacco prevention programs and tailor these to the specific requirements of the population. When designing the intervention, thought needs to be given to exposure and duration of treatment, and training Indigenous project officers wherever possible to enhance the uptake of prevention messages and collect process measures to quantify the degree of implementation.

Until effective evaluation procedures are routinely conducted alongside tobacco cessation and prevention investigations, we cannot identify components of existing interventions most likely to impact on a successful long-term reduction in tobacco prevalence for Indigenous populations. Methodologically rigorous investigations are needed to distinguish components of the less-successful interventions from the successful ones that can be used to aid future policy, practice and research initiatives. Importantly, this review has identified studies producing better results in the control population compared to the intervention group. Future evaluations should consider not only the 'number needed to treat' for a given intervention, but also the 'number needed to harm'.

To battle the tobacco epidemic multi-faceted programs are needed, with consistent messages from all sectors including governments, health institutions, retailers and education

centres, as well as from within individual families and smaller community groups. We do not need to reinvent the wheel; future programs, policies and research should build upon the evidence produced in this review. The next phase of research needs to have a heavy translational focus. All future work in this area needs to address how we can support the intervention into standard practice, policy and/or the front-line of clinical care to maximise benefits to the community. It is possible to reduce and even eliminate the tobacco epidemic by sharing our resources and knowledge between these groups and throughout the global population. In light of recent funding cuts from governments and a lack of reporting on existing heavily resourced interventions, the gap between Indigenous and non-Indigenous health will continue to remain a problem within our society for as long as we allow it to be one.

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Table 1 Characteristics and results of included tobacco cessation studies

Study reference and design	Sample (n) and age in years	Intervention duration	Intervention description	Findings
Campbell et al. 2014 CCT	Aboriginal and TSI Australian (n=702) 15 and over	2 months	SmokeCheck QLD; Training health professionals; Brief intervention training for two-days based on stages of change model about making every opportunity to help smokers to quit; Training of motivational interviewing techniques for health workers with Indigenous clients and patients; Ongoing post-training support, printed newsletters and other resources; Smoke-free support group, enforcement of tobacco sales legislation; Monitoring of compliance with legislation on tobacco sales; Youth aspect with ‘Smokin’ – no way’ multimedia education program training provided to teachers and resources supplied to schools; Event support program available with organisations able to apply for sponsorship of community events and anti-smoking branded merchandise; ‘Smoke Rings’ support program with five week group support sessions for people trying to quit smoking	<ul style="list-style-type: none"> • No statistically significant difference between intervention and control for daily smoking prevalence • Statistically significant change from baseline observed for daily smoking in the intervention communities at 12 months (43.6%–35.2%; $p=0.011$; 8.4% quit rate) • Non-significant trend in decline observed for control in daily smoking from baseline to follow-up (44.7%–36.5%; $p=0.075$; or 8.2% quit rate) • Evaluation of 217 health workers from urban, regional and remote communities producing statistically significant outcomes with increased skills in delivering the intervention, confidence, self-efficacy and role legitimacy
Glover et al. 2014 Pre-post study	Māori New Zealand (n=148) 18 and over	3 months	WERO study (the Māori word meaning challenge); Quit and win competition competing for NZ\$5000 to charity or community group of winning teams choice; Utilised incentives, competition, social support, behavioural therapy, pharmacological therapy, and interactive iPad application website	<ul style="list-style-type: none"> • Biochemically validated quit rate of 36% at 3 months and 26% at 6 months • Pacific and rural Māori teams had high quit rates of 46% and 44% at 3 months and 36% and 29% at 6 months respectively (point prevalence)
Maddison et al. 2014 RCT	Māori New Zealand (n=906; 30.9% of subjects were Māori) 18 and over	6 months	Fit2Quit intervention consisting of 10 exercise telephone counselling sessions over six months plus usual care (behavioural counselling and NRT); Control group received usual care alone (behavioural counselling and NRT); Fit2Quit is a comprehensive community based exercise program delivered by Green Prescription services where trained exercise facilitators (patient support persons) contacted participants to offer telephone support	<ul style="list-style-type: none"> • No significant group difference in 7-day point prevalence (23% intervention and 22% control) and continuous abstinence (17% intervention and 18% control) at six months • Probability of smoking significantly higher among Māori participants ($p=0.01$) in regression model • The more intervention calls successfully delivered the lower the probability of smoking in the intervention group ($p=0.01$)

Study reference and design	Sample (n) and age in years	Intervention duration	Intervention description	Findings
Marley et al. 2014 RCT	Aboriginal Australia (n=168) 16 and over	12 months	Locally-tailored, intensive, multidimensional smoking cessation program including motivational interviewing techniques, diversions and strategies to deal with smoking related triggers action plans for preventing and dealing with short term relapses, discussion regarding the positives of smoking cessation, referral for and titration of pharmacotherapy, identifications of smoking risk factors, with links to additional non-health support agencies (e.g. public housing, welfare) and monthly peer support groups; Control group received usual care from local primary health service including advice to quit, pharmacotherapy and self-initiated follow-up	<ul style="list-style-type: none"> • Smoking cessation rate for intervention participants:11% (n=6) and 5% for usual care group (n=5) though the difference was not statistically significant • No subjects who had been recently incarcerated, chewed tobacco, or drank alcohol daily quit smoking
Smith et al. 2014 RCT	American Indian and Alaska Native United States of America (n=103) 18 and over	3 months	Culturally tailored smoking cessation treatment for American Indian and Alaska Native smokers; Evidence-based cessation intervention included four counselling sessions and 12 weeks of varenicline tartrate; Intervention tailored to address tobacco related issues specific to Menominee and other American Indian and Alaska Native smokers; Counselling provided by the study coordinator who was an enrolled member of the Menominee tribe and trained as an alcohol and other drug abuse counsellor; Control received standard treatment cessation intervention	<ul style="list-style-type: none"> • No statistically significant group differences in 7-day point prevalence at six months (22.6% intervention and 14% control; intention to treat analysis; responder rate 42%) • Overall 90.2% of subjects reported taking varenicline at one week post-quit, 84% at three weeks post-quit and 32.1% at 12 weeks post-quit
Cosh, Hawkins, Skaczkowski, Copley, & Bowden 2014 Pre post study	Aboriginal and TSI Australians Australia (n=281) 15 and over	3 months	One-on-one telephone counselling support for smokers wanting additional support through the South Australian Quitline telephone smoking cessation service, using a callback service, where counsellors regularly call smokers	<ul style="list-style-type: none"> • Higher proportion of non-Indigenous callers received 3 month quit certificates (14.4%) compared to Indigenous callers (2.5%) • Indigenous callers were also less likely to use cessation medication such varenicline or bupropion (39.5% vs 65.1%) compared to non-Indigenous callers, but were more likely to use NRT patches (9.6% vs 6.9%) and other NRT (4.3% vs 3.7%) respectively
Eades et al. 2012 RCT	Aboriginal and TSI Australians Australia (n=263) 16 and over	9 months (three visits scheduled over this time)	Smoking intervention for pregnant women including general practitioner and other health care worker delivered tailored advice and support to quit smoking during first antenatal visit; Utilised evidence-based communication skills and engagement with woman's partner and other adults in supporting the quit attempts; NRT offered after two failed attempts to quit smoking; Control group received usual care with advice delivered by health professional	<ul style="list-style-type: none"> • At 36 weeks there was no significant difference in smoking rates between intervention group (89%) and usual care group (95%) • Authors report possible contamination of the intervention across groups or the nature of the intervention itself may have contributed to the result

Study reference and design	Sample (n) and age in years	Intervention duration	Intervention description	Findings
Walker et al. 2012 RCT	Māori New Zealand (<i>n</i> =1410; 25% of subjects were Māori) 18 and over	2 months	Very low nicotine content cigarettes plus usual Quitline care (NRT and behavioural support); Very low nicotine content cigarettes were supplied in a carton of 200 (Quest 3 brand Vector Tobacco Inc.) by a courier at no cost; Participants were instructed to stop smoking their regular cigarettes on a 'quit day' and start smoking the low nicotine cigarettes whenever they had an urge to smoking during the subsequent 6 weeks; Standard Quitline smoking cessation support with vouchers given to purchase subsidised NRT at a pharmacy and telephone support from Quitline advisors over 8 weeks (with 10–15 minute calls) were also included; Control group received usual Quitline care alone	<ul style="list-style-type: none"> • At six months intervention participants were significantly more likely to have quit smoking compared to control subjects with 23% continuously abstinent compared to 15% respectively • Seven day point prevalence estimates at six months were also significant (33% for intervention compared to 28% in usual care) • Results were not reported separately for Māori and Non-Māori subjects
D'silva, Schillo, Sandman, Leonard, & Boyle 2011 Pre post study	American Indian Unites States of America (<i>n</i> =317) 18 and over	Not specified; 90-day follow-up; 'Exit' of intervention occurred prior to 90-day follow-up	Culturally specific curriculum for tobacco dependence treatment with four 1-hour individual or group sessions of behavioural counselling paired with pharmacotherapy; Sessions were conducted by counsellors who had specialised training in tobacco dependence treatment; NRT and cessation medications were offered to subjects free of charge; Subjects had to enrol in the program and completed a counselling session to receive pharmacotherapy; All clients were offered a \$25 gift card for completing all four sessions	<ul style="list-style-type: none"> • Of subjects who completed 90-day follow-up (47% of <i>n</i>=317 subjects), self-reported abstinence (7-day point prevalence) was reported in 47% of subjects • A missing = smoking analysis (intention to treat analysis) yielded a 21.8% quit rate (7-day point prevalence) at 90 days • Continuing smokers cut their daily smoking by half from 17 to eight cigarettes per day
Hearn et al. 2011 Pre post study with a delayed intervention control (CCT)	Aboriginal Australia (<i>n</i> =165) Adults	6 months	Culturally specific smoking cessation training program (SmokeCheck) for health professionals working in NSW; Training aimed to increase professional's knowledge, skills and confidence to offer an evidence-based quit smoking brief intervention to Aboriginal clients; Personal smoking behaviour, current practice regarding delivery of smoking cessation brief intervention and availability of resources were also incorporated; History of tobacco use, national and state Indigenous smoking data, social determinants and health effects of smoking and how to advise clients who smoke to quit were all incorporated into the intervention model; Training was provided jointly by an Aboriginal and non-Aboriginal presenter, both with experience in Aboriginal health and education	<ul style="list-style-type: none"> • No changes reported in smoking behaviours or intentions to quit • Control population showed no significant changes however a higher proportion of intervention participants were more confident in talking about the health effects of tobacco use (22% <i>p</i>=0.001), offering quit advice (27% <i>p</i>=0.001), assessing readiness to quit (31% <i>p</i>=0.001) and initiating a conversation about smoking (24% <i>p</i>=0.001) • After training more intervention participants provided advice about NRT (15% <i>p</i>=0.001), environmental tobacco smoke exposure (12% <i>p</i>=0.006) and reducing tobacco use (10% <i>p</i>=0.034)

Study reference and design	Sample (n) and age in years	Intervention duration	Intervention description	Findings
Whittaker et al. 2011 RCT	Māori New Zealand (<i>n</i> =226; 24% of subjects were Māori) 16 to 25	6 months	Automated package of video and text messages over six months that was tailored to self-selected quit date, role model and timing of messages; Subjects received one message per day for one week prior to quitting, three messages per day for the next four weeks, one message every two weeks following that and one every four days for 20 weeks after that (approx. 6 months after randomisation); Extra messages were available on demand for cravings and to address lapses; Six role models were chosen (three Māori) and subjects were asked to select one person from whom they would receive messages; Control group also set a quit date and received general health video messages sent to their phones every two weeks	<ul style="list-style-type: none"> • Continuous smoking abstinence (intention to treat) at six months was 26.4% in the intervention group and 27.6% for the control • Results were not reported separately for Māori and Non-Māori subjects • Initial target sample of 1300 was unable to be collected (226 recruited) • Biochemical validation of abstinence (NicAlert test-strips) occurred in a subset of subjects with 14 quitters in the intervention group returning the strips (48% of 29 self-reported quitters) with seven confirmed as non-smokers; Fifteen quitters in control group (47% of 32 subjects) returned strip and 11 (31%) were confirmed non-smokers
Bullen, Howe et al. 2010 RCT	Māori New Zealand (<i>n</i> =1100; 28% of subjects were Māori) 18 and over	10 weeks	Smokers calling the New Zealand Quitline service were provided with 2 weeks of nicotine patches and/or gum prior to target quit date, followed by usual care being 8 weeks of patches and/or gum plus support from Quitline advisors; Control group received usual care being 8 weeks of patches and/or gum plus support from Quitline advisors	<ul style="list-style-type: none"> • Seven day point prevalence of abstinence was reported in 22.7% of intervention subjects and 21% of control subjects at six months follow-up • Results were not reported separately for Māori and Non-Māori subjects
Makosky Daley et al. 2010 Pre post study	American Indian Unites States of America (<i>n</i> =not reported) Not reported	Not specified	Pilot study of the All Nations Breath of Life smoking cessation program; Four iterations of the program was examined with changes to the intervention made in each; Intervention included weekly in-person group support sessions with individual telephone calls using motivational interviewing, an education curriculum and pharmacotherapy	<ul style="list-style-type: none"> • Preliminary self-reported data revealed quit rates of 65% at program completion and 25% at six months post-baseline • Definition of abstinence and number of participating subjects not reported
Patten et al. 2010 RCT	Alaska Native Unites States of America (<i>n</i> =35) 18 and over	2 months	Cessation intervention for pregnant Alaska Native women residing in the Yukon-Kuskokwim Delta region of Western Alaska; Intervention included face-to-face counselling at the first visit, four telephone calls, a video highlighting personal stories and a cessation guide; Control group received brief face-to-face counselling at the first visit and written materials	<ul style="list-style-type: none"> • Biochemically confirmed abstinence rates at follow-up were 0% and 6% for the intervention and control groups respectively • Participant rate low with 12% of eligible women enrolled (35/293); Authors suggest that the low enrolment rate reflects that the program was not feasible or acceptable

Study reference and design	Sample (n) and age in years	Intervention duration	Intervention description	Findings
Boles et al. 2009 Pre post study	Alaska Native Unites States of America (n=102; and n=670 non-Alaska native) 18 and over	3 months	Tobacco cessation Quitline service in Alaska providing a 24 hour 7-day a week telephone service staffed by trained nurses; Intervention consisted of tobacco use assessment, treatment planning based on stage of readiness to change, up to eight proactive follow-up counselling calls, a quit kit and free NRT; One Alaska Native nurse was available to speak with Alaska Native callers if requested	<ul style="list-style-type: none"> • Seven day point prevalence of abstinence was 22.2% at three month follow-up, compared to non-Alaska Native participants with a quit rate of 40.7% • 90% of Alaska Native smokers accepted NRT compared to 96% of non-Alaska Native callers
Gould et al. 2009 Pre post study	Aboriginal Australia (n=15) 18 and over	2 months	Pilot study of Give Up the Smokes (GUTS) program including one 3-hour group sessions per week for three weeks presented by a general practitioner and health advisor; Culturally-appropriate intensive cessation program including a range of evidence-based interventions such as motivation to quit, pharmacotherapies, behaviour modification and stress management, Indigenous history of tobacco use, prevalence and health effects of smoking; Two months of NRT was provided	<ul style="list-style-type: none"> • At six month follow-up there was a 30% quit rate (3/10 subjects) compared to a non-Indigenous program (CATS – Chronically Addicted Tobacco Smokers) with a 25% quit rate (19/76 subjects) • Completion rate for the GUTS course was 53% (8/15 subjects) • Definition of abstinence not reported
Grigg, Waa, & Bradbrook 2008 Pre post study	Māori New Zealand (n=655) All ages	12 months	National television campaigns running from August 2001 to September 2002 including 15 television commercials utilising interviews with real Māori smokers and their Whānau (the traditional Māori family unit), talking about quitting smoking and how this has affected them; The end of each add shows the Quitline number with a voiceover giving the call to action “it’s about Whānau, call the Quitline 0800 778 778”	<ul style="list-style-type: none"> • Seventy eight per cent of smokers and 73% of whanau recalled viewing the campaign one year following its launch • Fifty four per cent of smokers stated that the campaign had made them more likely to quit • No quit smoking participant data was reported
Digiaco, Davidson, Davison, Moore, & Abbott 2007 Pre post study	Aboriginal and TSI Australians Australia (n=37) 18 to 70	10 month	High intensity smoking cessation program within a primary care setting for clients and staff of a suburban Aboriginal Medical Service; Weekly cessation counselling sessions occurred with two non-Indigenous health professionals couple with dispensation of free NRT to subjects participating in ongoing counselling sessions; Aboriginal health workers concurrently engaged in culturally appropriate cessation counselling via brief opportunistic interventions	<ul style="list-style-type: none"> • Thirty two of the 37 subjects reported quit attempts during the observation period with three subjects (9%) reported to have quit smoking • Chronic and recurrent life stressors were reported as being the primary barriers to cessation • Definition of abstinence not reported

Study reference and design	Sample (n) and age in years	Intervention duration	Intervention description	Findings
Hayward, Campbell, & Sutherland-Brown 2007 Pre post study	Aboriginal Canada (<i>n</i> =243; and <i>n</i> =2,953 non- Aboriginal) 18 and over	Not specified though randomised to 30-day or 6 month follow- up	Canadian Quitline call service across seven provinces (Newfoundland, and Labrador, Nova Scotia, Prince Edward Island, New Brunswick, Ontario, Manitoba and Saskatchewan) where callers receive basic information and advice, motivational counselling based on scientific protocols and mailed materials; Proactive services are also offered to those callers who are committed to quitting smoking within a given timeframe. Pharmaceutical aids are not provided; This was not a culturally tailored Quitline call service but rather a mainstream program	<ul style="list-style-type: none"> • Six month prolonged abstinence was experienced by 10.7% of Aboriginal callers and 8.8% of non-Aboriginal callers • More Aboriginal males (16.7%) than females (7.2%) achieved long-term abstinence, a discrepancy that was not observed among the non-Indigenous • 30-day point prevalence was achieved by 16.9% of Aboriginal callers and 14.2% of non-Aboriginal callers • 7-day point prevalence was achieved by 18.9% of Aboriginal callers and 16.5% of non-Aboriginal callers
Bramley et al. 2005 RCT	Māori New Zealand (<i>n</i> =355 Māori and <i>n</i> =1350 non- Māori) 16 and over	26 weeks	STOp smoking by Mobile Phone (STOMP); Regular personalised text messages providing smoking cessation advice, support and distraction; Māori specific text messages related to Māori language, support messages (in Māori and English) and information on Māori traditions; After six weeks the number of messages reduced from 5 per day to 3 per day until 26-week follow-up; Text messaging was also free for one month; Control group received no smoking related information but did receive one text message per fortnight reminding them that completed follow-up would be rewarded with a free month of text messaging	<ul style="list-style-type: none"> • Seven day point prevalence at six weeks for Māori participants was 26.1% in the intervention group and 11.2% in the control • No significant difference observed between Māori and non-Māori participants with the latter reporting 28.6% and 13.2% abstinence at six weeks for intervention and control groups respectively • At 26 week follow-up 21.6% of Māori intervention subjects and 18.4% of control subjects reported cessation
Holt et al. 2005 RCT	Māori New Zealand (<i>n</i> =134) 16 to 70	7 weeks	Seven weeks of the cessation medication bupropion (Zyban) using 150mg once daily for three days followed by 150mg twice daily for seven weeks; Control population received an identical placebo for the same duration of time; Both treatment groups also received smoking cessation counselling	<ul style="list-style-type: none"> • Continuous smoking abstinence were statistically significant in favour of the intervention arm at three months (44.3% and 17.4%) and at six months (21.6% and 10.9% for the intervention and control groups respectively)

Study reference and design	Sample (n) and age in years	Intervention duration	Intervention description	Findings
Horn et al. 2005 CCT	American Indian United States of America (n=74) 14 to 19	10 weeks	Pilot study of the American Indian Not On Tobacco (N-O-T) program; Intensity of intervention included 10-hour long sessions occurring weekly; Program addressed topics such as understanding reasons for smoking, preparing to quit, understanding nicotine addiction and withdrawal, accessing and maintain social support, coping with stress and preventing relapses; Delivered in same-sex groups of up to 12 teens and led by a same-sex facilitator; Control group received a brief 15-minute intervention	<ul style="list-style-type: none"> • Intention to treat analysis identified 18% of intervention males compared to 10% of control males quit smoking at three months (24 hour abstinence; not statistically significant) • For compliant subject sample 28.6% of intervention males and 14.3% of control males quit smoking at three months • No females quit smoking during the study
R. G. Ivers et al. 2003 CCT	Aboriginal and TSI Australians Australia (n=111) 18 and over	10 weeks	Forty Indigenous smokers self-selected to receive free nicotine patches and a brief intervention for smoking cessation compared to 71 who chose the brief intervention only; NRT therapy included six weeks of 21mg patches, two weeks of 14mg patches and two weeks of 7mg patches, used 24 hours per day; Each participant received a one week supply of patches with instructions to return to collect more patches from the health centre; The brief intervention included advice on quitting, advice on the health effects of smoking, support in setting a quit date, counselling on cessation, being shown a flip-chart about tobacco and being offered a pamphlet (approximately 5 minutes to administer)	<ul style="list-style-type: none"> • Fifteen per cent of the intervention group and (10% with carbon monoxide validation) and 1% of the control group (carbon monoxide validated) reported that they had quit smoking at six months • Seventy six per cent of the intervention group and 51% of the control group reported reduced tobacco consumption
Johnson, Lando, Schmid, & Solberg 1997 CCT	Native American United States of America (n=601) 18 and over	Not specified	Doctors Helping Smokers (DHS) program across four urban Indian health clinics; A 2-day training session was conducted with medical and laboratory personnel for the intervention, smoking cessation education and recruitment and follow-up procedures; DHS intervention included: screening of patients for smoking status, use of a smoke card as a reminder to providers, clinician message giving, supportive reinforcement by clinic staff and monitoring of quit progress; Control subjects received usual care and smoking cessation materials for distribution; Subjects received a \$25 cash incentive to return to the clinics at one year follow-up	<ul style="list-style-type: none"> • At one year follow-up 7.1% of intervention subjects and 4.9% of control subjects reported abstinence • Of the subjects making at least one visit to the clinics in the 12 month follow-up period 9.4% of intervention subjects and 3.9% of control participants self-reported abstinence • Cotinine validated cessation occurred in 6.7% of intervention and 6.8% of control subjects

Study reference and design	Sample (n) and age in years	Intervention duration	Intervention description	Findings
Hensel et al. 1995 Pre post study	Alaska Native United States of America (n=193) 18 and over	2 months	Tobacco cessation program including behavioural modification classes and NRT (patches); Four group counselling and behavioural modification sessions were conducted over a two week period, followed by seven sessions over a six week period; Content of the group sessions were based on the American Lung Association 'Freedom From Smoking' and American Cancer Society 'Fresh Start' programs; A physician or pharmacist attended the group session and discuss and prescribe NRT	<ul style="list-style-type: none"> • Quit rates at three, six, nine and 12 months respectively were 31%, 30%, 24% and 21% • At three months follow-up 193 subjects (31%) were still enrolled • Twenty-two subjects (12%) did not use any NRT products

RCT= randomised controlled trial; CCT= controlled clinical trial; NRT = nicotine replacement therapy

Table 2 Australian government policy initiatives and community projects

Program name	State, year and reference	Funding body	Intervention type, target group and description	Findings
<i>National</i>				
Break the Chain	National 2011-ongoing (Australian Government 2013)	The Australian Government of Health	Media campaign; Targeting recent quitters between 16–40 years of age; The Media campaign was shown across both mainstream and Indigenous TV, radio and print including newspapers and magazines; The campaign supported quit attempts among smokers and promoted strategies to avoid relapse among quitters; It included Elder and peer role-models	<ul style="list-style-type: none"> • The campaign was found to be a success and resonated well with the target audience; The main messages about ‘Breaking the Chain’ and the harms of smoking were conveyed and received well and encouraged Indigenous smokers to decrease their smoking while encouraging recent quitters to not pick up the habit again
<i>Northern Territory</i>				
Asthma and smoking prevention project	Northern Territory Ongoing (Shah et al. 2013)	Menzies School of Health Research	Multi-component tobacco intervention; Targeting Aboriginal youth; This study uses peer-led education to promote messages to do with smoking and taking action to quit	<ul style="list-style-type: none"> • Ongoing – not yet evaluated
Enhancement Campaign	Northern Territory and South Australia 2014 (Cancer Council South Australia 2014)	Cancer Council of South Australia	Multi-component Tobacco Intervention; Targeting community; This was an advertisement campaign which featured 60 second commercials which centred around three main themes: footy, men and women; The footy ads focussed on health and sports fitness, the male ads focussed on health and the financial gain and the ads targeted at females focused on health and social/family benefits for offspring and careers; These advertisements were intermingled with feature people calling Quitline and asking for help quitting	<ul style="list-style-type: none"> • The campaign has yet to be evaluated but will be done through the use of a pre-post survey which will measure awareness and use of Quitline services and recall of the campaign
Healthy Starts (Te Piriphotanga)	Northern Territory 2009–2012 (Ramamoorthi 2009)	Menzies School of Health Research	Multi-component tobacco intervention; Targeting families; Family based programs about ETS smoke were delivered by Aboriginal community workers to see if the number of Indigenous infants (<12 months) coming into hospital with respiratory illness would decrease	<ul style="list-style-type: none"> • A full evaluation is still yet to be released but at last review the program was going well; Recruitment recorded 93 Indigenous participants in Darwin and 228 Māori participants enrolled in New Zealand

Program name	State, year and reference	Funding body	Intervention type, target group and description	Findings
Monitoring and evaluating Aboriginal tobacco control	Northern Territory 2007–2009 (Thomas 2007)	Collaborative Research Centre for Aboriginal Health and the National Health and Medical Research Council	Community based survey; Targeting community; This was a 2 phase project; Phase 1 consisted of using national surveys, local interview data to understand the reasons as to why Aboriginal people smoke, quit smoking, or never start smoking; Phase 2 consisted of 6 monthly audits of local stores to monitor tobacco sales in the area and to obtain trend data	<ul style="list-style-type: none"> • As of 2008, trend data on tobacco sales has been obtained for 10 communities; The interviews revealed that the biggest factor for this community in influencing their pattern of smoking was family influence as to whether they smoked, continued smoking or never began smoking
Smoke Check NT	Northern Territory Unclear (Jenkinson 2007)	Department of Health and Families ADSCA	Training health professionals; Targeting health professionals; Free workshops were run to help train Indigenous Health Workers in remote areas in brief intervention approaches; There were 2x1 workshops that were run in Alice Springs and Tennant Creek	<ul style="list-style-type: none"> • The workshops had good feedback from participants and in general the program was well received
"Starting to Smoke" Experiences of Indigenous Youth	Northern Territory 2011 (V. Johnston et al. 2013)	Lowitja Institute	Interviews; Targeting Indigenous youth; The aim of the project was to explore what factors cause Indigenous youth to begin smoking and to gain an insight into the social and cultural processes that impact on tobacco use among this group; Peer researchers recruited and conducted a series of group and individual interviews to gain knowledge relating to tobacco use trends	<ul style="list-style-type: none"> • Final study group comprised of 46 Indigenous (46% smoking) and 19 non-Indigenous youth (16% smoking); Smoking facilitators included family influences, access to tobacco, role modelling, socialisation, with similar influences reported by non-Indigenous youth • Anti-smoking socialisation in the home was a key determinant of not smoking
The Tobacco Action Project (TAP)	Northern Territory 1999-2002 (R. Ivers et al. 2005)	Territory Health Services Centre for Aboriginal Health	Multi-component Tobacco Intervention; Targeting community; The study was a multicomponent tobacco intervention that involved six matched and controlled Aboriginal communities in the Northern Territory (NT); The intervention included sports sponsorship, health promotion campaigns, training health professionals in the delivery of smoking cessation advice, school education about tobacco and policy on smoke-free public places; Surveys were also used to measure changes in knowledge about smoking, prevalence of tobacco use and attitudes to smoking and cessation in intervention communities	<ul style="list-style-type: none"> • Tobacco consumption decreased in one of the three intervention communities as compared to its matched control community; The other two communities did not fully implement the intervention; This study suggests that the success of the intervention relies on the community itself as well as the tobacco unit to help support and implement the intervention

Program name	State, year and reference	Funding body	Intervention type, target group and description	Findings
Top End Tobacco Project	Northern Territory 2007-2012 (Robertson 2007)	National Health and Medical Research Council	Multi-component Tobacco Intervention; Targeting community; Intervention includes: baseline and follow up surveys to measure tobacco use in each community, monitoring tobacco sales in the communities, support for community-developed strategies to reduce and prevent tobacco use, making NRT more readily available, employing local research workers, provision of regular feedback to each community and key stakeholders and support for capacity building of local health workers	<ul style="list-style-type: none"> • The project is still ongoing. However, preliminary data indicates that 77% of the 400 community members interviewed identified themselves as current smokers and that greater than 50% of them are either trying to quit or are thinking about quitting
<i>Queensland</i>				
Butt Out: NRT trial	Queensland 2007 (Young & Campbell 2007)	James Cook University	Nicotine Replacement Therapy Trial; Targeting community; Patches, gum and counselling were made available to assess the uptake and effectiveness of having free NRT readily available	<ul style="list-style-type: none"> • The study wasn't overly effective. Of the 64 which were recruited, only 26 could be located after 6 months; Of those 9 said that they were smoke free however only 2 of the 9 completed the 10 week NRT
I-Quitt	Queensland 2009–2012 (Hippi 2009)	Australian Government's Department of Health and Ageing	Multi-component tobacco intervention; Targeting community; The program promotes smoke-free messages throughout the community, and raises community awareness of chronic health conditions caused by smoking and second-hand smoke; The program provides one-on-one support and advice on NRT, provides motivational counselling, educational sessions for youth, focus groups for adults and provides general information about cessation aids; Targeting lactating mothers, parents and carers, school students, sporting participants and supporters and community	<ul style="list-style-type: none"> • Not available – completed
Murri Places, Smoke-free Spaces	Queensland 2011–ongoing (Institute for Urban Indigenous Health 2011)	Institute for Urban Indigenous Health	Multi-component tobacco intervention; Targeting community; The intervention focuses on making workplaces and medical organisations smoke-free zones; The program involves collaborating with community organizations to create smoke free policies, raise awareness of the smoke free policy, provide smoking cessation and wellness programs available to staff including one-on-one support, quit group and NRT; Smoke-free Murri radio consultations underway	<ul style="list-style-type: none"> • The main finding was that staff and community ownership of smoke-free policies are essential when it comes to determining the success of intervention campaigns

Program name	State, year and reference	Funding body	Intervention type, target group and description	Findings
Our Space Smoke Free	Queensland 2010–ongoing (Gussy 2010)	Wuchopperen Health Service	Multi-component Tobacco Intervention; Targeting community; Intervention will include media releases, broadcasting on WHS telephone system, website and waiting room displays of the exposure of environmental tobacco smoke (ETS) and dangers of smoking; Handouts, brochures and education sessions through community services and schools on the exposure to ETS and the dangers of smoking. Smoking cessation support and education programs will also be provided	<ul style="list-style-type: none"> • 'Our space smoke free' project plan is in the early stages of implementation
Smoke Free Life Research Project	Queensland Unclear (Bond 2012)	Australian Institute of Aboriginal and Torres Strait Islander Studies	Interview; Targeting community; During the course of the study, 20 Indigenous ex-smokers were interviewed using a semi-structured interview guide; In particular, the study was interested in finding out what the motivators of smoking change were and the enablers and barriers that were important in their attempts	<ul style="list-style-type: none"> • The study revealed that there was no 'hinge factor' for quitting smoking among those interviewed. Often, the reasons as to why participants gave up smoking were quite complex rather than just realising that it was a toxic and unhealthy habit • Frequently, the reasons as to why they quit smoking were intertwined with life experiences such as experiencing the death of a loved one due to smoking, and came down more to the experiences that they had during their life
<i>New South Wales</i>				
Aboriginal Tobacco Resistance Tool Kit	New South Wales 2013 (Finlay 2013)	NSW Ministry of Health	Education tool for Health Workers; Targeting health professionals; This was a kit designed to help to Aboriginal health workers with tobacco resistance and control initiatives; Includes NRT management, counselling with smoking cessation referrals, a workplace smoking policy, community policy and social marketing policy	<ul style="list-style-type: none"> • Not available – completed
'Butt Busters' Program	New South Wales 2005–ongoing (Davison 2005)	Aboriginal Medical Service Western Sydney (AMSWS)	Multi-component tobacco intervention; Targeting community; This program uses Aboriginal Health Workers to work closely with community members using a one-on-one approach to raise awareness and help quit attempts; general counselling, NRT and access to other smoking cessation tools are provided	<ul style="list-style-type: none"> • Evaluation of intervention involving weekly cessation counselling and free NRT between August 2005 and June 2006 found that there was a 9% quit rate at 6 months

Program name	State, year and reference	Funding body	Intervention type, target group and description	Findings
Clean Air Dreaming	New South Wales 2007–2009 (Sarin, Graham, & Walker 2007)	Commonwealth Department of Health and Ageing under the National Drug Strategy	Multi-component tobacco intervention; Targeting community; This intervention ran a series of school and community education programs and focused on reducing smoking in Aboriginal communities through the use of promotion and prevention campaigns, raising treatment awareness of smoking cessation tools, providing treatment programs, training health professionals to better help with quit attempts and by encouraging communities and organizations to go 'smoke free'	<ul style="list-style-type: none"> • Early evaluations suggest that the program is a successful as mainstream interventions; Evaluations suggest that more community members are at least thinking about quitting then before; The program was expanded to nearing areas due to its success
Engaging an Aboriginal Elder in Promoting Tobacco Control Messages to the Aboriginal and Torres Strait Islander Community Project	New South Wales 2005 (Minniecon 2005)	NSW Health for World No Tobacco Day	Multi-component tobacco intervention; Targeting population of Aboriginal smokers in Sydney; The intervention encouraged Aboriginal smokers to give up smoking by using culturally suitable health promotion strategies which included the telling of a quit attempt story by a local Elder, radio promotions, promotional postcards with smoking and health information and cessation services were developed and promoted; The Elder was also involved in Koori radio talks about his experience in quitting; Information stalls at the Aboriginal Medical Service, Redfern	<ul style="list-style-type: none"> • Not available – completed
Give Up The Smokes	New South Wales 2006–ongoing (Gould 2006)	Cancer Institute NSW	Education/training; Targeting health professionals; The program aims to provide intensive support to Aboriginal health workers to better improve their confidence and skills when helping their clients stop smoking; The program aimed to raise awareness within the community about the harms of smoking through the running of workshops	<ul style="list-style-type: none"> • Ongoing – not yet evaluated • Related to (Gould et al. 2009) reported in table 1 above
Justice Health Quit Smoking Project	New South Wales 2009 (Griffiths 2009)	Justice Health Aboriginal Health Unit	Multi-component tobacco intervention; Targeting prison inmates; Promotions were done through the Chronic Care staff in Prison Health Centres. Patients were provided with NRT and counselling support services to stop smoking	<ul style="list-style-type: none"> • In general the program was well received by the inmates and a large majority of them are in the process of thinking about quitting or have quit
Keep Koori Kids Smoke Free	New South Wales 2004–2013 (Martinez 2013)	Centre for Population Health and Aboriginal Health Unit	Multi-component tobacco intervention; Targeting community; The intervention includes the use of a smoke free register where those that register are given access to an Aboriginal support officer over the phone, the program also uses social marketing for promotion and also incorporates the training of Aboriginal Health Workers to provide more culturally suitable advice to help clients stop smoking; Run across nine government areas aiming to reduce environmental tobacco smoke exposure	<ul style="list-style-type: none"> • Not available – completed

Program name	State, year and reference	Funding body	Intervention type, target group and description	Findings
Kick the Habit	New South Wales 2011–ongoing (Aboriginal Health and Medical Research Council of New South Wales 2010)	Aboriginal Health and Medical Research Council and the NSW Ministry of Health	Social Marketing Campaign; Targeting community; The campaign has three target audiences and uses different ways of conveying messages about smoking to elders, parents and kids and youth; The campaign uses films, radio, brochures, posters, stickers and branded clothing and accessories to spread the message about the perils of smoking and what the community can do to get help; Each film stars an age appropriate local community role model who tells their inspiring story of how they gave up smoking	<ul style="list-style-type: none"> • A survey conducted after the completion of the study indicates that participants had a high level of recall about the main messages of the campaign and hence the campaign was thought to be a success
NSW SmokeCheck Project	New South Wales 2006–2011 (Carroll 2006)	NSW Health and the Cancer Institute NSW	Multi-component tobacco intervention; Targeting community; The intervention had four primary areas of focus; Firstly, it aimed to redesign health care systems/environments to support brief interventions, secondly it aimed to train Aboriginal Health Workers in cessation interventions, thirdly it aimed to increase the number of quit attempts at its own workshops and finally they wanted to focus on smoking cessation programs specifically for Aboriginal women; The intervention included the use of evidence-based cessation counselling, individual support to clients as well as increasing awareness of cessation tools such as NRT	<ul style="list-style-type: none"> • The impact evaluation results showed that improvements were achieved across a number of areas for all workshop participants, in particular there were statistically significant increases in the confidence and in skills and knowledge about NRT and environmental tobacco smoke
No Smokes North Coast	New South Wales 2010–2012 (Gould 2010)	Mid North Coast Division of General Practice	Multi-component Tobacco Intervention; Targeting community; The program included the training of Aboriginal health workers, the creation of promotional DVDs campaigning to stop smoking, school competitions to involve youth to create anti-smoking messages and art, promotional quit days and raising awareness of smoking cessation tools such as NRT; DVD titled 'Blow away the smokes' created with web-site support; Special guest launch included Tom Calma and Sean Chulburra	<ul style="list-style-type: none"> • The DVD has been successful at educating, informing and inspiring community members to quit smoking
Smokers Program	New South Wales 2005–ongoing (Lynch 2005)	Office for Aboriginal and Torres Strait Islander Health	Multi-component tobacco intervention; Targeting community; The intervention aims to raise awareness to the community about the detrimental effects of smoking through focus groups and having a trained professional assist the participants one-on-one and monitor them closely; Conducted across seven health services, patients are also given advice on pharmacotherapies (including varenicline and bupropion) and subsidised NRT; Includes Healthy start program with maternal infant health focus and keeping well from school age up; Provision of information sessions at correctional facilities	<ul style="list-style-type: none"> • As of the end of 2009, 444 quit attempts made by 328 people have been recorded. 24% of these people (n=78) are now ex-smokers and have been for a minimum period of at least 6 months

Program name	State, year and reference	Funding body	Intervention type, target group and description	Findings
Stop smoking in its tracks: understanding smoking by rural Aboriginal Women	New South Wales 2007 (Passey 2009; Passey et al. 2009)	Commonwealth Department of Health and Ageing	Multi-component Tobacco Intervention; Targeting pregnant Aboriginal women; The intervention includes counselling for women, provision of specially designed resources, free NRT for women and their households, rewards for confirmed quitting, household resources, and quitting support groups, with support continuing for 6 months post-partum	<ul style="list-style-type: none"> • Ongoing – not yet evaluated
Australian Capital Territory (ACT)				
No More Boondah	Australian Capital Territory 2012–2014 (Webb 2012)	Winnunga Nimmityjah Aboriginal Health Service	Multi-component tobacco intervention; Targeting community; The program provides one on one phone support and coaching, and support groups weekly; Social marketing campaigns to spread awareness of the campaign as well as encouraging workplaces to develop a smoke free policy was also part of the intervention; Aims to increase understanding of the effects of environmental tobacco smoke, improve the uptake of prevention programs and utilises other health care workers	<ul style="list-style-type: none"> • It was found that most people in the program did not like setting a quit date as the pressure was too much; It was also found that most people preferred to be assisted with their quit attempts
Victoria				
Reducing smoking among pregnant aboriginal women in Victoria: a holistic approach	Victoria 2008–2011 (Chamberlain 2008)	Victorian Department of Human Services	Multi-component tobacco intervention; Targeting Aboriginal pregnant women; The intervention included project workers engaging and collaborating closely with health workers and women; Creating supportive environments and providing group support was vital to the success of the intervention as well as providing ongoing training to ultimately reduce smoking prevalence among pregnant Aboriginal women	<ul style="list-style-type: none"> • The results of the study indicate that interventions aimed at pregnant Aboriginal women should incorporate adequate training to Aboriginal Health Workers to build up their confidence and increase their ability to provide effective and suitable clinical-based interventions and community-based tobacco activities; Supportive environments also need to be created in these sorts of interventions so that the women feel safe, secured and not judged; Targeting the whole family is also vital when it comes to the success of the women quitting

Program name	State, year and reference	Funding body	Intervention type, target group and description	Findings
Rumbalara Quit Program	Victoria Ongoing (Rumbalara Aboriginal Co-Operative 2012)	Healthy for Life Funding	Multi-component Tobacco Intervention; Targeting community; The program provides one-on-one counselling services to members of the community wanting to quit smoking through nurses and other health care workers; As part of the program television commercials were developed as well as short articles published in local newsletters; Small, short programs were also implemented to aid with peoples quit attempts; Supports pregnant women to stop smoking during pregnancy and to reduce exposure to second hand smoke for themselves and their children; Designated smoking areas at health services	• Ongoing – not yet evaluated
Smoking No Good Aye	Victoria 2010–2012 (Ryan 2010)	Australian Government's Indigenous Tobacco Control Initiative	Multi-component Tobacco Intervention; Targeting Indigenous youth; The intervention included the use of media to promote anti-smoking messages through advertisements on TV and radio, posters were also distributed with similar messages; Community workshops were run to provide help to those wanting to quit and mentors were used to inspire youth	• Not available – completed
Tasmania				
Alcohol, tobacco and other drugs program (Tasmanian Aboriginal Centre)	Tasmania Ongoing (Tasmanian Aboriginal Centre Inc 2012, 2014)	Tasmanian Aboriginal Centre	Multi-component tobacco intervention; Targeting community; The alcohol, tobacco and other drugs program runs services which include counselling and preventative tobacco use and smoking cessation programs for young people and the community	• Ongoing – not yet evaluated
Tasmanian Aboriginal Tobacco Control Project	Tasmania 2006–2010 (Boadle 2006)	Office for Aboriginal and Torres Strait Islander Health	Multi-component tobacco intervention; Targeting community and health professionals; The intervention includes the training of health professionals to specifically tailor cessation advice to Aboriginal community members, smoking cessation workshops for community members, promotion and awareness at community events of anti-tobacco messages	• Feedback from the community so far is good on the project; However, areas that have been highlighted as areas that need work include more work on motivational interviewing and information about quitting medications
South Australia				
Ceduna day centre	South Australia Ongoing (Drug and Alcohol Services South Australia 2012, 2014)	Drug and Alcohol Services South Australia	Multi-component tobacco intervention; Targeting community; The centre provides free confidential treatment, counselling and referral services for Aboriginal people concerned about alcohol, tobacco and other drug issues	• Ongoing – not yet evaluated

Program name	State, year and reference	Funding body	Intervention type, target group and description	Findings
Deadly Nunga's Say No to Puiya	South Australia Ongoing (Day 2007)	Muna Paiendi Aboriginal Community Health Service	Multi-component Tobacco Intervention; Targeting community youth between 12–25 years; The intervention will include health promotion campaigns, community surveys, media engagement to promote specific Indigenous events where messages will be relayed, handing out media CDs, smoking cessation and education workshops and NRT	<ul style="list-style-type: none"> • Ongoing – not yet evaluated
Enhancement Campaign	South Australia and Northern Territory 2014 (Cancer Council South Australia 2014)	Cancer Council of South Australia	Multi-component Tobacco Intervention; Targeting community; This was an advertisement campaign which featured 60 second commercials which centred around three main themes: footy, men and women; The footy ads focussed on health and sports fitness, the male ads focussed on health and the financial gain and the ads targeted at females focused on health and social/family benefits for offspring and careers; These advertisements were intermingled with feature people calling Quitline and asking for help quitting	<ul style="list-style-type: none"> • The campaign has yet to be evaluated but will be done through the use of a pre-post survey which will measure awareness and use of Quitline services and recall of the campaign
Improving health for Aboriginal people through tobacco related research	South Australia Ongoing (Carson 2012)	The Queen Elizabeth Hospital	Interviews; Targeting two communities being Adelaide and Murray Bridge (urban and inner regional); 10 focus groups with health care workers, ex-smokers, never smokers and current smokers as well as 30 interviews with key community stakeholders, respiratory doctors and other doctors to be performed or until data saturation is reached	<ul style="list-style-type: none"> • Ongoing – not yet evaluated
Puyu Wiya Smokecheck	South Australia Ongoing (Stewart 2011)	Aboriginal Health Council of SA	Multi-component tobacco intervention; Targeting community; The intervention mainly focuses on providing smoking cessation with quit coaching to members of the community and also raising awareness of quit tools such as NRT	<ul style="list-style-type: none"> • The main finding of the study was that for successful quit attempts, ongoing support is vital to prevent relapses due to stress or because other triggers of smoking

Program name	State, year and reference	Funding body	Intervention type, target group and description	Findings
Remote Aboriginal Tobacco Project	South Australia 2008–2012 (Gentle 2008)	Country Health SA Hospital Incorporated	Multi-component tobacco intervention; Targeting community; The intervention includes training Aboriginal health professionals in better more suitable intervention methods and promoting smoking cessation messages at community events; Education projects are also run specifically targeting youth and their smoking habits at local schools and youth centres	• Not available – completed
Rewrite your story campaign	South Australia 2013 (Nunkuwarrin Yunti of South Australia Inc 2013)	Cancer Council of South Australia	Multi-component Tobacco Intervention; Targeting community; This was a campaign that embraced the culture of story-telling. It featured 16 local ambassadors re-telling their own inspiring story about giving up smoking and trying to inspire other Aboriginal community members to re-write their own story and give up smoking; Posters, drink coasters and a series of films were created to raise awareness for the campaign	• The campaign was greeted positively by the local aboriginal community; The campaign doesn't preach the 'don't smoke message', but encourages the community to come together, share their stories and support one another to break the smoking cycle
Smoke-free pregnancy project– Aboriginal women and their families	South Australia 2006–2011 (Quit Sa 2011)	Quit SA	Multi-component tobacco intervention; Targeting pregnant women and their families; The program provides counselling services to pregnant women and their families, as well as providing access to NRT and promotional resources from the campaign about quit messages	• The project has raised awareness about why it is the importance to talk not only with the pregnant women but also with their families when it comes to dealing with quitting smoking during pregnancy
Smoking reduction strategy development and intervention among Aboriginal health workers	South Australia 2008–2011 (Daniel 2008)	University of South Australia	Training health professionals; Targeting health professionals; The intervention used focus groups and interviews to obtain information relevant to smoking cessation and interventions; This information is being used to guide and develop culturally suitable interventions for Aboriginal health workers in South Australia in an effort to decrease smoking rates among Aboriginal health workers	• Not available – completed
Western Australia				
Beyond the Big Smoke	Western Australia 2008–2010 (Lewis 2006)	Australian Health Council of Western Australia	Multi-component Tobacco Intervention; Targeting community; The intervention included support groups, advertising of anti-smoking banners as well as anti-smoking campaigns, presentations from tobacco support groups, stories from community members that had given up smoking and community organised competitions	• Not available – completed
Drug and Alcohol Awareness	Western Australia Ongoing (Kickett 2009)	Aboriginal Alcohol and Drug Service	Visual and media; Targeting Indigenous youth; Visuals such as diagrams and pictures were used to raise participants awareness of the effects of tobacco on major organs such as the lungs	• Not available – completed

Program name	State, year and reference	Funding body	Intervention type, target group and description	Findings
Gnumaries Hurt Program	Western Australia 2010–2013 (Dean 2010)	COAG 'Tackling Indigenous Smoking' initiative	Multi-component tobacco intervention; Targeting community; The intervention includes providing access to community workshops that aid with smoking cessation; These workshops are based around Quit program initiatives; Smoke free days as well as school expos are incorporated	<ul style="list-style-type: none"> • Ongoing – not yet evaluated
Indigenous Women's Project	Western Australia 2009 (Murphy 2009)	Department of Health, Government of Western Australia	Multi-component tobacco intervention; Targeting pregnant women and their families; The program works with pregnant Aboriginal women and their families to encourage them to give up smoking to reduce the chance of their child developing asthma and other tobacco related illnesses; The program also runs workshops to help train health workers that work with these women in smoking cessation techniques	<ul style="list-style-type: none"> • The program was successful at increasing awareness of the dangers of smoking during pregnancy. The project is in the process of trying to get funded again to expand the project to other locations
Make Smoking History	Western Australia 2000–ongoing (Chapman 2000)	Tobacco Programs, Cancer Council WA	Advertising campaign; Targeting adult smokers; The intervention includes mass media advertising, community support based strategies to target Indigenous community members, the distribution of public education materials and public activities to help promote the quitting campaign	<ul style="list-style-type: none"> • The knowledge gained from the intervention provided information on why certain members of the Aboriginal community smoke or do not smoke and to gain an insight into their attitudes and feelings about smoking; This information is currently being used to make a promotional DVD promoting success stories which will eventually be available nationally
My Heart My Family Our Culture	Western Australia 2004 (Dimer 2004)	National Heart Foundation WA	Multi-component tobacco intervention; Targeting community; This was a program designed to raise awareness of the risk factors for heart disease within the Indigenous community; It was designed for both consumers and health professionals. Consumers received DVDs, magnets, recipe booklets and risk factor information sheets while health professionals received posters, booklets and flip charts to use as aids and to increase their knowledge	<ul style="list-style-type: none"> • The campaign was thought to be quite successful; There were several attempts at quitting and succeeding throughout the program; The program was well received by the community and health professionals alike
Prisons Smoking Reduction Plan	Western Australia Ongoing (Read 2012)	Adult Custodial Directorate	Social media; Targeting Aboriginal inmates in Western Australia; CDs and booklets were used to promote quit attempt stories from local entertainers and identities to prisoners; This was designed to be of particular relevance with the non-literate inmates	<ul style="list-style-type: none"> • Ongoing – not yet evaluated

Program name	State, year and reference	Funding body	Intervention type, target group and description	Findings
Reducing the Risk of SIDS in Aboriginal Communities	Western Australia 2005–ongoing (Ford 2005)	Office of Aboriginal and Torres Strait Islander Health (OATSIH)	Multi-component tobacco intervention; Targeting families and health professionals; Smoking is one of the contributing factors to SIDS; The program is an awareness campaign to highlight to Indigenous members and local professionals the importance of smoking cessation and to encourage community to stop smoking; The program conducts focus groups, community awareness programs and implements training for health workers	<ul style="list-style-type: none"> • The program has highlighted the need for culturally suitable interventions; The program is thought to be successful and has currently engaged over 400 local professionals, 900 community members and over 115 agencies
Regional Tackling Smoking and Healthy Lifestyle Workforce and Activities	Western Australia 2010 (Coole & Schultz 2010)	Council of Australian Governments (COAG) Closing the Gap Initiative.	Multi-component tobacco intervention; Targeting community; The project builds on the work from the Beyond the Big smoke project; The project uses social marketing campaigns, focuses on training of health professionals and encourages tobacco control policies at work places; The intervention aims to educate community members about healthy lifestyle choices; The program provides members of the community with information about chronic illnesses, encourages regular health checks, provides quit smoking support and promotes anti-smoking messages at community events; Smoke check including consultation with access to NRT and other pharmacotherapy; Included healthy lifestyle education at youth sporting events; Creation of smoke-free areas and events in health organisations; Media releases for newspapers, radio and television	<ul style="list-style-type: none"> • Not available – completed
Rockingham and Kwinana Tobacco Control Project	Western Australia 2010–2012 (Yarran 2010)	South Metropolitan Public Health University	Multi-component tobacco intervention; Targeting community; This intervention included the use of promotional aids such as pledge cards, posters and smoking fact sheets; Art therapy workshops were also run as well as promotion of the campaign at local events where tobacco control stalls were set up; Movie nights, sporting activities and festivals were also part of the program to specifically target youth; Service providers given prompt cards and fact sheets to aid quit attempts	<ul style="list-style-type: none"> • Ongoing – not yet evaluated

Program name	State, year and reference	Funding body	Intervention type, target group and description	Findings
The 'Say No to Smokes' Project – Success Stories Campaign (WA)	Western Australia 2002 (Healthway Western Australian State Government 2002)	Healthway (Western Australia State Government)	Promotional media campaign; Targeting population of Aboriginal smokers in Western Australia; This was a campaign designed to encourage more Aboriginal smokers to give up smoking or make more attempts at stopping smoking; The campaign was one that was centred around the sharing of local successful quitting stories that were distributed to the public as a booklet to people considering stopping smoking and also as a CD which was played on local radio, Aboriginal medical services and used in health promotion advertisements	• Not available – completed
Yarning It Up	Western Australia 2013 (M. Davis 2013)	South Metropolitan Public Health Unit	Multi-component tobacco intervention; Targeting community; Numerous interactive information stalls with visual resources, learning groups, workshops delivering smoke free information were incorporated into this intervention; Collaboration with three public health services each containing a health worker	• Ongoing – not yet evaluated

Table 3 Ongoing tobacco cessation studies identified from published protocols

Study reference and design	Sample (n) and age in years	Intervention duration	Intervention description	Outcome measures or objectives
Pacheco 2014 RCT	American Indian and Alaska Native United States of America (n=300) 18 and over	Not reported (follow-up at six months)	Web-based smoking cessation program for Tribal College Students; Intervention includes nicotine gum, patch or Lozenge or bupropion hydrochloride or varenicline tartrate; Other intervention: Honouring the Gift of Heart Health; Other intervention: Internet All National Breath of Life (I-ANBL)	<ul style="list-style-type: none"> • Primary outcome: Smoking cessation at six months • Secondary outcomes: Adherence to program participation, cigarettes smoked and number of quit attempts all measured at six months
Maddox, Davey, Cochrane, Lovett, & Van Der Sterren 2013 Pre and post study	Aboriginal and Torres Strait Islander Australia (n=102) 12 and over	Not specified (follow-up to occur 12 months after first wave of surveys, focus groups and interviews)	Tobacco control programs under the Action Area 1 of the Australian Capital Territory Aboriginal and Torres Strait Islander Tobacco Control Strategy 2010–2014; These programs include smoking cessation groups, youth and community health promotion programs and education campaigns; Data will be collected through surveys, interviews, focus groups and use of existing de-identified health data including the Talking About the Smokes survey data, pharmaceutical benefit scheme data related to smoking and Quitline call data and volume	<ul style="list-style-type: none"> • Objectives to determine if: individual's social networks influence smoking behaviours; is there an association between various social and cultural factors and being a smoker or non-smoker and do tobacco control programs under the Action Area 1 of the Tobacco Control Strategy 2010–2014 impact on tobacco behaviours, attitudes and beliefs in the Indigenous population
Bonevski et al. 2011 RCT	Aboriginal and Torres Strait Islander Australia (n=585) 18 and over	6 weeks (two face-to-face visits each two weeks apart followed by two phone contacts each one week apart)	Smoking cessation for socially disadvantaged populations with a cohort of Aboriginal and Torres Strait Islander Australians; Intensive client centred smoking cessation intervention offered by a caseworker over two face-to-face and two telephone contacts; Intervention uses motivational interviewing to encourage repeated quit attempts, maximise effective quitting strategies and provide support for life 'stressors' contributing to relapse in disadvantaged populations; Incorporates behavioural contracting, provision of pharmacotherapy subsidies, allocation of support person and support pack, referral to specialist quit services as well as centre-run Life Skills courses; Tailoring to disadvantaged groups for level of need, unique circumstances and access; Control group will receive minimal ethical care consisting of on-screen information at completion of survey including advice to quit and the telephone smoking cessation assistance Quitline number	<ul style="list-style-type: none"> • Primary outcome: Client validated self-reported smoking cessation through 24-hour carbon monoxide validated self-report and 7-day point prevalence abstinence at one, six and 12 month follow-up • Secondary outcomes: Six and 12 month continuous abstinence, sociodemographic characteristics, nicotine dependence via the heaviness of smoking index and two-item Fagerström tolerance questionnaire, quit attempts, use of cessation aids, partner smoking behaviour, depression via the two-item patient health questionnaire, financial stress as well as collection of process measures including acceptability of intervention, staff and client intervention checklists and costs relating to intervention delivery and community service sector costs

Study reference and design	Sample (n) and age in years	Intervention duration	Intervention description	Outcome measures or objectives
Choi et al. 2011 RCT	American Indian and Alaska Native United States of America (n=448; 46 groups with 8 smokers per group) 18 and over	6 months (intervention weekly for 12 weeks and one session at six months then data collection again at 12 months)	All Nations Breath of Life smoking cessation intervention including tailoring to the needs of individuals and communities; Includes five primary components of group support sessions, individual telephone counselling using motivational interviewing, a culturally tailored educational curriculum, pharmacotherapy and participant incentives, all of which have been tailored specifically to a heterogeneous group of American Indian and Alaska Native people; Free pharmacotherapy includes varenicline tartrate, bupropion hydrochloride or NRT; Control group will receive the non-tailored current best practice care	<ul style="list-style-type: none"> • Primary outcome: Biochemically verified continuous abstinence at 12 months • Secondary outcomes: number of quit attempts, number of cigarettes smoked, pharmacotherapy utilisation, number of completed group sessions, cost effectiveness of the intervention

Table 4 Characteristics and results of included tobacco prevention studies

Study reference and design	Sample (n) and age in years	Intervention duration	Intervention description	Findings
Mckennitt & Currie 2012 RCT	Aboriginal (Indian – First Nations; Inuit; Métis) Canada (n=18) Mean 9.3	1 hour	Pilot study of two grade four classrooms with n=11 Aboriginal students in the culturally sensitive smoking prevention program and n=7 in the standard smoking prevention program, each session lasted 60 minutes; Culturally sensitive intervention began with a traditional Aboriginal smudge ceremony that ‘cleaned’ students with tobacco smoke and other ceremonial plants, discussion of differences between commercial and traditional tobacco use, the harmful chemical and consequences of commercial tobacco use and peer pressure refusal strategies; Standard program (control group) included statistics of smoking among youth, peer pressure refusal strategies, emphasis on harmful chemicals in cigarettes and the cosmetic and health changes of smoking	<ul style="list-style-type: none">• A significant reduction in intention to smoke was observed among intervention participants from baseline (mean 5.18 ± 1.40) to follow-up (mean 4.09 ± 1.04; <i>p</i>=0.05); No difference was observed among control participants• Small overall sample size precluded direct comparison between intervention and control populations• No difference was observed for knowledge about smoking or cultural knowledge• At baseline 16.7% of grade four students were experimenting with smoking
Baydala et al. 2009 Pre post study	Aboriginal (First Nation; Sioux) Canada (n=15) Grade 3 students	2 months (2-hour modules delivered once per week)	Evidence-based substance abuse prevention program (Life Skills Training (LST) program) tailored to incorporate cultural beliefs, values, language and visual images by the Alexis Nakota Sioux Nation; Adaptations to the program were Aboriginal ways of knowing including ceremonies, prayer, storytelling, circle theories and the recognition of people’s own life stories; Three day workshop prior to intervention delivery included training to inform community members of program content	<ul style="list-style-type: none">• Majority of participant questionnaire responses improved from pre-test to post-test with 55% of children’s scores increasing for overall knowledge, 55% increasing for drug knowledge, 64% for life skills knowledge, 46% for drug attitudes and 73% for life skills summary

Study reference and design	Sample (n) and age in years	Intervention duration	Intervention description	Findings
Glover et al. 2009 CCT	Māori New Zealand (n=4508) Range 11–13	9 months	Community level intervention (Keeping Kids Smoke Free) including schools, public and tribal health providers, parents, local businesses, sporting events, parents and other organisations; Key intervention components included promoting smoking cessation to parents and school staff, promoting protective parental behaviour to reduce child uptake of smoking and reducing social supply of tobacco to minors; Detailed intervention components included promoting smoking cessation through quit competitions and teacher weekly support sessions, promote proactive parental behaviours through a DVD 'Our choice, Their future', reduce social supply through visiting retailers and posters, student smoke-free art competition, communication with parents through newsletters and health promotion events in shopping malls; Control group received no intervention	<ul style="list-style-type: none"> • No difference between intervention and control at follow-up (OR 1.30, 95% CI 0.24 to 7.08) as a whole • Māori (OR 4.60, 95% CI 3.24 to 6.52) and Pacific Islander (OR 2.75, 95% CI 1.92 to 3.82) students were more likely to initiate smoking by follow-up compared to other ethnicities; However, these results have not been adjusted by ethnicity and authors report more Indigenous youth were present in the intervention arm with Indigenous youth more likely to take up smoking during the study period
Dixon et al. 2007 RCT	Native American United States of America (n=685) Range 8–10	12 months 10 lessons 2 boosters	Culturally tailored video-enhanced prevention initiative 'Keepin' it R.E.A.L.'; School based program teaching drug resistance skills through: Refuse, Explain, Avoid and Leave (R.E.A.L.); In-class curriculum was supplemented by a media campaign consisting of television, radio and billboard advertisements to reinforce the four strategies of R.E.A.L. with follow-up booster activities at school assemblies, poster projects, murals and essay contests	<ul style="list-style-type: none"> • No significant interaction was observed between treatment and control conditions or American Indian ethnicity compared to the Non-American Indian population or treatment and ethnicity combined

Study reference and design	Sample (n) and age in years	Intervention duration	Intervention description	Findings
Davis & Cunningham-Sabo 1999 RCT	Native American United States of America (<i>n</i> =1589) Range 11–18	7 months 16 lessons	School based curriculum for 'Pathways to Health' developed for South-western American Indian youth integrating activities, storytelling, parent education and school staff training; Developed for and with input from target population primarily around cancer prevention targeting areas of nutrition, tobacco and the skills needed to resist the social influences surrounding children and youth, while encouraging responsibility for one's health; Traditional customs included into the program for example traditional and ceremonial uses of tobacco are distinguished from daily and recreational use of commercial tobacco, a rich heritage of stories, poems, songs and games regarding healthful living is used as a resource; Elders from local communities are included as teachers in the curriculum and instruct the children about traditional Native American culture with importance placed on taking measures to prevent illness and promote healthful lifestyle; Teachers trained during a 2-day session; Delayed intervention control	<ul style="list-style-type: none"> • No statistically significant differences were observed in pre and post-test change categories for fifth or seventh graders self-report of smoking tobacco • Approximately 14% of fifth grade subjects in both intervention and control arms reported smoking at post-test; For seventh grade students 38% of intervention subjects reported tobacco use compared to 25% in the control group at follow-up • Intervention subjects were more likely to have reported smoking within 24 hours of each test and were also more likely to have smoked before the post-test when they had not smoked at baseline, in comparison to controls • Intentions to smoke in the future were also more likely in the intervention subjects (25% at both pre and post-test; 15% changing from 'unsure' to 'yes' at post-test)
Johnston, Beecham, Dalgleish, Malpraburr, & Gamaranian 1997 CCT	Aboriginal Australia (<i>n</i> =221) 5 to 17	2 weeks	A 2-week school based educational intervention for primary and high school students with community programs; CD including positive images of non-smokers, stories about peer-group pressure and how to say 'no' to cigarettes, as well as information about the health effects of smoking; Communities visited by well-known sporting personalities who conducted health education and sporting classes; Prizes awarded for best Be Smoke Free Song written by students; Two local rock bands performed a Be Smoke Free concert; Staff at the school and health centre agreed to be smoke free for a fortnight; Classes about the benefits of healthy, smoke-free living were conducted at all levels in the school; Control community received no intervention	<ul style="list-style-type: none"> • Self-reported smoking behaviour and exposure to tobacco smokers in the home remained constant in both groups • A greater proportion of subjects in both the intervention and control communities gave correct answers in the knowledge quiz in the follow-up questionnaire; However authors report that these results may be artefact due to different cohorts of children participating in follow-up data collection

Study reference and design	Sample (n) and age in years	Intervention duration	Intervention description	Findings
Davis et al. 1995 RCT	Native American United States of America (<i>n</i> =2066) Range 9–13	5 years 2hrs/week 13 weeks/yr	The Southwest Cardiovascular Curriculum project; Multifactorial curriculum focusing on areas of other cardiovascular health programs being: the cardiovascular system, exercise, nutrition, obesity, tobacco use, habit change and social influences. These activities were designed to be culturally appropriate to rural American Indian children in the South-west; American Indian health educators, researchers, teachers and advisers from the community contributed to the design and content of the intervention activities; Focus groups were also employed to determine the educational and cultural appropriateness of the curriculum; Curriculum was taught two hours a week for 13 weeks and was divided into five teaching units: the cardiovascular system, exercise, nutrition, tobacco and social influences.; Delayed intervention control	<ul style="list-style-type: none"> • Among the pre-test non-users, only eight students (<i>n</i>=4 intervention and <i>n</i>=4 control) reported having initiated smoking at post-test • A greater proportion of boys compared to girls had tried smoking (36.5% vs. 26.2%, <i>p</i><0.001) and a greater proportion of Pueblo students had tried smoking compared with Navajo students (35.2% vs. 26.7%, <i>p</i><0.001) • A greater proportion of boys in the curriculum group when compared to the control reported smoking less from pre to post-test (41.2% vs. 22%) however this difference was not observed for the girls • Among Pueblo students the proportion reporting smoking less from pre to post-test in the intervention compared to control groups was significantly different (35.9% vs. 18.2%)

Study reference and design	Sample (n) and age in years	Intervention duration	Intervention description	Findings
Moncher & Schinke 1994 RCT	Native American United States of America (n=1396) Mean 11.3	6 months 15 x 50 min lessons + booster	School based curriculum for one intervention arm and School curriculum plus community involvement for other incorporating parents and media; Culturally tailored; Skills-only: Fifteen classroom group interventions and booster sessions six months after initial intervention; Interventions included material on bicultural competence, tobacco use knowledge, cognitive and behavioural techniques for problem solving, communication and resistance and stress and coping; Interactive classroom work was used with participation in rehearsals of techniques to avoid tobacco use; Skills-community: As above plus an annual intervention designed to involve the community including various activities in which students modelled the skills they had learned in classrooms to their parents and other community members; Publications and posters were produced to further educate parents and other community members about the nature and purpose of the intervention; Media was used to enhance participation using traditional Native American legends and puppets to initiate and enhance classroom discussion; Group leaders and group discussions were employed to encourage students to discuss their learning experiences at home and in the community; Control not described – assumed no intervention control	<ul style="list-style-type: none"> • No significant differences in weekly smoking between the intervention and control groups at any follow-up, though all rates more than trebled to 35 to 40% over 3.5 years • Both control conditions and all females reported an increase in daily smoking disproportionate to the rest of the sample at 12 months, however this was not significant • For weekly smoking, the skills-community condition reported the greatest increases; however smoked tobacco use did rise across the entire sample; During the previous month, a slight uptake of smoking was shown across all conditions
Gilchrist, Schinke, Trimble, & Cvetkovich 1987) RCT	Native American United States of America (n=109) Mean 11.3	10 x 60 min lessons	School based curriculum discussing myths concerning drug use, impact of stereotypes and health education; Culturally tailored with Native American involvement; Intervention included: discussion of myths concerning Indian drug use, impact of stereotypes on behaviour, provision of health education information through games, handouts, films and posters, group discussions and peer guest speakers sharing personal reasons for rejecting drug use, discussions around SODAS problem solving model, opportunities for skills practice, creation of videotape and adult guest speaker invited from tribal alcohol treatment program	<ul style="list-style-type: none"> • Positive changes in tobacco use found at post-test ($p < 0.05$; change score of -0.15 for intervention and -0.01 for control) were not maintained at 6 months follow-up ($p = \text{NS}$, change score of -0.11 for intervention and 0.07 for control) • No intervention effects were observed in subjects' self-identification as tobacco users

Means \pm standard deviations are reported in the results unless otherwise stated; OR= odds ratio; 95%CI= 95% confidence interval; RCT= randomised controlled trial; CCT= controlled clinical trial; NRT = nicotine replacement therapy

Figure 2 Summary risk of bias assessment for each included and completed tobacco cessation study



Figure 4 Summary risk of bias assessment for each included and completed tobacco prevention study



Chapter 9.

Methodological challenges and options for addressing them in Aboriginal and Torres Strait Islander health research

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Contribution to the paper	Researched the literature, established the outline, identified the methodological issues to be discussed in the manuscript, wrote the first draft of the manuscript, contributed to writing the manuscript, agree with manuscript results and conclusions, jointly developed the arguments and structure for the paper, made critical revisions and approved final version.		
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Historically, research among Indigenous peoples has been a source of distress due to inappropriate methods and practices (144) as well as historical abuse of research, which is non-collaborative in nature, paternalistic and self-serving (123). As such, there are long standing difficulties in conducting methodologically rigorous research studies even with Aboriginal and TSI collaboration and partnership.

National guidelines are available that outline the requirements for ensuring adequate cultural sensitivity, capacity building, community engagement, sustainability, priority and significance (145). Yet currently these publications lack in depth dialogue about issues faced in attempting to conduct methodologically rigorous research designs whilst maintaining cultural appropriateness. This is particularly relevant considering the lack of high quality empirical evidence from Indigenous research trials that can be used to underpin policy and practice, as evident in the proceeding chapters (67, 110). Moreover, based on clinical trial registry searches from the two Cochrane reviews, few people are currently attempting to conduct these types of investigations, despite the obvious need. As such, the intention of the following publication is to discuss some of the current methodological challenges faced when conducting research related activities and provides possible solutions for addressing them.

Exchange of ideas about ways to improve the quality of Aboriginal and TSI health research are of particular importance as we cannot just assume that any intervention is going to be a successful one. Indeed we could be doing more harm than good, as identified in one of the youth tobacco prevention studies (110). Moreover, empirical evidence is needed to underpin current practices and policy and to guide future research initiatives. Discussions about choosing study design, appropriate sample sizes, contamination in cluster designs, access to resources, recognising successful achievements and future perspectives are discussed. In particular, evaluations of existing practice are required to make sure that the current investments are effective and should be continued. If it is discovered that any of the existing programs are not working or even causing more harm, funding can then be discontinued and redirected into those initiatives more likely to make an impact toward closing the gap. Translational research was also identified as a priority area. Taking existing evidence that has been produced by communities and ensuring that these programs are made available on the frontlines of clinical care where they are most needed is essential to providing maximum investment on expenditure and optimal uptake among the community. Research is needed that addresses issues of translation and establishes optimal channels of evidence implementation.

Carson, K.V. & Smith, B.J. (2014). Methodological challenges and options for addressing them in Aboriginal and Torres Strait Islander health research. *Australasian Epidemiology*, 21(2), 47-50.

NOTE:

This publication is included on pages 266 - 272 in the print copy of the thesis held in the University of Adelaide Library.

Chapter 10.

Current and emerging pharmacotherapeutic options for smoking cessation

(Literature review)

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A myriad of smoking cessation pharmacotherapies have been trialled over the years, some originally as other treatments with influence over tobacco use as a welcome side effect. The efficacy of varenicline tartrate, bupropion hydrochloride and nicotine replacement therapy products are well established as first-line pharmacotherapy. However, little is known about these products when used in populations such as Indigenous, people with mental health problems, pregnant women and youth. This review was requested by editors of this journal to explain in detail the properties of each smoking cessation medication from a scientific perspective (including structural formula, molecular formula, substance, trade names and chemical names) in order to provide a document repository for scientific, clinical and research use. From a clinical practice perspective, this review provides information about recommended dosing and prescribing, empirical evidence of efficacy, limitations, adverse events and precautions in easy to digest tables.

In addition to standard 'first line' pharmacotherapy, a systematic review of all other medications approved for use as smoking cessation aids over the years have also been described. These include nicotine receptor agonists, anxiolytics, other antidepressants, opioid antagonists, cannabinoid type 1 receptor antagonists, lobelia, silver acetate and nicobrevin. These 'other pharmacotherapeutic options for smoking cessation available at present' i.e., approved by at least one regulatory authority, are presented in a detailed table. Several novel approaches are also summarised into the same document, for example a straw containing nicotine beads, which allows the smoker to place drops of nicotine directly into a beverage, new formulations of the most efficacious of the known cessation aids, varenicline tartrate, including a controlled release formulation, a free base solution and a free base patch. Other innovative though little researched treatments are also discussed including e-cigarettes, immunotherapy, alternative medical interventions and the role of pharmacogenomics.

Efficacy of smoking cessation therapies are then discussed for the following specific populations: young people, males and females, hospitalised individuals, those awaiting surgery, cancer patients, individuals with mental health problems, pregnant and breastfeeding women and Indigenous people. To conclude a dialogue concerning implications for tobacco cessation in clinical practice, public policy and future research is presented. This published review establishes the body of evidence for all areas evaluated in this PhD.

REVIEW

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Current and Emerging Pharmacotherapeutic Options for Smoking Cessation

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Abstract: Tobacco smoking remains the single most preventable cause of morbidity and mortality in developed countries and poses a significant threat across developing countries where tobacco use prevalence is increasing. Nicotine dependence is a chronic disease often requiring multiple attempts to quit; repeated interventions with pharmacotherapeutic aids have become more popular as part of cessation therapies. First-line medications of known efficacy in the general population include varenicline tartrate, bupropion hydrochloride, nicotine replacement therapy products, or a combination thereof. However, less is known about the use of these products in marginalized groups such as the indigenous, those with mental illnesses, youth, and pregnant or breastfeeding women. Despite the efficacy and safety of these first line pharmacotherapies, many smokers continue to relapse and alternative pharmacotherapies and cessation options are required. Thus, the aim of this review is to summarize the existing and developing pharmacotherapeutic and other options for smoking cessation, to identify gaps in current clinical practice, and to provide recommendations for future evaluations and research.

Keywords: smoking, smoking cessation, pharmacotherapy, pharmacotherapeutic, nicotine, varenicline tartrate, Champix, nicotine patches, bupropion, zyban

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Tobacco Use

Since the 1950s, we have observed significant reductions in tobacco use prevalence across many countries.¹⁻⁴ Despite these reductions, tobacco smoking remains the single most preventable cause of morbidity and mortality, contributing to more drug-related hospitalizations and deaths than alcohol and illicit drug use combined.¹ Every year, approximately 5.4 million people die from tobacco-related diseases, translating to 1 in every 10 deaths among adults worldwide.⁵ Tobacco use is known to cause up to 90% of all lung cancers and is a major risk factor of coronary heart disease, stroke, peripheral vascular disease, chronic obstructive pulmonary disease, reproductive and fetal developmental diseases, and many other conditions.^{1,6} Tobacco cessation, even after a short period of time, is known to produce significant health benefits within as little as 20 minutes. Within 12 weeks of smoking cessation, improvements in oxygen transportation, smell, taste, breathing, energy, and immune responses are observed. Within 12 months, the risk of coronary heart disease will return to half that of a current smoker and is reduced to that of a non-smoker by 15 years.⁷ Moreover, smoking cessation treatments have greater cost effectiveness and clinical efficacy in comparison to other preventative health measures such as treatment of hypertension and hypercholesterolemia,⁸⁻¹⁰ and research has shown that the cost per life year saved by smoking cessation interventions makes it one of the most cost-effective health care interventions.^{10,11}

For these reasons, assisting individuals to stop smoking is a key health improvement objective in many countries¹²⁻¹⁴ and pharmacotherapeutic options are increasingly being considered, particularly for individuals with high levels of nicotine addiction. Current first-line pharmacotherapies include nicotine replacement therapy, bupropion hydrochloride, and varenicline tartrate, with research suggesting that combining these with behavioral counseling increases efficacy and helps smokers achieve long term abstinence.¹⁵ Yet, these medications show some limitations and significant resources are invested into the development of designer smoking cessation pharmacotherapies, which target specific pathophysiological mechanisms in nicotine addiction in an attempt to improve the effectiveness and safety of pharmacotherapeutic cessation aids. In addition, adaptation of medications

used primarily to treat other conditions which have the potential to act as smoking cessation aids are also being evaluated,¹⁶ as are novel adaptations to existing smoking cessation treatments.¹⁷⁻¹⁹ As such, this article is intended to provide the reader with an overview of current and emerging pharmacotherapeutic options for smoking cessation and provides recommendations for clinical practice, future evaluations, and research.

Current Pharmacotherapeutic Options for Smoking Cessation

The choice of any pharmacotherapy for smoking cessation should be guided by an individual's preference, contraindications, and precautions for use.¹³ Consideration should be given to specific factors such as the potential for adverse events, possible drug interactions, the individual's experience with pharmacotherapy, convenience, availability, and cost before prescribing any pharmacological interventions to aid smoking cessation.¹⁰ The level of nicotine addiction the individual is reported to have should also be taken into account based on a validated scale such as the Fagerström test for nicotine dependence.²⁰ Smoking cessation guidelines and treatment algorithms recommend the use of pharmacotherapy only in the presence of nicotine addiction to increase chances of a successful quit attempt, while non-pharmacological support is recommended for smokers who are not nicotine-dependent and those unwilling or unable to use pharmacotherapy.^{10,13,14,21} A systematic search of the Cochrane Database of Systematic Reviews' Tobacco Addiction Group register was conducted to identify current and emerging pharmacotherapeutic options for smoking cessation. In addition, a search of Medline, EMBASE, and online clinical trial registries were also conducted with the key words smoking OR tobacco OR nicotine OR tobacco cessation OR smoking cessation AND pharmacotherap*. First-line pharmacotherapies have been listed in ranked order of efficacy.

First-line therapies

Varenicline tartrate (Chantix or Champix) is a nicotinic receptor partial agonist designed to selectively activate the $\alpha 4\beta 2$ nicotinic acetylcholine receptor. It blocks the effect of subsequent nicotine challenge on mesolimbic neuronal dopamine release, while



mimicking the action of nicotine, causing the release of mesolimbic dopamine.²² Clinical practice guidelines report that varenicline is the most effective form of single pharmacotherapy for smoking cessation based on available evidence.¹⁰ A Cochrane meta-analysis of 14 trials comparing varenicline to placebo with respect to quit rate produced a risk ratio of 2.27 (95% CI 2.02 to 2.55), and compared to pharmacologically unassessed quit attempts varenicline improved the chances of long-term abstinence by two- to three-fold.²³ Statistically significant improvements have also been shown with varenicline for patients admitted to the hospital with smoking-related illnesses at 12 months follow-up.²⁴ Varenicline is reported to be a superior smoking cessation aid to date for long-term abstinence in the general population, with direct and indirect comparisons with bupropion,¹⁰⁰ nicotine replacement therapy products,⁸⁶ and cytosine.¹⁰¹ The most common adverse event is nausea, which is reported to be mild, self-limiting, and resolving over time (RR 3.28; 95% CI 2.89 to 3.73). Further details pertaining to dosing and prescription, efficacy, and adverse events are reported in Table 1.

Bupropion hydrochloride (Zyban SR or Wellbutrin SR) is a norepinephrine and dopamine re-uptake inhibitor that decreases nicotine cravings and symptoms of withdrawal²⁶ while also interacting with neural pathways underlying nicotine addiction.²⁵ It can also be used as an antidepressant and is thought to reduce the depressive symptoms of nicotine withdrawal, as nicotine itself may cause antidepressant effects that bupropion helps maintain.²⁶ Evidence from clinical trials report that bupropion aids long-term smoking abstinence when compared to placebo and nicotine replacement therapy products; however, when compared to varenicline, it showed reduced quitting success.^{23,25,27} The most common adverse events include insomnia, dry mouth, and nausea.²⁵ Further details pertaining to dosing and prescription, efficacy, and adverse events are reported in Table 2.

Nicotine replacement therapy (NRT) products are designed to control cravings by replacing nicotine through various delivery systems. Nicotine patches differ from other NRT products (eg, lozenges and gum) in that they deliver nicotine slowly and passively over time.²⁸ Transdermal patches are available in doses varying from 5 mg to 22 mg over a 16- to 24-hour period. Lozenges and chewing gum are

available in strengths of 2 mg or 4 mg; however, no available NRT products deliver nicotine as quickly as a cigarette, being between 1 mg and 3 mg of nicotine per cigarette with the typical pack-per-day smoker absorbing 20 to 40 mg of nicotine per day.^{28,29} The most recent product on the market is the nicotine quick mist, which is a 1-mg oral mouth spray that produces levels of plasma nicotine similar to nicotine gums and lozenges.³⁰ A review of 132 trials found that NRT patches improved the likelihood of successful smoking cessation by 50% to 70% regardless of the setting.²⁸ NRT products are available over the counter and the major side effects vary depending on the type of product, but typically include skin irritation from patches and irritation to the inside of the mouth from gum and tablets.²⁸ Further details pertaining to dosing and prescription, efficacy, and adverse events are reported in Table 1.

Other pharmacotherapeutic treatment options for smoking cessation

Nicotine receptor antagonists

Nicotine receptor antagonists include varenicline tartrate (as reported above), cytosine, dianicline, and mecamylamine, all of which moderate levels of dopamine to counteract withdrawal symptoms (agonist) and reduce smoking satisfaction (antagonist).²³ A detailed summary of varenicline is described above and cytosine shows the highest efficacy of the remaining nicotine receptor agonists. A review of nicotine agonists identified one trial examining dianicline as a smoking cessation therapy, which was found to be ineffective.²³ A separate Cochrane review examining mecamylamine identified two studies for inclusion, the results of which suggested that a combination of nicotine replacement therapy and mecamylamine may be superior to nicotine replacement therapy alone.³¹ However, these results were based on two studies with small sample sizes, and confirmation in larger studies is required before the treatment can be recommended clinically.³¹

Cytosine (Tabex) is derived from the plant *Cytisus laburnum* and acts as a low-efficacy partial nicotine agonist binding to subtypes of neuronal nicotine receptors, particularly the $\alpha 4\beta 2$ subunits. Recent studies have highlighted the potential for this drug to be used in low- to medium-income countries^{27,33} where tobacco cessation is not supported by insurance plans

Table 1. Comprehensive summary of first line therapy options for smoking cessation available at present.

Structural formula	Molecular formula	Substance and (trade name/s)	Chemical name
<p>1. Varenicline</p>	$C_{13}H_{13}N_3$ $C_4H_6O_6$	Varenicline tartrate (Champix or Chantix)	7,8,9,10-tetrahydro-6,10-methano-6H-pyrazino [2,3-h] [3] benzazepine
Dosing and prescription			Dosage: 0.5 mg daily for 3 days, 0.5 mg twice daily for four days, 1 mg twice daily for remaining treatment duration Prescription: Oral, tab.; recommend commencement 1 week before estimated quit date; repeat scripts are available within a 1 year period depending on country; total course duration is between 3 and 6 months; take with food; prescription only medicine; authority required A meta-analysis of 14 RCTs produced a statistically significant benefit in favor of varenicline for sustained CA (≥ 24 weeks; RR 2.27; 95% CI 2.02 to 2.55; total n = 6,166; $P < 0.00001$). ⁴⁴ It has shown superiority over bupropion, ¹⁰⁰ cytisine ¹⁰¹ and NRT. ⁸⁶ A study using varenicline initiated in the inpatient setting including patients with acute cardiovascular, respiratory, neurological, and vascular illnesses, showed no exacerbation of cardiovascular events or psychological conditions. ^{24,44} Limitations: The efficacy of varenicline has yet to be adequately evaluated in patients with psychiatric disorders, pregnant and breast feeding women, youth, and indigenous populations. Adverse effects: Nausea (29%), insomnia (14%), headache (10%), constipation (6%), and dry mouth (6%); there is an increased risk of serious neuropsychiatric symptoms including depressed mood, agitation, suicidal behavior, and suicidal ideation, ^{74,102,103} Post-marketing reports include hypersensitivity reactions (including angioedema, which can be life-threatening due to respiratory compromise) and severe cutaneous reactions including Erythema Multiforme and Stevens-Johnsons Syndrome (also potentially life-threatening). Precautions: Recent evidence suggest a possible association with increased cardiovascular events ¹⁰⁴⁻¹⁰⁷ and psychiatric conditions; ^{102,108,109} Though one small study found improved mood in outpatient smokers with persistent depressive symptoms, ¹¹⁰ Reduced dosing frequency of 1 mg daily is recommended for patients with severe renal impairment.
<p>2. Bupropion</p>	$C_{13}H_{18}ClNO$	Bupropion hydrochloride (Zyban SR or Wellbutrin SR) (SR being sustained release)	(±)-1-(3-chlorophenyl)-2-[(1,1-dimethylethyl)amino]-1-propanone hydrochloride
Dosing and prescription			Dosage: 150 mg tab. taken daily for 3 days, increasing to 150 mg twice daily. Prescription: Oral, tab.; commence whilst smoking with estimated quit date within the first 2 weeks; should be an interval of at least 8 hours between successive doses; prescription only medicine; authority required; course minimum 7 weeks.

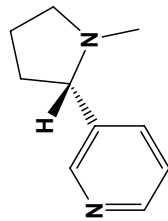
Efficacy
 A meta-analysis of 36 RCTs found sustained CA compared to placebo (RR 1.69; 95% CI 1.53 to 1.85; total n = 11,140; $P < 0.00001$); six RCTs were unable to produce sufficient evidence that adding bupropion to NRT provides additional long-term CA (RR 1.23; 95% CI 0.67 to 2.26; total n = 1,106; $P = 0.51$); three RCTs showed lower quitting with bupropion compared to varenicline (RR 0.66; 95% CI 0.53 to 0.82; total n = 1,622; $P = 0.0002$).²⁵

Limitations, adverse events, and precautions
 The efficacy of varenicline has yet to be adequately evaluated in pregnant and breast feeding women, youth, and in most indigenous populations.

Adverse effects: Insomnia (40%), rhinitis (12%), dizziness (10%), nausea (9%), disturbed concentration (9%), constipation (8%), and anxiety (8%).¹¹¹

Precautions: Prescription to patients with an increased risk of seizures should be avoided with a risk of 1 in 1,000.²⁵ There is a possibility of metabolism and age-related reductions in drug clearance requiring modification of the standard dosing protocol to 150 mg per day (first week) increased to 300 mg in the absence of adverse events.¹¹² Reports of seizures in the early formulation resulting in the development of the slow release (Bupropion SR) preparation;²⁵ Contraindicated in patients with known CNS.¹¹¹

3. Nicotine



$C_{10}H_{14}N_2$ Nicotine (including Nicotinell, QuitX, Nicobate, Nicoderm, Nicotrol and Nicorette) 3-[(2S)-1-methylpyrrolidin-2-yl]pyridine

3.1. Nicotine patch

Dosing and prescription

Dosage: Vary from 5 mg, 10 mg and 15 mg 16 hour patch or 7 mg, 14 mg, 21 mg, and 22 mg 24 hour patch.

Prescription: Transdermal, patch; available over the counter; 12-week course recommended, step-down titration recommended.

Efficacy
 A review of 41 trials comparing NRT patches to no-treatment or placebo produced a statistically significant benefit in favor of patches (RR 1.66; 95% CI 1.53 to 1.81; total n = 18,237; $P < 0.00001$).²⁸ One study compared NRT to bupropion with subjects using the nicotine patch producing a lower quit rate.¹¹³ Varenicline was superior to NRT for long-term CA through indirect comparisons when compared to placebo (OR 1.66 95% CI 1.17 to 2.36; $P = 0.004$) and to all controls at 1-year follow-up (OR 1.73; 95% CI 1.22 to 2.45; $P = 0.001$),¹¹⁴ and in a direct comparison of 746 participants across five countries (OR 1.40; 95% CI 0.99 to 1.99; $P = 0.056$).⁸⁶

Limitations, adverse events, and precautions
 Not appropriate for use in pregnant or breast feeding women; smoking cessation efficacy less than that of varenicline tartrate and bupropion hydrochloride.

Adverse effects: Application site reaction (35%), headache (30%), cold and flu-like symptoms (12%), dysmenorrhea (7%), insomnia (6%), nausea (6%), myalgia (6%), and dizziness (6%).¹¹⁵

Precautions: Contraindicated in people with diseases of the skin that may complicate patch application; precautions are advised for patients with underlying cardiovascular disease, diabetes mellitus, moderate to severe hepatic impairment, peptic ulcers, pheochromocytoma, and uncontrolled hyperthyroidism; smoking while on patches may increase the risk of cardiovascular events (eg, angina);¹¹⁵ contraindications to nicotine or any component of the patch.

Dosage: 2 mg gum recommended for smokers of <25 cigarettes per day, 4 mg for smokers ≥ 25 cigarettes per day.

Prescription: Do not exceed 24 pieces in a day; course max. 12 weeks; avoid eating or drinking anything except water for 15 min before or during chewing; various flavors: classic, mint and citrus;¹⁴ available over the counter.

Efficacy
 A review of 53 trials comparing nicotine gum to no-treatment or placebo produced a statistically significant benefit in favor of gum (RR 1.43; 95% CI 1.33 to 1.53; total n = 19,090; $P < 0.00001$).²⁸

(Continued)



Table 1 (Continued)

Structural formula	Molecular formula	Substance and (trade name/s)	Chemical name
Limitations, adverse events, and precautions	Limitations: Not recommended beyond 12 weeks; smoking cessation efficacy less than that of varenicline tartrate and bupropion hydrochloride.		
3.3. Nicotine inhaler Dosing and prescribing	Adverse effects: Hiccoughs, gastrointestinal disturbances, jaw pain, orodental problems, ²⁸ headache, indigestion and nausea; ³⁰ Some symptoms may be relieved by chewing more slowly and resting the gum. ^{30,116,117} Precautions: It is possible that people using the gum may transfer their nicotine addiction from cigarettes to the gum, ¹¹⁶ Contraindications to nicotine or any component of the chewing product. Dosage: Use 6 to 12 cartridges per day. Prescription: Draw breath through the mouth piece taking shallow sucking breaths every 2 seconds or 4 strong deep breaths per minutes; 20 minutes of continuous use will deplete one cartridge; avoid eating or drinking anything except water for 15 minutes before use of inhaler; course minimum 12 weeks, then reduce number of cartridges and use for extra 6–8 weeks; prescription only medicine. ¹¹⁸ A review of 4 trials comparing nicotine gum to no-treatment or placebo produced a statistically significant benefit in favor of inhaler (RR 1.90; 95% CI 1.36 to 2.67; total n = 976; P = 0.0002). ²⁸ Limitations: Smoking cessation efficacy less than that of varenicline tartrate and bupropion hydrochloride. Adverse effects: local irritation around mouth, increased symptoms of throat irritation, coughing, oral burning, ²⁸ sneezing, runny nose, headache, nausea, heart burn, and hiccoughs; most users rate these reactions as mild, if the side effects do not subside within 1–2 weeks seeking medical advice is recommended; if severe symptoms occur, do not smoke and seek medical advice. ¹¹⁸ Precautions: Contraindications to nicotine or any component of the inhalers.		
Efficacy			
Limitations, adverse events and precautions			
3.4. Nicotine nasal and mouth spray Dosing and prescription	Dosage: 10 mg/mL nicotine concentration; one spray delivers 0.5 mg nicotine. ¹¹⁹ Prescription: Use one spray in each nostril 1–2 times per hour; recommended 8–40 doses per day; course minimum 3 months, max. 6 months; prescription only medicine. ¹⁰¹ A review of 4 trials comparing nicotine gum to no-treatment or placebo produced a statistically significant benefit in favor of nasal spray (RR 2.02; 95% CI 1.49 to 2.73; total n = 887; P < 0.00001). ²⁸ Limitations: Smoking cessation efficacy less than that of varenicline tartrate and bupropion hydrochloride. Adverse effects: Local irritation in and around nose, runny nose, ²⁸ headache (18%), back pain (6%), dyspnea (5%), nausea (5%), arthralgia (5%). ¹¹⁹ Most users rate these reactions as mild, if the side effects do not subside within 1–2 weeks seeking medical advice is recommended. ¹¹⁹ For mouth spray adverse effects included increased hiccups, burning sensation on the lips, and local irritation of the mouth, though none of these were severe. ¹²⁰ Precautions: Contraindications to nicotine or any component of the sprays.		
Efficacy			
Limitations, adverse events, and precautions			
3.5. Nicotine lozenge Dosing and prescription	Dosage: 4 mg lozenge if first cigarette within 30 minutes of waking up otherwise 2 mg. Prescription: Weeks 1–6 × 1 lozenge every 1–2 hours, weeks 7–9 × 1 every 2–4 hours, weeks 9–12 × 1 every 4–8 hours; max. 5 in 6 hours; allow lozenge to dissolve in mouth, do not chew or swallow whole; various flavors including mint or cherry; usual pack sizes are 24, 36, 48, 72, and 100; available over the counter; for tablet, swallow whole with water. ¹⁰¹		



Efficacy	A review of 6 trials comparing nicotine lozenges/tab. to no-treatment or placebo produced a statistically significant benefit in favor of lozenge (RR 2.00; 95% CI 2.63 to 2.45; total n = 3,109; $P < 0.00001$). ²⁸
Limitations, adverse events, and precautions	<p>Limitations: Smoking cessation efficacy less than that of varenicline tartrate and bupropion hydrochloride.</p> <p>Adverse effects: Hiccoughs, burning and smarting sensation in the mouth, sore throat, cough, dry-lips, mouth ulcers,²⁸ indigestion, gas, and nausea.^{121,122} most users rate these reactions as mild, if the side effects do not subside within 1–2 weeks seeking medical advice is recommended.^{121–124}</p> <p>Precautions: Contraindications to nicotine or any component of the lozenge/micro-tab.</p>

or the national health service²³ as well as in the indigenous setting.³⁴ Efficacy trials show modest improvements in quit rates with outcomes similar to studies using nicotine replacement therapy,²³ though twice as effective as placebo.³⁴ Further details pertaining to dosing and prescription, efficacy, and adverse events are reported in Table 2.

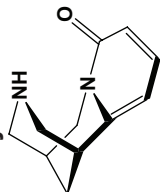
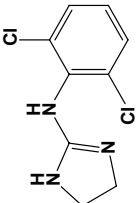
Pharmacological therapies that are used primarily to treat other medical conditions may also be used for treating nicotine addiction. As research aimed at exploring and understanding the biological mechanisms of nicotine addiction develop, new opportunities are arising for existing pharmacological agents to be translated into the tobacco arena. The following section provides a summary of such medications, which have potential applications in treating nicotine addiction.

Anxiolytics

Anxiolytics are proposed as a smoking cessation treatment because of their ability to abate anxiety, one of the common symptoms of smoking cessation.³⁵ There are many types of anxiolytics that may have a role as smoking cessation treatments including clonidine, buspirone, diazepam, doxepin, meprobamate, ondansetron, and the beta-blockers metoprolol, oxprenolol, and propranolol.³⁵ The anxiolytic clonidine has the most evidence evaluating efficacy for smoking cessation out of the nine anxiolytics, and as such are a more detailed description of clonidine is reported below and in Table 2.

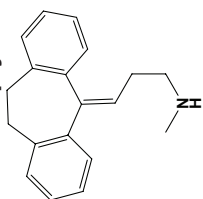
Clonidine is marketed as an antihypertensive but also has applications for drug and alcohol withdrawal symptoms,^{36,37} as a treatment for chronic pain,³⁸ menopausal flushes^{39,40} and Tourette's syndrome. In a systematic review of tobacco withdrawal symptom studies, clonidine has been reported to ameliorate cravings, anxiety, restlessness, tension, and hunger, but also caused some side effects such as sedation, dry mouth, and dizziness, with twice as many patients taking clonidine discontinuing medication compared to placebo.⁴² For these reasons, clonidine is not considered a first-line treatment; however it may be beneficial for targeted populations such as smokers who are likely to experience high levels of anxiety and agitation when stopping smoking and subsequently may benefit from the sedative effects.⁴² Further details pertaining to dosing and prescription, efficacy, and adverse events are reported in Table 2.

Table 2. Comprehensive summary of other pharmacotherapeutic options for smoking cessation available at present.

Structural formula	Molecular formula	Substance and (trade name/s)	Chemical name
<p>1. Cytisine</p> 	$C_{11}H_{14}N_2O$	Cytisine (Tabex, Bapitoxine, Sophorine)	(1 <i>R</i> ,5 <i>S</i>)-1,2,3,4,5,6-hexahydro-1,5-methano-8 <i>H</i> -pyrido[1,2 <i>a</i>][1,5]diazocin-8-one
Dosing and prescription			Dosage: Oral, tab.; increasing dosages from every 2 hours to 1–2 tabs per day. Prescription: Commence 1 tab. every 2 hours for 3 days while reducing number of cigarettes; days 4–12 × 5 tab. per day; days 13–16 × 4 tab. per day; days 17–20 × 3 tab. per day; days 21–25 × 1 to 2 tab. per day; total course approximately 22 days. A meta-analysis of two RCTs comparing cytisine to placebo at longest follow-up for CA produced statistically significant benefits in favor of cytisine (RR 3.98; 95% CI 2.01 to 7.87; total n = 937; $P < 0.0001$); ²³ Quit rates were around 9% in the treatment groups. ²³ Limitations: Limited research data available to determine full efficacy.
Efficacy			Adverse effects: Nausea, restlessness, insomnia, and irritability (23% of one study population compared to 20% in placebo) and gastrointestinal disorders (13% vs. 8% in placebo); ²³ not currently licensed for use in the European Union mainly due to insufficient CA data. ³²
Limitations, adverse events, and precautions			Precautions: Contraindications to cytisine or any component of the tablet.
<p>2. Clonidine</p> 	$C_9H_9Cl_2N_3$	Clonidine (Catapres)	<i>N</i> -(2,6-dichlorophenyl)-4,5-dihydro-1 <i>H</i> -imidazol-2-amine
Dosing and prescription			Dosage: Oral, tab.; 0.1 mg twice daily; transdermal patch once/week or 0.2 µg patch per day. Prescription: One tablet twice daily for between 4 and 12 weeks; transdermal nicotine patch for 12 weeks. A review of six studies found that all trial favored clonidine, yet only one produced a statistically significant result in favor of the intervention arm, with pooled analysis suggesting that clonidine is effective as a smoking cessation treatment (RR 1.63; 95% CI 1.22 to 2.18). ⁴² There is some evidence of clonidine being more effective for women however these results are only based on sub-group analyses and should be interpreted with caution as only one study stratified by gender prior to randomisation. ¹²⁵
Efficacy			Limitations: Efficacy and safety has not been established in the pediatric setting.
Limitations, adverse events, and precautions			Adverse events: Adverse events with clonidine are common with twice as many patients discontinuing use prematurely in comparison to the placebo population in one review of studies ¹²⁶ with 23% to 92% (median 71%) of clonidine subjects and 4% to 61% (median 28%) for subjects taking placebo reporting adverse effects. Symptomatic hypotension was reported in 10% of subjects taking the 0.3 mg dose. Precautions: Contraindications to clonidine or any component of the tablet or patch.



3. Nortriptyline



$C_{19}H_{21}N$

Nortriptyline (Aventyl)

3-(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-ylidene)-N-methyl-1-propanamine

Dosing and prescription

Dosage: Oral, tab.; 25 to 100 mg per day or titrated dosages to serum levels recommended for depression.

Prescription: Titration recommended for one week to one month prior to estimated quit date; first dose suggested at 25 mg, increasing to 75–100 mg after quit date, continuing for 12 weeks.

Efficacy

A Cochrane review of antidepressants identified nine studies examining the effects of nortriptyline for smoking cessation, producing a statistically significant increase in long-term smoking cessation as evidence in the six studies that were able to be pooled (RR 2.03; 95% CI 1.48 to 2.78).²⁵ The three remaining studies that used nortriptyline in conjunction with nicotine replacement therapy showed no evidence of any additional benefit over that of nicotine patch therapy.²⁵

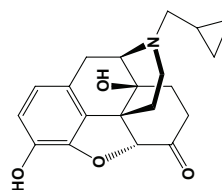
Limitations, adverse events, and precautions

Limitations: Not evaluated in the pediatric setting or for use by pregnant or breastfeeding women.

Adverse events: Drowsiness, dry mouth, light-headedness, blurred vision, urine retention, constipation, and tremor; the most significant adverse event in the reported efficacy studies was collapse/palpitations, which was thought to possibly be caused by treatment.

Precautions: Nortriptyline has the potential for serious side effects but none have been observed in the methodologically rigorous smoking cessation studies reported to date;²⁵ contraindications to nortriptyline or any component of the tablet; nortriptyline can be lethal in high doses.

4. Naltrexone



$C_{20}H_{23}NO_4$

Naltrexone (Narpan TM, Revia TM (injectable formulation under Vivitrol))

17-(cyclopropylmethyl)-4,5 α -epoxy-3,14-dihydroxymorphinan-6-one

Dosing and prescription

Dosage: Oral, tab.; test dose of 25 mg first; dosage between 25 mg to 200 mg.

Prescription: Following test dose multiple treatment plans can be administered including: 50 mg daily Mon-Fri with 100 mg Sat; 100 mg every other day, 150 mg every third day, 100 mg Mon and Wed and 150 mg Fri; 150 mg Mon, 200 mg Tue. Duration varies but recommended dosage up to six months.

Four studies were identified from a Cochrane review of opioid antagonists reporting long-term smoking abstinence (six months or more). All four studies were unable to identify significant differences in quit rates between naltrexone and placebo when pooled in a meta-analysis (OR 1.26; 95% CI 0.80 to 2.01).⁴³

Efficacy

Limitations, adverse events, and precautions

Limitations: Treatment with opiate derivatives for cough, diarrhea and pain may no longer be effective if undergoing treatment with naltrexone for smoking cessation.

Adverse events: Mood swings, light-headedness, dizziness, head-rush following cigarette, nausea, vomiting, diarrhea, cramps, headache, insomnia, anxiety, irritability, and depression.⁴³

Precautions: Can be toxic if high doses are administered over prolonged periods of time.

(Continued)

Table 2. (Continued)

Structural formula	Molecular formula	Substance and (trade name/s)	Chemical name
<p>5. Rimonabant</p>	$C_{22}H_{21}Cl_3N_4O$	Rimonabant (Acomplia, Bethin, Monaslim, Remonabant, Riobant, Slimona, Rimoslim, Zimulti, and Riomont)	5-(4-Chlorophenyl)-1-(2,4-dichloro-phenyl)-4-methyl-N-(piperidin-1-yl)-1H-pyrazole-3-carboxamide
Dosing and prescription		Dosage: Oral, tab.; 5 mg to 20 mg daily.	
Efficacy		Prescription: 10 weeks of treatment with either the 5 mg or 20 mg dose recommended, followed by a maintenance dose of an additional 40 weeks. A Cochrane review of cannabinoid type 1 receptor antagonists identified three studies of rimonabant for inclusion with a 20 mg dose increasing the chances of quitting by one and a half fold (OR 1.50; 95% CI 1.10 to 2.05), though no evidence was detected to support long-term abstinence. ⁴⁴	
Limitations, adverse events and precautions		Limitations: Post-marketing surveillance of rimonabant in 2008 led to Sanofi Aventis withdrawing the product due to links with mental disorders. ⁴⁴ Adverse events: Nausea, upper respiratory tract infections, fatigue, depressed mood, anxiety, suicidal thoughts and nasopharyngitis. ⁴⁴ Precautions: Withdrawn from the market in 2008 due to links with mental disorders.	
<p>6. Lobeline</p>	$C_{22}H_{27}NO_2$	Lobeline (Lobelin, lobeline)	2-((2R,6S)-6-((S)-2-hydroxy-2-phenylethyl)-1-methylpiperidin-2-yl)-1-phenylethanone
Dosing and prescription		Dosage: Oral, tab.; 5 mg with some studies examining 8 mg doses; lozenges 0.5 mg.	
Efficacy		Prescription: Oral tablet twice daily; lozenge used in addition when there is an urge to smoke. A recent Cochrane review identified no studies that met the inclusion criteria to examine the efficacy of lobeline. ⁴⁶ Other reviews have identified studies examining lobeline, though few included studies had control populations and most were of poor methodological design resulting in an inability to draw reliable conclusions about efficacy. ^{127,128}	
Limitations, adverse events, and precautions		Limitations: Lobeline has been banned by the FDA as a smoking cessation aid as of 1993 due to a lack of efficacy data to ascertain safety and effectiveness. ⁴⁹ Adverse events: Gastric side effects, dizziness, nausea, vomiting and throat irritation. ^{47,48} Precautions: Contraindications to lobelia inflate; uterine tone loss observed with use during pregnancy/lactation. ¹²⁹	
<p>7. Silver acetate</p>	$AgC_2H_3O_2$	Silver acetate (Healthbreak, Tabmit)	Acetic acid, silver (1+) salt Silver ethanoate

**Dosing and prescription**

Dosage: Oral, 2.5 mg lozenge, 1.6 mg chewing gum, and sprays to no more than a total of 756 mg.

Prescription: Use lozenge, gum or sprays six times per day for three to six weeks providing the total dose does not exceed 756 mg.

Efficacy

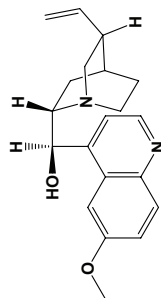
A Cochrane review of two studies found no evidence of effect for silver acetate for smoking cessation, though the upper limit of the confidence interval equates to an absolute increase in the smoking cessation rate of approximately 4%.¹²⁹ Therefore any effect of silver acetate is likely to be less than that observed with nicotine replacement therapy use.¹²⁹

Limitations, adverse events, and precautions

Limitations: Little evidence to support the use of silver acetate.

Adverse events: Main adverse events are those experienced as part of aversive stimulus being unpleasant taste, sensations in the mouth, and gastrointestinal disturbances; if the dose of silver acetate exceeds 756 mg, it can lead to argyria, which is silver deposition in body tissue.¹³⁰

Precautions: Excessive ingestion of silver acetate can lead to argyria;¹³⁰ contraindications to silveracetate or any components of the lozenge, gum, or spray.

8. Nicobrevin

$C_{20}H_{24}N_2O_2 \cdot H_2O$

Combination of quinine, menthyl valerate, camphor and eucalyptus oil (Nicobrevin, Qualaquin)

(8 α ,9R)-6'-Methoxycinchonan-9-ol trihydrate

Dosing and prescription

Dosage: Oral, tab.; 1–3 capsules per day.

Prescription: Four weeks to three months duration; week 1: 1 capsule in the morning and 2 capsules at night; week 2: 1 capsule in the morning and 2 capsules at night; weeks 3 to 12: 1 capsule at night.

A 2009 Cochrane review of nicobrevin for smoking cessation was unable to identify any studies meeting the inclusion criteria for the review.⁵² Efficacy for nicobrevin is unknown.

Limitations: Withdrawal of the product from the UK and other markets in 2011.⁵¹

Limitations, adverse events, and precautions

Adverse events: Primarily gastrointestinal related and including nausea, stomach pains, constipation, loss of appetite, vertigo, heartburn, burning tongue or dry mouth, diarrhea, vision problems (light sensitivity), headaches, insomnia, sweating, biliary colic, and pimples.⁵¹

Precautions: Withdrawal of the product from the UK and other markets in 2011.⁵¹ Not recommended for use during pregnancy.



Other antidepressants

Other antidepressants, including tricyclics (doxepin, imipramine, and nortriptyline), monoamine oxidase inhibitors (moclobemide and selegiline), selective serotonin reuptake inhibitors (fluoxetine, paroxetine, and sertraline), atypical antidepressants (bupropion—mentioned above, tryptophan, and venlafaxine), and extracts (St. John's Wort—*Hypericum perforatum* L.) have also been examined as smoking cessation aids.²⁵ A Cochrane review of antidepressants for smoking cessation identified 66 trials, 49 of which were investigating bupropion and 9 nortriptyline.²⁵ Pooling of bupropion and nortriptyline studies indicated long-term smoking cessation efficacy similar to that of nicotine replacement therapies, while selective serotonin reuptake inhibitors did not.²⁵ As bupropion is discussed above as a first-line smoking cessation aid, a detailed summary of nortriptyline is reported below and in Table 2 as it shows the most evidence of the remaining antidepressants for use as a smoking cessation medication.

Opioid antagonists

Opioid antagonists including naltrexone, buprenorphine, and naloxone are thought to be potentially effective smoking cessation medications as they have the potential to attenuate the rewarding effects of cigarette smoking.⁴³ Smokers report both positive and negative effects associated with smoking with the reinforcing properties of nicotine theorized to be mediated through the release of various neurotransmitters in the brain. There is evidence to suggest that the endogenous opioid system may have a reinforcing role in smoking, while other studies report that the system may also have a mediating role with nicotine withdrawal.⁴³

Naltrexone is a long-acting opioid agonist marketed as a drug that blunts certain effects of narcotics such as heroin, meperidine, morphine, and oxycodone and is also used in the treatment of alcoholism.⁴³ Naltrexone is thought to reduce nicotine cravings by diminishing the activation of mesolimbic dopamine receptors; thus, combination therapy with NRT is thought to offer an additive effect for achieving smoking abstinence due to its different mechanisms of action.⁴³ Further details pertaining to dosing and prescription, efficacy, and adverse events are reported in Table 2.

Cannabinoid type 1 receptor antagonists

Cannabinoid type 1 receptor antagonists such as rimonabant and taranabant are thought to assist smoking cessation by restoring the balance of the endocannabinoid system, which can be disrupted with prolonged exposure to nicotine. Central cannabinoid receptors have been implicated in brain reward function and are thought to play a role in dependence and habituation.⁴⁴ It is thought that rimonabant may work by blocking the central cannabinoid receptors thus restoring the balance and inhibiting nicotine and food cravings.⁴⁴

Rimonabant was originally manufactured to treat obesity and was later proposed as a smoking cessation aid due to its potential for protecting successful quitters from significant post-cessation weight gain. Smoking cessation itself is associated with weight gain, which deters some smokers from making quit attempts; it was hoped that rimonabant would act as a cessation aid for these smokers. Reports of increased levels of suicidal thoughts and depression resulted in withdrawal of rimonabant as a prescription drug in European Countries in 2008.⁴⁴ Further details pertaining to dosing and prescription, efficacy, and adverse events are reported in Table 2.

Lobelia

Lobelia (lobeline) is derived from the Indian tobacco plant *Lobelia inflata* and was first synthesized in the early 1900s when it was classified as a partial nicotinic agonist.⁴⁵ The first documented use of lobeline as a smoking cessation treatment was in the 1930s with a variety of dosages and delivery mechanisms tested since then, including tablet (8 mg as lobeline sulphate), parenteral injection, buffered tablets, and flavored pastilles.⁴⁶ All of these formulations produced varying degrees of adverse effects including gastric side effects, dizziness, nausea, vomiting, and throat irritation.^{47,48} In 1993, the FDA announced a ban on all over the counter smoking cessation products in the United States due to a lack of efficacy data.⁴⁹ Further details pertaining to dosing and prescription, efficacy, and adverse events are reported in Table 2.

Silver acetate

Silver acetate is designed to act as an aversive stimulus to inspire smoking cessation by producing an unpleasant metallic taste when combined with cigarettes.⁵⁰



Smokers are encouraged to use silver acetate products such as lozenges, gums, and sprays so that the act of smoking becomes unpleasant to diminish or stop the urge to smoke.⁵⁰ Efficacy studies have shown a possible small effect of silver acetate, though any benefit observed is less than that produced by nicotine replacement therapy (NRT) and therefore silver acetate is not widely used to promote smoking cessation in the clinical setting with the exception of a possible combination use with NRT.⁵⁰ Further details pertaining to dosing and prescription, efficacy, and adverse events are reported in Table 2.

Nicobrevin

Nicobrevin has been marketed as a smoking cessation aid in 11 countries including the United Kingdom (UK), New Zealand, and Germany, though in 2011 a governmental review found Nicobrevin to be ineffective as a smoking cessation aid and identified several side effects. Thus, the risks of the product outweighed the benefits.⁵¹ This resulted in withdrawal of the product from the UK and other markets. Nicobrevin is a proprietary product containing four active ingredients, including quinine (15 mg, thought to reduce cravings), menthyl valerate (100 mg, acts as a sedative), camphor (10 mg, relieves respiratory congestion and gastrointestinal disturbances), and eucalyptus oil (10 mg, relieves respiratory congestion and gastrointestinal disturbances).⁵² Further details regarding to dosing and prescription, efficacy, and adverse events are reported in Table 2.

Adaptive and novel approaches

New formulations and innovative delivery systems for existing products are in development^{53,54} such as a straw containing nicotine beads, which allows the smoker to place drops of nicotine directly into a beverage,¹⁹ though safety and efficacy data remains unknown. Galenic formulations of varenicline are also being developed, including a controlled release formulation (ClinicalTrials.gov Identifier: NCT00741884 and NCT005227150), a free base solution (NCT00774605), and a free base patch (NCT01234142, NCT01013454, NCT00774605). Tailoring dosages of existing medications such as varenicline and nicotine patches are also being evaluated with administration of up to 5 mg dosages per day of varenicline for smokers not experiencing any

adverse events during the standard first week of titration (NCT01206010) and 42 mg patches for fast metabolizers of nicotine (NCT00956943). Combinations of existing products are also being explored as options for enhancing abstinence rates, with some evidence of success for combining varenicline with nicotine replacement therapy⁵⁵ (NCT01184664) and bupropion⁵⁶ (NCT00935818).

Electronic nicotine delivery systems or 'E-cigarettes' are becoming increasingly popular, particularly among the youth and adolescents as flavored varieties are now being introduced.¹⁸ These small cigarette-shaped electronic devices use a battery-powered heating element, across which a solution of nicotine and propylene glycol (though other solutions are also used) is drawn. This causes the humectant to vaporize and subsequently be inhaled via a small tube as a mist.¹⁷ Despite marketing of the product as a safe alternative to cigarette smoking as it does not contain the harmful ingredients normally found in cigarettes, there are concerns regarding the wide-spread use of these devices, with FDA reports of some tested samples containing toxic substances including nitrosamines and even diethylene glycol.¹⁸ Moreover, many manufacturers still evade government regulation, raising issues around safety and harm reduction.^{17,18} E-cigarettes are currently being trialed for smoking cessation and reduction in smokers who are unwilling to quit (NCT01195597).

Immunotherapy, also referred to as nicotine vaccines, are currently being developed and evaluated through pharmaceutical studies some of which are phase III trials, with the most advanced vaccines expected to be launched in the first years of the 2010 decade.^{54,57} Nicotine is a small molecule that is unable to induce antibodies directed against it.⁵⁸ Immunotherapy is designed to chemically link nicotine to a carrier so that it acts as a hapten.⁵⁹ This allows antibodies to bind to nicotine molecules in the plasma, resulting in a nicotine-antibody complex too large to cross the blood-brain barrier.⁶⁰ Thus, anti-nicotine antibodies change the kinetics of nicotine accumulation in the brain as well as the distribution of nicotine between the brain and other body tissues. A review of four pharmaceutical trials found no long-term smoking cessation success to date,⁶¹ with none of these studies reporting any major side effects (NCT01178346, NCT001102114, NCT01280968).



Alternative medical interventions and the role of pharmacogenomics

To date, alternative therapies such as acupuncture,⁶² hypnotherapy,⁶³ quit and win contests,⁶⁴ and exercise interventions⁶⁵ have, for the most part, been unsuccessful as a smoking cessation aid. There is evidence to support the use of behavior modification and cognitive interventions (including counseling and support programs), and these should be considered in combination with all pharmacological interventions^{24,66} and alternatives for people with contraindications to pharmacotherapies.⁵⁰

Studies are currently underway to test genetic factors that may predict the effectiveness of smoking cessation therapies, including varenicline (NCT01228175) and nicotine replacement therapy (NCT00326781). Additionally, examinations into potential genetic moderators of nicotine, such as the mu opioid receptor gene (OPRM1) A118G polymorphism, are being investigated with the hypothesis that AG/GG genotype smokers will have attenuated subjective-rewarding from intravenous administered nicotine compared to those with AA genotypes (NCT00969137). Specific nicotine biomarkers are also being evaluated to understand how these may influence a smoker's decision to quit (NCT01314001). Using biological indicators as a motivator for smoking cessation is not a new concept, with spirometric 'lung age' used as a persuader in the early to mid-1980s.⁶⁷ It is theorized that providing a smoker with an estimate of their individualized and personalized damage as a result of their tobacco use will motivate them into a quit attempt, though the exact mechanisms by which improvements are obtained remains unclear.⁶⁸

Specific Populations

Young people

Some evidence-based guidelines recommend nicotine replacement therapy as a means of cessation for youth aged 12 to 18 years who are dependent on nicotine (ie, it is not recommended for use by occasional smokers).¹³ Other pharmacological interventions such as varenicline tartrate, however, have not yet specifically been evaluated for safety or efficacy in youth and should be considered with caution. Considering that tobacco use typically begins in childhood or early adolescence⁶⁹ with only 10% of new smokers

initiating the habit after the age of 18 years,⁷⁰ more investigation is needed in this area, particularly to prevent youth from experimenting with tobacco use in the first place.

Gender differences

Research suggests that gender differences exist in relation to nicotine dependence with females tending to smoke less and commence tobacco use at a later age than their male counterparts.⁷¹ Females are also less likely to be tobacco-dependent and subsequently less responsive to nicotine replacement therapy and more responsive to the sensory and behavioral aspects of smoking, which should be considered when considering smoking cessation initiatives.⁷¹ Moreover, clinical research trials suggest that females may be more susceptible to the effects of tobacco use with greater deterioration of lung function, and more severe disease in subjects with chronic obstructive pulmonary disease.⁷²

Hospitalized individuals, those awaiting surgery, and cancer patients

Each medical institution should have their own system for assisting individuals with craving control during times of enforced abstinence such as hospitalization, where smokers may not be able to access outdoor areas to smoke.¹³ This period of enforced abstinence also yields an opportunistic time to offer assistance to achieve long term abstinence. Varenicline tartrate has been trialed in hospitalized patients with tobacco-related illnesses, producing successful results at 12 months follow-up.²⁴ However, if craving control during hospitalization is the primary objective, then nicotine replacement therapy products offer the fastest delivery of nicotine to control cravings.¹³ Additional cessation support should be offered to patients with multi-session treatments and medications continuing for at least one month post-discharge.¹³ Smoking cessation pharmacotherapies for cancer patients are also recommended to assist with craving control during hospitalization or for obtaining long-term abstinence as described above. However, it is important to consider timing of quit attempts for these individuals due to physiological changes following cessation that may affect the metabolism of some drugs and targeting precision and accuracy of dose-volume histogram analyses for radiation therapy.⁷³



Individuals with mental health issues

Pharmacotherapies for smoking cessation have been specifically evaluated in individuals with mental health issues. There are contraindications for some products such as varenicline tartrate and bupropion hydrochloride, which carry boxed warnings from the FDA for people with suicidal ideation, self-injurious behavior, and severe depression.⁷⁴ People with mental health issues who stop smoking while taking medications for their illness should be monitored closely to determine if dosage reductions in their medications are necessary.¹³

Pregnant and breastfeeding women

It is well-known that smoking during pregnancy can have devastating health consequences not only on the mother, but also the unborn child including growth restriction, preterm delivery, and stillbirth.^{75–77} However, there are reports of up to 13% of women in the US⁷⁸ and 18% in France⁷⁹ continuing to smoke up until delivery, with higher prevalence estimates reported amongst indigenous women (45% during pregnancy increasing to 63% post-partum in one Australian population).⁸⁰ Nicotine replacement therapies can be considered for use by pregnant women; however, oral products are preferable to transdermal patches (for example gum, inhalers, micro tabs, and lozenges).¹³ Potential adverse effects are associated with all smoking cessation pharmacotherapies; thus, psychological interventions should be considered as the first line of treatment during pregnancy. There is a lack of evidence regarding safety for the use of other forms of pharmacological smoking cessation therapies during pregnancy or while breastfeeding, though the risks of continued smoking must be weighed against the detrimental health consequences of continuing smoking.

Indigenous populations

A 2012 Cochrane systematic analysis identified four studies evaluating pharmacological interventions for smoking cessation in indigenous populations globally. This review highlighted the paucity of data in this cohort, despite indigenous populations being over-represented in the burden of smoking related morbidity and mortality.⁸¹ The authors were able to conclude that there was some evidence of effectiveness for combined pharmacological and cognitive

initiatives that were culturally-tailored to the population; however, the evidence base is not strong and highlights the need for methodologically rigorous trials to bridge the gap between tobacco-related health disparities between the indigenous and non-indigenous populations. To date, FDA-approved nicotine transdermal patches and bupropion have been evaluated in the indigenous setting, producing some success in smoking abstinence, though studies are still needed to evaluate the safety and efficacy of varenicline tartrate.

Challenges to Consider

Although many believe that the tobacco epidemic is under control, the latest epidemiological evaluations in developing countries suggest otherwise, with an increase in youth tobacco use, particularly amongst girls aged 13–15 years; aggressive tobacco industry marketing campaigns are mostly to blame.⁸² Moreover, the 2012 US Surgeon General's Report states that rates of decline for tobacco smoking amongst youth have now stalled with smokeless tobacco use once again on the rise (Centers for Disease Control and Prevention and US Department of Health and Human Services, 2012). For each person that dies because of a smoking related illness (more than 1,200 per day), at least two youths or young adults are becoming regular smokers.² This increase in youth tobacco use today means an increase in adult daily tobacco users tomorrow. As an example, had the success that was made between 1997 and 2003 been maintained in reducing youth tobacco use, there could potentially be three million fewer smokers in the United States of America today.² On a worldwide scale, tobacco use currently costs governments and consumers hundreds of billions of dollars each year in lost productivity and health care expenditures.⁴ Data on the global impact of tobacco is incomplete; however, it is known to be high, with annual tobacco-related health care costs US\$81 billion in the US, US\$7 billion in Germany, and US\$1 billion in Australia.⁸³ The cost in both human lives and economic resources will continue unless immediate action is taken to assist current tobacco users to quit, particularly those in high-risk populations, such as low- to medium-income countries, indigenous populations, and youth.

A major challenge for all tobacco researchers are smokers that are unwilling to quit. Most research to



date has focused on highly motivated individuals who are eager to attempt cessation. However, recalcitrant smokers who continue to smoke despite the known consequences pose the greatest problems, yet attract the least amount of attention. This may partly explain why smoking cessation pharmacotherapies that succeed within a randomized controlled trial fail to completely translate into the real world setting.¹⁵ Some research projects are underway to examine pharmacotherapeutic options for smokers unwilling to quit (NCT01195597); however, more research is needed. Similarly, insufficient research and clinical attention are given to maintaining abstinence once a person has made a quit attempt. Supporting long-term abstinence can be considered a costly endeavor over the short-term, requiring regular follow-up, prescription of ongoing pharmacological support, and alterations to existing cessation strategies that may require in-depth consultations and discussions with the individual regarding their quitting status. However, the long-term benefits such as improved health, reduced health care costs, lower governmental expenditure, and quality of life should outweigh the short-term output, but more research is needed in this area to encourage policy makers and governments to consider such initiatives.⁸⁴

Implications for Tobacco Cessation in Clinical Practice and Public Policy

Although many people will quit tobacco use unaided, for some, particularly those with greater nicotine addiction, pharmacotherapies may offer the extra support needed to produce a successful long-term quit attempt. Many comprehensive, evidence-based clinical practice guidelines for smoking cessation have been developed. These are regularly updated by local governments and health institutions^{10,12–14,85} and provide recommendations for clinical practice based on the latest available evidence. All of these guidelines recommend smoking cessation pharmacotherapies for smokers addicted to nicotine in addition to some form of regular counseling, as the chances of long-term abstinence are cumulative when used in combination.¹² Efficacy data to date suggest that varenicline tartrate offers the best chance of long-term successful quit attempts,^{44,86} while nicotine replacement therapy is ideally situated for short-term craving control and for individuals with contraindications to

varenicline or bupropion. Advice from health professionals trained in smoking cessation strategies have been shown to increase the number and success of quit attempts among their patients.⁸⁷ Providing brief advice to most smokers (as little as 3 minutes) is more effective than spending longer time with a few patients.¹⁰ Moreover, a Cochrane systematic review evaluating the training of health professionals in smoking cessation techniques found no evidence of additional benefits for interventions of greater duration over brief interventions.⁸⁷ It is important to remember that most patients will relapse multiple times before achieving successful long-term abstinence (known as the transtheoretical model of behavioral change theory), and guidelines for consultations are available to help individuals move from pre-contemplation to contemplation, preparation, action, and maintenance, which will eventually result in a successful quit attempt.⁸⁸

Recalcitrant and continued smoking fails to be classified in many medical circles as an illness, with too many health professionals considering tobacco use as an individual's right and freedom of expression foremost and as an illness second. Thus, implementation of tobacco cessation interventions is hindered. In reality, smokers become biologically dependent on nicotine, and until perceptions and attitudes within the health professions change, tobacco cessation programs will continue to be hampered.

Development of successful pharmacotherapies will do little if translation from research into public policy does not effectively occur. A multi-faceted approach is needed to increase the likelihood of success, which includes public policies such as smoking bans in public places, restrictions on the purchase of tobacco products, increased governmental legislations, and mass media awareness campaigns. Increased taxation of tobacco products has been shown to prompt smoking cessation attempts and reduce existing purchases of tobacco products, with research indicating that regular increases in tobacco tax may further encourage quitting activity.⁸⁹ Governmental policies including tobacco product content regulation with extreme de-nicotinization and smoke pH regulation of cigarettes by tobacco companies have the potential to significantly impact tobacco use by reducing the addictive properties within cigarettes. Such legislation is necessary and overdue in many countries, as absorption of nicotine across biological membranes



largely depends on pH.⁹⁰ Thus, controlling the manufacture of cigarettes will reduce the addictive properties, allowing tobacco users to truly make an informed decision about wanting to smoke. As part of this multifaceted approach, smoking cessation training programs including motivational interviewing techniques for health professionals should be a mandatory component of medical training. Evidence confirms that a lack of training is a barrier to offering advice, as untrained health professionals report that they do not feel they have the skills, ability, or confidence to implement tobacco cessation programs,^{91,92} and yet the patients of health professionals trained in smoking cessation initiatives show statistically and clinically significant improvements in long-term abstinence.⁸⁷

Future Evaluations and Research (Gaps in Current Practice)

Nicotine addiction is a complex psychosocial, behavioral, and biological process that is not well-understood. For global reductions in tobacco use to occur, future researchers need to consider the biological and psychological aspects of nicotine addiction, as well as environmental factors contributing to existing levels of tobacco use prevalence. Particularly, a key area lacking investigation concerns the transportation of smokers from pre-contemplation through to action. Research is needed to identify motivational triggers among these individuals and determine existing barriers to smoking cessation. As technology advances, medical disciplines are moving toward the goal of personalized medicine, with individualized pharmacotherapies based on specific genetic and environmental factors associated with each individual smoker, which may increase the number of quit attempts. Researchers are consistently identifying new genetic properties that influence the pharmacokinetics and pharmacodynamics of nicotine, such as the polymorphism of the CYP2A6 isoenzyme, resulting in a developing field of research that requires attention. The inability of preliminary immunotherapy studies to produce efficacy in long-term smoking abstinence also requires investigation, with potential limitations of existing animal models under the spotlight.⁵⁷

Research into gender variances are needed to understand the impact that biological and cognitive differences have in smoking cessation strategies

between the sexes,⁷¹ particularly with evidence suggesting that females may be more susceptible to the lung-damaging effects of cigarette smoking than males.⁷² Additionally, the steady increase in female tobacco use and reduction in male tobacco use over recent decades needs to be considered in relation to observed gender differences in addiction and health effects resulting from tobacco use.⁹³ Efficacy research examining existing pharmacotherapeutic aids for smoking cessation is also lacking in other specific populations such as youth, individuals with mental health issues, and indigenous populations.

There is a paucity of research to determine the efficacy of pharmacological interventions for smoking cessation in the indigenous setting, while most indigenous populations are overrepresented in the burden of substance-related morbidity and mortality. Current evidence suggests that significant amounts of resources are being invested, particularly by government bodies, yet methodologically rigorous evaluation procedures are significantly lacking.⁸¹ This carries substantial dangers with funding being invested into ineffective programs (which is possible without effective evaluations to determine true treatment efficacy), resulting in an opportunity cost for potentially effective initiatives.⁹⁴ Moreover, the few previous studies report significant shortcomings relating to the effective implementation of research methodology as intended, particularly related to the uptake of pharmacotherapies and behavioral change interventions.^{81,94,95} This indicates that the next phase of tobacco-related research for the indigenous setting should be qualitative in nature to examine where and why difficulties in existing research projects have occurred and to determine how they can be overcome.

Qualitative research has been underutilized in the tobacco arena mostly due to concerns regarding methodological rigor and ambiguity in analyses resulting in qualitative analyses that lack strength.⁹⁶ However, because the nature of nicotine abuse is two-fold and includes physiological addiction to nicotine and behavioral components including habit, a mixed method approach (combination of qualitative and quantitative research) should be considered. This will facilitate more thorough evaluation of areas where existing evidence is lacking, particularly for the specific populations as listed above



in which existing smoking cessation approaches produce little effect.^{81,97–99} Such process evaluations, particularly for key components such as context and fidelity, can provide essential information to intervention studies across all settings.

Conclusions

The most common pharmacological aids for smoking cessation include nicotine replacement therapy, varenicline tartrate, and bupropion hydrochloride, with varenicline producing the greatest chance of long-term abstinence. Clinical practice guidelines recommend the use of counseling programs in conjunction with pharmacological interventions, with regular follow-up and continued support to improve chances of success. Emerging pharmacotherapies include adaptations to existing treatments, evaluation of medications used to treat other conditions, and the use of genetic and biological factors that have the potential to influence the mechanisms of nicotine addiction. A primary objective of future research should be to develop initiatives, which may include high efficacy pharmacotherapies, to assist smokers who are not willing or report being unable to quit. Moreover, for smoking cessation pharmacotherapies to be successful, effective implementation strategies must be clearly established with a multi-faceted approach that includes instigation of public policies, tobacco taxes, adequate support structures, and easy access to low-cost medications with high treatment efficacy.

Author Contributions

Conceived and designed the manuscript: KC, MB, TR, RT. Analysed the data: KC, MB, TR, RT, AE. Wrote the first draft of the manuscript: KC. Contributed to the writing of the manuscript: KC, MB, TR, RT, AE, MP, BS. Agree with the manuscript results and conclusions: KC, MB, TR, RT, AE, MP, BS. Jointly developed the arguments and structure for the paper: KC, MB, TR, RT, AE, MP, BS. Made critical revisions and approved final version: KC, MB, TR, RT, AE, MP, BS. All authors reviewed and approved of the final manuscript.

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Disclosures and Ethics

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Chapter 11.

Smoking cessation interventions for lung cancer patients

(Literature review)

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With identification of all smoking cessation interventions available for clinical use in the last chapter, this publication aims to summarise smoking cessation options for patients diagnosed with lung cancer. A sense of futility often exists amongst these individuals. Coupled with habits formed from many years of smoking and the perception that it is too late for any worthwhile health benefits to come from quitting, people with lung cancer are among the most difficult in which to facilitate long-term smoking abstinence. Additionally, people with lung cancer may require further support owing to the stigma that present or past smoking imposes. From a clinical practice perspective, attempting to quit smoking whilst simultaneously undergoing cancer treatment may also have a confounding effect that needs to be considered. This is of particular concern in terms of the impact of smoking status and smoking cessation on the effectiveness and side effects of lung cancer treatments.

Evidence is summarised about the benefits of smoking cessation in lung cancer patients including discussion about the effects of continued smoking, impact on cancer treatment, impact of smoking cessation and time of quitting. The various methods for cessation among lung cancer patients including health professional-led interventions, cognitive and behavioural interventions, pharmacological interventions and alternative approaches are described in detail. A discussion about the various challenges and lung cancer risk factors for high risk populations, Indigenous peoples, youth and women are presented. To conclude, a dialogue relating to unmet needs, possible future developments and future perspectives for smoking cessation amongst lung cancer patients summarise the available evidence.

This literature review was requested and invited by editors of this journal to establish an evidence base and summarise in detail the most effective options for smoking cessation among lung cancer patients. The work establishes a body of evidence for successful smoking cessation amongst recalcitrant and unwell smokers who are typically unmotivated to quit and provides practical information for use in standard clinical care.

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Chapter 12.

Is cancer risk still reduced if you give up smoking in later life?

(Literature review)

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Although effective smoking cessation options are available to help even the most recalcitrant of tobacco users quit, the benefits to quitting are not always perceived by the smoker. This paper attempts to examine and quantify the benefits of smoking cessation in later life on reducing cancer risk for different types of cancer.

Regardless of age smoking cessation is known to have substantial health benefits, even after a short period of time. With reductions in blood pressure, blood carbon monoxide levels, risk of wound infection and respiratory complications post-surgery, risk of coronary heart disease and stroke and improvements in circulation, lung function, energy and immune response, as highlighted in Chapter 11. Yet the possibility that smoking cessation can decrease the risk of cancers or even reverse the likelihood for risk of development among some cancers is not as well known. This becomes even more pressing among smokers of advanced age who have consumed tobacco for a large period of their lives. It is within this population that a sense of fatality often impedes any attempts to successfully implement smoking cessation strategies. Therefore a clear understanding of the benefits and risk reductions of cancer development following smoking cessation later in life may provide a useful clinical aid for doctors and healthcare workers when suggesting quit attempts amongst older patients. Indeed there is a potential for this information, if presented in the right context, to improve the knowledge base amongst older smokers and thus influence their behaviour.

As such this article is intended to systematically consolidate the available evidence from experimental and epidemiological studies to determine the impact smoking cessation has on particular cancers. As the effects of tobacco use on some cancers are less researched than others, the level of evidence has been judged using the International Agency of Research on Cancer criteria. A summary of available evidence linking individual cancers to tobacco use are described, followed by an evidence based description of cancer risk reduction after smoking cessation in later years of life. Based on this evidence some recommendations for future research is provided, suggesting that the next phase of investigation should consider tailoring smoking cessation packages to particular populations of smokers. For example, older recalcitrant tobacco users who have more difficulty quitting than other smokers, often due to years of habits and social practices firmly establishing tobacco use as the norm.

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Chapter 13.

Smoking Termination Opportunity for inPatients (STOP): superiority of a course of varenicline tartrate plus counselling over counselling alone for smoking cessation: a 12-month randomised controlled trial for inpatients

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The last three chapters provided an evidence base that has established the efficacy of available smoking cessation pharmacotherapies, identifying varenicline tartrate to be the most effective; Chapter 11 identified that quitting smoking can be safe and effective even when undergoing treatment for a serious tobacco-related illness such as lung cancer; and Chapter 12 has identified that positive health benefits are possible with smoking cessation even in later life. With this in mind, a smoking cessation intervention among hospitalised smokers admitted due to tobacco-related illnesses such as cardiovascular, vascular, lung diseases and stroke should be evaluated. Hospitalised smokers are amongst the most recalcitrant and often have great difficulty in maintaining long-term quit attempts. Typically they carry a large burden of disease, are very costly to the health system and costly to society as a whole through lost productivity and absenteeism.

All of the available literature evaluating the effectiveness of varenicline tartrate, the leading smoking cessation aid, have to date occurred in the outpatient setting among healthy volunteers and they have all been funded by Pfizer, the drug company that owns varenicline tartrate. This piece of original research presented in Chapter 13 has made a significant contribution to the literature by being the first known methodologically rigorous publication to evaluate the use of varenicline tartrate among hospitalised smokers, following admission due to an acute tobacco-related illness. A statistically and clinically significant benefit for the primary outcome of continuous abstinence at 12 months follow-up was observed in favour of the intervention arm (31.1% abstinent), which consisted of a 12-week course of varenicline tartrate plus Quitline counselling over the phone, compared to the same Quitline counselling alone for the control population (21.4% abstinent; $p=0.03$). The combined use of varenicline tartrate plus Quitline telephone counselling when initiated in the inpatient setting is a novel and effective approach in aiding long-term smoking abstinence among intractable smokers.

The STOP trial is the first study to provide a real world assessment of the package of varenicline tartrate plus Quitline counselling in the inpatient setting, demonstrating significant efficacy in aiding long-term smoking abstinence. This research provides evidence to support our recommendation that smoking cessation interventions using varenicline tartrate plus telephone counselling be used for all inpatients where admissions result from smoking-related diseases. This best practice treatment is currently being underutilised.

Smith, B.J., Carson, K.V., Brinn, M.P., Labiszewski, N.A., Peters, M.J., Fitridge, R., Koblar, S.A., Jannes, J., Veale, A.J., Goldsworthy, S., Litt, J., Edwards, D. & Esterman, A.J. (2013). Smoking Termination Opportunity for inPatients (STOP): superiority of a course of varenicline tartrate plus counselling over counselling alone for smoking cessation: a 12-month randomised controlled trial for inpatients. *Thorax*, 68(5), 485-486.

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Chapter 14.

Safety of a course of varenicline tartrate and counselling over counselling alone for smoking cessation: a 52-week randomised controlled trial for inpatients

Kristin V Carson¹, Brian J Smith¹, Malcolm P Brinn¹, Matthew J Peters², Robert Fittridge³, Simon A Koblar⁴, Jim Jannes⁵, Kuljit Singh⁶, Antony J Veale¹, Sharon J Goldsworthy⁷, John Litt⁸, David Edwards⁹, Khin Hnin¹, Adrian J Esterman¹⁰

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Chapter 13 proved that varenicline tartrate plus Quitline counselling was effective in aiding continuous smoking abstinence at 12-months follow-up among inpatients admitted with tobacco related illnesses. However, studies of healthy volunteers regarding the safety of varenicline tartrate found an increased risk of developing neuropsychiatric symptoms, cardiovascular events, skin conditions including Steven Johnson's syndrome and other problems. As such, it is necessary that varenicline tartrate undergo a thorough safety evaluation if it is to be considered as a viable treatment option for smoking cessation in the acute hospital setting when patients are already vulnerable and feeling unwell.

Based on the available literature the most common side effect experienced by users of varenicline tartrate are nausea and abnormal dreams, as identified in studies of healthy volunteers (146-148). However, this population profile is not generalisable to the individuals included in the STOP trial as the smokers in our population would have been excluded from these efficacy studies due to recent hospitalisation and unstable health status. Targeting hospitalised smokers does provide an opportunity for increased tobacco cessation but simultaneously there is a risk of increased adverse events. With the addition of new pharmacotherapies, drug-drug interactions, poly-pharmacy and the body attempting to adapt following a serious illness episode, there are consequently greater numbers of concerns around development of varenicline tartrate-related adverse events.

In the STOP trial varenicline tartrate was found to be well tolerated with no increase in adverse events above those reported in outpatient studies. The most common self-reported adverse event was transient nausea, identified in 16.3% of intervention subjects compared to 1.5% in the control population. There were no significant differences observed between groups for development or exacerbation of neuropsychiatric symptoms, cardiovascular events or skin conditions, despite the fact that 50% of intervention subjects and 49.5% of control subjects were recruited following admission due to cardiovascular events. This trial is the first known original research investigation to evaluate the safety and tolerability of varenicline tartrate when used in combination with counselling among smokers in the acute setting following admission to hospital due to a serious tobacco-related illness. The findings confirm that varenicline tartrate is well tolerated with adverse event frequency similar to or less than those reported in outpatient healthy volunteer studies (147-150). Craving and anxiety were significantly reduced after the first week of varenicline tartrate treatment compared to control subjects. This suggests that varenicline tartrate can assist in craving control and reducing levels of anxiety during a time often associated with increased levels of stress and fear.

Carson, K.V., Smith, B.J., Brinn, M.P., Peters, M.J., Fitridge, R., Koblar, S.A., Jannes, J., Singh, K., Veale, A.J., Goldsworthy, S., Litt, J., Edwards, D., Hnin, K.M. & Esterman, A.J. (2014). Safety of varenicline tartrate and counselling versus counselling alone for smoking cessation: A randomised controlled trial for inpatients (STOP study).

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Chapter 15.

Training health professionals in smoking cessation

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Building on the evidence base and concepts presented within the publications and manuscripts from the preceding 11 chapters, this publication considers the use of training health professionals in smoking cessation as a means of addressing some of the barriers to successful quit attempts. Previous chapters highlighted the lack of health professional confidence to deliver smoking cessation advice, limited knowledge about the latest treatment options and a lack of skills to deliver interventions for Aboriginal and TSI patients in particular. Yet these issues are not limited to the Indigenous setting and are uniformly recognised as a barrier to effective smoking cessation delivery within the international literature (151, 152). Subsequently, this impacts the quality of care provided to current smokers who are interested in quitting. The training approach has the potential to provide a cost-effective means by which a population wide reduction in tobacco prevalence could occur.

Health professionals, which include doctors, nurses and dentists, are often seen as reliable and influential sources of information. They are also at the forefront of tobacco epidemics as they consult millions of people and are in a prime position to encourage patients to quit smoking (90). As such, training of health professionals in these fundamental skills may provide an opportunistic means of tackling smoking on a much broader level than focusing on the individual smoker.

The meta-analysis showed statistically significant results not only for improving health professional care delivery, but also with successful long-term quit attempts amongst the patients of health professionals who received the training intervention. An interesting and important finding from this review is that health professionals who were trained using only a single session and in a group setting were more likely to have patients quit smoking as those being trained with multiple delivery sessions and with one-on-one training. On a similar point, duration of training between 40 minutes and two hours was just as effective if not more so than studies employing interventions for greater than two hours in duration. This suggests that short intervention studies may be all that is needed to effectively change practice, providing the correct content and delivery mechanisms are employed. Importantly, training programs can be resource intensive to establish and simply providing programs for health care professionals, without addressing the constraints imposed by the conditions in which they practise, is unlikely to be a wise use of health care resources.

Training health professionals in smoking cessation (Review)

Carson KV, Verbiest MEA, Crone MR, Brinn MP, Esterman AJ, Assendelft WJJ, Smith BJ



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[Intervention Review]

Training health professionals in smoking cessation

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ABSTRACT

Background

Cigarette smoking is one of the leading causes of preventable death world wide. There is good evidence that brief interventions from health professionals can increase smoking cessation attempts. A number of trials have examined whether skills training for health professionals can lead them to have greater success in helping their patients who smoke.

Objectives

To determine the effectiveness of training health care professionals in the delivery of smoking cessation interventions to their patients, and to assess the additional effects of training characteristics such as intervention content, delivery method and intensity.

Search methods

The Cochrane Tobacco Addiction Group's Specialised Register, electronic databases and the bibliographies of identified studies were searched and raw data was requested from study authors where needed. Searches were updated in March 2012.

Selection criteria

Randomized trials in which the intervention was training of health care professionals in smoking cessation. Trials were considered if they reported outcomes for patient smoking at least six months after the intervention. Process outcomes needed to be reported, however trials that reported effects only on process outcomes and not smoking behaviour were excluded.

Data collection and analysis

Information relating to the characteristics of each included study for interventions, participants, outcomes and methods were extracted by two independent reviewers. Studies were combined in a meta-analysis where possible and reported in narrative synthesis in text and table.

Main results

Of seventeen included studies, thirteen found no evidence of an effect for continuous smoking abstinence following the intervention. Meta-analysis of 14 studies for point prevalence of smoking produced a statistically and clinically significant effect in favour of the intervention (OR 1.36, 95% CI 1.20 to 1.55, $p=0.004$). Meta-analysis of eight studies that reported continuous abstinence was also statistically significant (OR 1.60, 95% CI 1.26 to 2.03, $p=0.03$).

Healthcare professionals who had received training were more likely to perform tasks of smoking cessation than untrained controls, including: asking patients to set a quit date ($p<0.0001$), make follow-up appointments ($p<0.00001$), counselling of smokers ($p<0.00001$), provision of self-help material ($p<0.0001$) and prescription of a quit date ($p<0.00001$). No evidence of an effect was observed for the provision of nicotine gum/replacement therapy.

Authors' conclusions

Training health professionals to provide smoking cessation interventions had a measurable effect on the point prevalence of smoking, continuous abstinence and professional performance. The one exception was the provision of nicotine gum or replacement therapy, which did not differ between groups.

PLAIN LANGUAGE SUMMARY

Can training health professionals to ask people if they smoke increase offers of advice and help patients quit?

Training programs are used to encourage health professionals to ask their patients if they smoke, and then offer advice to help them quit. The review of 17 trials found that these training programs help health professionals to identify smokers and increase the number of people who quit smoking. The programs also increase the number of people offered advice and support for quitting by health professionals.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Training health professionals for smoking cessation						
Patient or population: Smokers treated by health professionals Intervention: Training						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Training health professionals				
Point prevalence of smoking cessation self-report and some biologically validated Follow-up: 6 to 14 months	78 per 1000	107 per 1000 (88 to 131)	OR 1.41 (1.13 to 1.77)	13459 (14 studies)	⊕⊕⊕○ moderate ^{1,2}	
Continuous smoking abstinence self-report and some biologically validated Follow-up: 6 to 14 months	27 per 1000	42 per 1000 (28 to 62)	OR 1.60 (1.26 to 2.03)	9443 (8 studies)	⊕⊕⊕○ moderate ^{1,2}	
Number of smokers counselled self-report Follow-up: 6 to 48 months	465 per 1000	664 per 1000 (578 to 739)	OR 2.28 (1.58 to 3.27)	8531 (14 studies)	⊕⊕○○ low ^{1,3}	

Patients asked to make a follow-up appointment self-report Follow-up: 6 to 12 months	166 per 1000	400 per 1000 (233 to 593)	OR 3.34 (1.52 to 7.30)	3114 (7 studies)	⊕○○○ very low ^{1,2,3}
Number of smokers receiving self-help material self-report Follow-up: 6 to 48 months	134 per 1000	351 per 1000 (227 to 500)	OR 3.51 (1.90 to 6.47)	4925 (9 studies)	⊕○○○ very low ^{1,2,3}
Number of smokers receiving nicotine gum/replacement therapy self-report Follow-up: 12 to 48 months	312 per 1000	416 per 1000 (283 to 563)	OR 1.57 (0.87 to 2.84)	5073 (9 studies)	⊕⊕○○ low ^{1,3}

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **OR:** Odds ratio

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

¹ Unclear methods of sequence generation and allocation concealment in the majority of studies and all studies had inadequate blinding of participants

² Wide confidence intervals around the estimate of effect

³ Significantly large amounts of heterogeneity were observed ($I^2 > 90\%$)

BACKGROUND

Description of the condition

Every year approximately 5.4 million people die from tobacco-related diseases, translating to 1 in every 10 deaths among adults world wide (Mathers 2006; WHO 2008). Approximately 80% of those deaths are from people living in less developed countries and by 2030 this figure will increase to more than 8 million per year if no action is taken (Mathers 2006). If current trends continue on this trajectory, an estimated 500 million people alive today will be killed by tobacco. In the 27 countries that form the European Union, over 25% of cancer deaths and 15% of all deaths can be attributed to smoking (European Commission 2004). Smoked tobacco is known to cause up to 90% of all lung cancers and is a significant risk factor for strokes and fatal heart attacks. In addition, tobacco use is linked to the development and treatment of many oral diseases (Bergstrom 2000; Balaji 2008; Petersen 2009) including oral cancer, delayed wound healing and periodontitis contributing to loss of teeth and edentulism (Tomar 2000; Mohammad 2006; Gordon 2009).

Description of the intervention

Health professionals are at the forefront of tobacco epidemics as they consult millions of people and can encourage them to quit smoking (WHO 2005; Zwar 2009). In developed countries, more than 80% of the population will see a primary care physician at least once a year, with doctors perceived to be influential sources of information on smoking cessation (Mullins 1999; Richmond 1999; Zwar 2009). It has been reported that most dentists and dental hygienists believe the lack of skills and training is a significant barrier to effectively providing tobacco cessation interventions into routine care (Gelskey 2002; Warnakulasuriya 2002; Gordon 2009; Rosseel 2009).

Providing training in smoking cessation care is one possible method for increasing the number and quality of delivered interventions by primary care health professionals, and a variety of training methods are available (Anderson 2004; Twardella 2004; Stead 2009). To date, individual studies have shown an effect of training on physician's activities, but there have been doubts about the extent to which this translates into changes in patient behaviour and actual smoking abstinence (Kottke 1989; Cummings 1989a; Cummings 1989b). Training health professionals to deliver smoking cessation messages has been known to increase the frequency with which interventions are offered to patients in the clinical context (Thorogood 2006).

How the intervention might work

Provision of advice and support to smokers by healthcare professionals in primary care settings has been shown to be the most cost-effective preventive service and has a small but significant effect on cessation rates (Maciosek 2006; Solberg 2006; Stead 2008). Even though these rates appear low from the perspective of many clinicians, they could translate into a substantial public health benefit if consistently provided, as approximately 70-80% of adults have contact with a health care practitioner, usually in primary care, at least once each year (Mullins 1999; Richmond 1999; Hung 2009; Zwar 2009). It is therefore disappointing that despite ongoing developments in this field worldwide, the number of patients who report receiving advice on smoking cessation from health professionals is still low (CDC 2007).

Why it is important to do this review

On a worldwide scale, tobacco use currently costs hundreds of billions of dollars each year (WHO 2008). Data on the global impact of tobacco is incomplete, however it is known to be high, with annual tobacco related health care costs being US\$81 billion for the USA, US\$7 billion for Germany and US\$1 billion for Australia (Guindon 2008).

The first systematic review on this topic was published over a decade ago and showed that training health professionals to provide smoking cessation interventions had a positive effect on professional performance. However, there was no strong evidence that it changed smoking behavior of patients (Lancaster 2008). Since then, a number of new trials have examined whether specific skills training for health professionals leads them to overcome frequently mentioned barriers and to have greater success in helping their patients to quit smoking.

We therefore systematically identified and reviewed the evidence from new published randomized controlled trials that have studied the effects of training and supporting health care professionals in providing smoking cessation advice. Furthermore, we assessed the effects of training characteristics, such as the content, setting, and intensity.

OBJECTIVES

The aim of this review was to assess the effectiveness of training health care professionals to deliver smoking cessation interventions to their patients, and to assess the effects of training characteristics (such as contents, setting, delivery and intensity).

METHODS

Criteria for considering studies for this review

Types of studies

We considered only randomized controlled trials.

Types of participants

We considered trials in which the unit of randomization was a healthcare practitioner or practice, and that reported the effects on patients who were smokers.

Types of interventions

We considered interventions in which health care professionals were trained in methods to promote smoking cessation among their patients. To be included in the review studies had to have allocated healthcare professionals to at least two groups (including one which received some form of training) by a formal randomization process. Studies that used historical controls were excluded. We included studies that compared a trained group to an untrained control group, and studies that examined the effectiveness of adding prompts and reminders to training.

Types of outcome measures

Primary outcomes

The primary outcome measure was abstinence from smoking six months or more after the start of the intervention, assessed as:

- point prevalence (defined as not smoking at a set period (e.g., seven days) prior to the follow-up), and
- continuous abstinence (defined as not smoking for an extended/prolonged period at follow-up)

The definition of point prevalence and continuous abstinence for each study can be found in the 'Outcomes' section of the [Characteristics of included studies](#) table.

The strictest available criteria to define abstinence were used. In studies where biochemical validation of cessation was available, only those participants who met the criteria for biochemically confirmed abstinence were regarded as being abstinent. Those lost to follow-up were regarded as being continuing smokers.

Secondary outcomes

Secondary 'patient level' outcome measures included process variables such as the number of smokers who were:

- asked to set a date for stopping (quit date)
- given a follow-up appointment
- counselled
- given self-help materials
- offered nicotine gum/replacement therapy
- prescribed a quit date, and
- cost effectiveness for interventions.

Secondary 'physician level' outcome measures include the number of referrals made (to local smoking cessation services).

To be included in the review, studies had to assess changes in the long term smoking behaviour of patients. Studies which only assessed the effect of training on the consultation process were excluded.

Search methods for identification of studies

We identified potentially relevant study reports from the Cochrane Tobacco Addiction Group Specialised Register. This Register includes reports of trials and other evaluations of interventions for smoking cessation and prevention, based on regular highly sensitive searches of multiple electronic databases including MEDLINE, EMBASE, PsycINFO and CENTRAL, and hand-searches of conference abstracts. For details of search strategies and dates see the [Cochrane Tobacco Addiction Group Module](#) in the Cochrane Library. The most recent search of the Register was in March 2012. Records were identified from the Register as potentially relevant if they included the free text terms 'training' or 'trained' or the MeSH keywords 'Education, Premedical' or 'Education, Professional' or 'Inservice Training' or 'Physician's Practice Patterns' or 'Dentist's Practice Patterns' or 'Delivery of Health Care' or 'Comprehensive Health Care' or 'Critical Pathways' or 'Disease Management' or the EMBASE indexing terms 'clinical education' or 'continuing education provider' or 'continuing education' or 'medical education' as indexing terms. We conducted an additional search of MEDLINE (via OVID, to 2012 Feb week 5) exploding the same MeSH keywords in combination with the terms for smoking cessation and controlled trials used in the regular search of MEDLINE for the Specialised Register. See [Appendix 1](#) for this strategy. Records included definite and probable reports of randomized trials, and reviews.

Data collection and analysis

Selection of studies

Two reviewers (KC, MV) prescreened all study reports identified from the Specialised Register (limited to papers published after 1999 for this update). Articles were rejected if the title and/or abstract did not meet the inclusion/exclusion criteria. In instances where the study could not be categorically rejected, the full text was obtained and screened. Reference lists of screened articles were scanned for other potentially relevant articles.

Two reviewers then independently assessed the relevant studies for inclusion (KC and MV), with discrepancies resolved by consensus. Studies which were excluded though relevant to the review topic are listed in the [Characteristics of excluded studies](#) table, with the reason for their exclusion described.

Data extraction and management

A combination of two reviewers independently extracted data from published reports (KC, MV, and MB). Disagreements were resolved by referral to a third party. No attempt was made to blind any of these reviewers to either the results of the primary studies or the intervention the subjects received.

The data extraction process identified information on the following design characteristics:

- Country and setting of study
- Description of training delivery method, duration, content
- Number of therapists (intervention, control, post randomization dropouts)
- Number of patient participants (intervention, control, losses to follow-up in each condition), method of identification/enrolment
- Number of patients per therapist (range and/or average)
- Description of intervention and control conditions
- Definition of abstinence for smoking cessation outcome(s), duration of follow-up, method of biochemical validation if used
- Secondary outcomes reported

Data was extracted and entered into Review Manager for the following outcome variables, where reported:

- Point prevalence abstinence at longest follow-up (preferred outcome for meta-analysis is continuous or sustained abstinence)
- Continuous or sustained smoking abstinence at longest follow-up
- Cost effectiveness analysis for intervention

We also extracted data on process outcomes where reported. These included patient reported or documented delivery of interventions, such as: setting a quit date, making a follow-up appointment, number of smokers counselled, provision of self-help materials, prescription of nicotine replacement therapy and/or prescription of a quit date.

Assessment of risk of bias in included studies

Two reviewers independently assessed the full text versions for all included papers for risk of bias using the Cochrane Handbook guidelines, using a domain-based evaluation (Higgins 2009). In addition, extra criteria developed by the Cochrane EPOC Group (EPOC 2009) were used to address potential sources of bias related to clustering effects. These domains included sequence generation, allocation concealment, blinding for participants, blinding for outcome assessors, incomplete outcome data, selective reporting, imbalance of outcome measures at baseline, comparability of intervention and control group characteristics at baseline, protection against contamination, selective recruitment of participants and any other sources of potential biases. The risk of bias was assessed for each domain as 'high risk', 'low risk', and 'unclear risk' (using the guidelines from Table 8.5.c of the Cochrane Handbook, Higgins 2009). Two of three reviewers (KC, MV or

MB) independently assessed the included studies for risk of bias. Conflicts were resolved by consensus or by referring to a third party if disagreement persisted.

Unit of analysis issues

The trials included in the review used cluster randomization. Outcomes relate to individual patients whilst allocation to the intervention is by provider or practice, and ignoring this may introduce unit of analysis errors. Using statistical methods which assume for example that all patients' chances of quitting are independent ignores the possible similarity between outcomes for patients seen by the same provider. This may underestimate standard errors and give misleadingly narrow confidence intervals, leading to the possibility of a type 1 error (Altman 1997). All trials were expected to be cluster randomized studies, with analysis performed at the level of individuals whilst accounting for the clustering in the data. This was performed by using a random effects model for pooled meta-analysis as recommended in the Cochrane Handbook (Chapter 16.3.3, Higgins 2009) and checked by a statistician (AE). For those studies which did not adjust for clustering the actual sample size was replaced with the effective sample size (ESS), calculated using a $\rho = 0.02$ as per Campbell 2000. Trials may use a variety of statistical methods to investigate or compensate for clustering; we have recorded whether studies used these and whether the significance of any effect was altered. In instances where the studies appeared homogenous via a combination of the statistical I^2 test in addition to homogeneity expressed in the visual inspection of a Funnel plot we meta-analysed using a fixed effect model. However in the presence of significant heterogeneity (as defined below under 'Data Synthesis') the random effects model was used. In the case of multi-arm trials each pair-wise comparison was included separately, but with shared intervention groups divided out approximately evenly among the comparators. However, if the intervention groups were deemed similar enough to be pooled, the groups were combined using appropriate formulas in the Cochrane Handbook (Table 7.7.a for continuous data and Chapter 16.5.4 for dichotomous data, Higgins 2009).

Dealing with missing data

Missing participant data were evaluated on an available case analysis basis as described in Chapter 16.2.2 of the Cochrane Handbook (Higgins 2009). Missing standard deviations were addressed by imputing data from the studies within the same meta-analysis or from a different meta-analysis as long as these use the same measurement scale, have the same degree of measurement error and the same time periods (between baseline and final value measurement, as per Chapter 16.1.3.2 of the Cochrane Handbook, Higgins 2009). Where statistics essential for analysis were missing (e.g. group means and standard deviations for both groups are not reported) and could not be calculated from other data, we attempted to contact the authors to obtain data. Loss of participants

that occurred prior to performance of baseline measurements was assumed to have no effect on the eventual outcome data of the study. Losses after the baseline measurement were taken were assessed and discussed. Studies that had more than 30% attrition (i.e., deaths and withdrawals) were reported in text only and excluded from the meta-analysis.

We made an attempt to contact all authors for verification of methodological quality, classification of the intervention(s) and outcomes data. We attempted to contact the second author if we were unsuccessful in contacting the first author.

Assessment of heterogeneity

The review was expected to have some heterogeneity due to factors such as differing characteristics of clinics, practices and medical surgeries, differences in intervention characteristics and varying measurement tools used to assess outcomes. The Chi² and I² statistic (Higgins 2009) were used to quantify inconsistency across studies. The presence of significant heterogeneity was further explored through subgroup analyses. These were conducted for:

1. 'treatment type' (e.g., counselling alone, counselling plus nicotine replacement therapy, counselling plus request for additional appointments, etc.)
2. 'treatment intensity' (number of sessions)
3. 'treatment intensity' (total exposure)
4. 'mode of delivery' (e.g., face-to-face, group sessions or both)
5. 'behavioural change techniques' (e.g., prompting, providing feedback, use of behavioural change theories)
6. 'type of professional being trained' (e.g., dentist, doctor, health care worker etc.)
7. 'length of follow-up' (i.e., ≥ 6 to ≤ 9 months, >9 to ≤ 12 months, >12 to ≤ 24 months), and
8. 'risk of bias' (i.e., high risk of bias for: ≤ 2 domains, 3 - 5 domains, 6 - 8 domains or ≥ 9 domains).

The likelihood of false positive results among subgroup analyses increase with the number of potential effect modifiers being investigated (Higgins 2009). As such we have adjusted these analyses using a Holm-Bonferroni method (Holm 1979) using $\alpha = 0.05$.

Assessment of reporting biases

With the inclusion of more than ten included studies, potential reporting biases were assessed using a funnel plot. Asymmetry in the plot could be attributed to publication bias, but may well be due to true heterogeneity, poor methodological design or artefact. Contour lines corresponding to perceived milestones of statistical significance ($p = 0.01, 0.05, 0.1$ etc.) were applied to funnel plots,

which may help to differentiate between asymmetry due to publication bias from that due to other factors (Higgins 2009).

Data synthesis

1. For dichotomous outcomes the fixed effect model with an odds ratio (OR) was calculated with 95% confidence interval (CI), which was synthesised using inverse variance. However for outcomes with greater than 10 included studies a test for heterogeneity was conducted using a combination of two methods. If heterogeneity was found (defined as the I² test $\geq 60\%$ and visual inspection of the funnel plot indicating no clustering of large or small studies) the random effects model was used in place of the fixed effect model, as suggested by the Cochrane Handbook (Section 9.5.2 and 9.5.3, Higgins 2009). Reasons for heterogeneity are further explored in the discussion. When studies appeared homogeneous, the meta-analysis was redone using the fixed effect model.
2. For continuous outcomes, a fixed effect model with a weighted mean difference (WMD) or standardised mean difference (SMD) with 95% confidence intervals were calculated as appropriate. However, in the presence of significant heterogeneity (as defined above) the random effects model was used in place of the fixed effect model.

Sensitivity analysis

Sensitivity analysis was conducted on studies with an unclear or high risk of bias for sequence generation and/or allocation concealment.

We include the Tobacco Addiction Group glossary of tobacco-specific terms (Appendix 2).

RESULTS

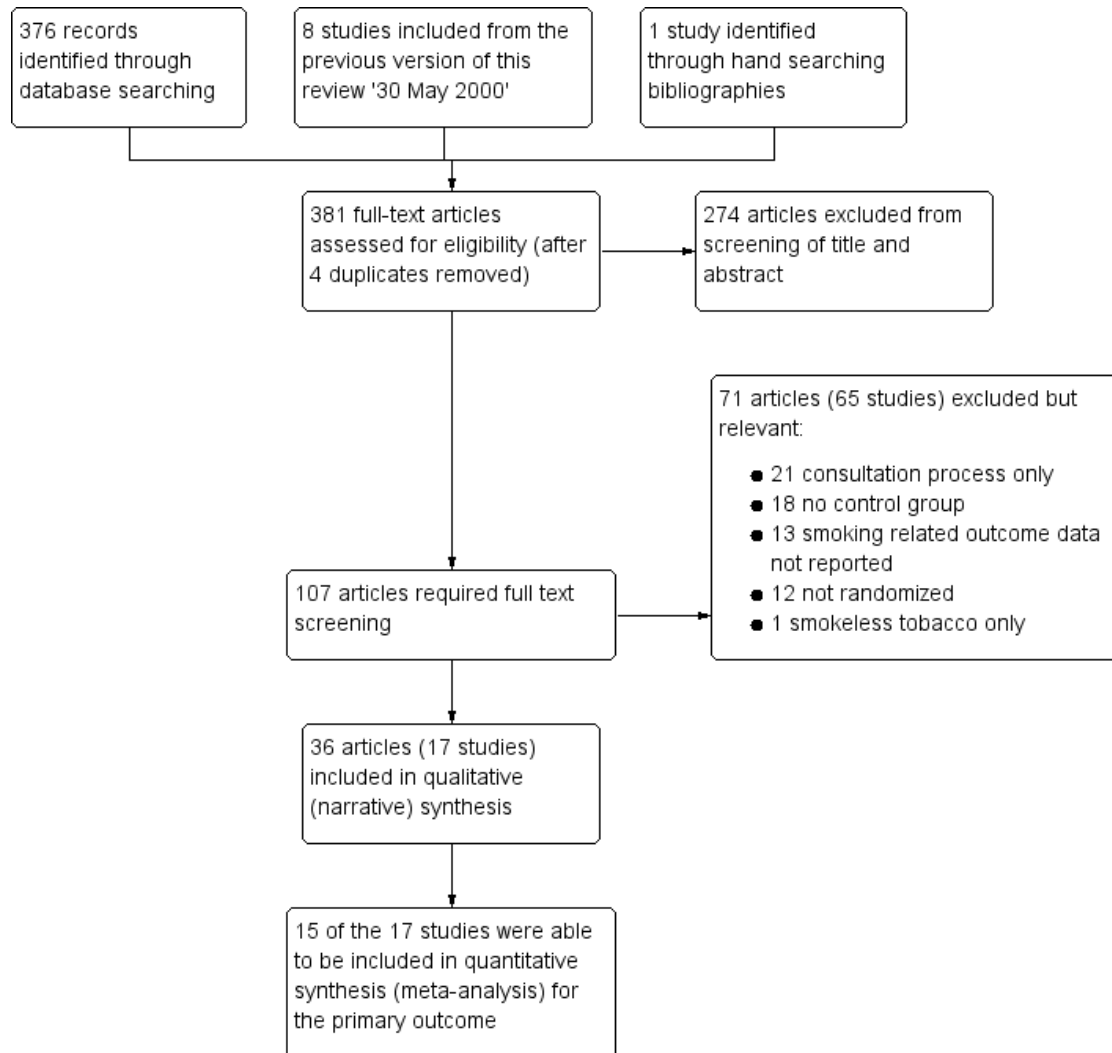
Description of studies

See the [Characteristics of included studies](#) and [Characteristics of excluded studies](#) tables.

Results of the search

Of 381 articles screened, 17 studies met all of the inclusion criteria (see [Figure 1](#) for PRISMA diagram). Detailed information relating to each included study is reported in the [Characteristics of included studies](#) table (for information relating to the 65 excluded studies see [Characteristics of excluded studies](#)).

Figure 1. Study flow diagram



Included studies

Design

All 17 included studies used a randomized controlled trial design with clustering and eleven studies also adopted nesting of participants within practices/hospitals (Wilson 1988; Cohen (Dent) 1989; Cohen (Doc) 1989; Cummings (Priv) 1989; Kottke 1989; Lennox 1998; Strecher 1991; Hymowitz 2007; Twardella 2007; Unrod 2007; Gordon 2010). One study (Twardella 2007) incorporated a 2x2 factorial design with randomization to: training plus

incentive, training plus medication, training plus incentive and medication or usual care.

Sample sizes

In total 28,531 patients were assessed at baseline (following randomization) with 21,031 remaining in the studies at final follow-up. Authors report a total of 1,434 individual health professionals recruited at baseline (across a known 260 practices) with follow-up available for 1,204. Sample sizes for individual studies were medium to large, with the smallest number of patients (randomized at baseline) found in the Wang 1994 study (n= 93) and the largest in the Kottke 1989 study. The smallest sample at follow-

up remained with the Wang 1994 study (n= 82), and the largest remained with the Kottke 1989 study (n= 5266) . At the health professional level, the Hymowitz 2007 study had the largest number of residents randomized at baseline (n= 275) and follow-up (n= 235) and likewise, Wang 1994 had the smallest number of residents at baseline and follow-up (n= 27 for both). Seven studies also reported baseline cluster sizes at the practice level: Lennox 1998 (n= 16); Sinclair 1998 (n= 62); Swartz 2002 (n= 50); Joseph 2004 (n= 20); Hymowitz 2007 (n= 16); Twardella 2007 (n= 82); and Gordon 2010 (n= 14).

Setting

Eleven of the 17 studies were conducted in the USA, one in Canada (Wilson 1988), one in Taiwan (Wang 1994), one in Scotland (Sinclair 1998), one in the United Kingdom (Lennox 1998), one in Switzerland (Cornuz 2002) and one in Germany (Twardella 2007). Two studies were performed in a dentistry setting (Cohen (Dent) 1989; Gordon 2010), whilst the remaining 15 were conducted within primary care clinics, HMO (Health Maintenance Organisation) medical centres (Cummings 1989; Swartz 2002), VAMC's (Veterans Affairs Medical Centres) (Joseph 2004) and one in a pharmacy setting (Sinclair 1998).

Participants

At the health professional level, two studies were performed with dentists (Cohen (Dent) 1989; Gordon 2010), six studies included only primary care physicians (Wilson 1988; Cohen (Doc) 1989; Cummings (Priv) 1989; Kottke 1989; Twardella 2007; Unrod 2007), two studies were conducted with residents (Cornuz 2002) and paediatric residents in Hymowitz 2007), three studies incorporated a combination of primary care physicians and internists (Cummings 1989; Strecher 1991; Wang 1994), one study used pharmacists (Sinclair 1998), whilst the remaining three studies used a combination of health professionals including physicians, nurse practitioners, physician assistants, psychologists, pharmacists and other health visitors (Lennox 1998; Swartz 2002; Joseph 2004).

The individual patients in 16 of the 17 included studies were those visiting their health professional during the recruitment phase of each study. They were recruited during standard GP, dentist or outpatient visits, emergency department visits or from waiting rooms. The Hymowitz 2007 study was the only one to perform the training in a paediatric setting, targeting the parents/guardians of children visiting 16 primary care clinics.

Interventions

Treatment type

Six studies provided patients with a counselling plus nicotine replacement therapy intervention arm (Wilson 1988; Cohen (Dent) 1989; Cohen (Doc) 1989; Sinclair 1998; Joseph 2004; Twardella 2007). The two Cohen et al studies had a second intervention arm of counselling plus a reminder for physicians to ask about smoking (chart prompt), and a third intervention arm combining the counselling, nicotine replacement therapy and chart prompt (Cohen (Dent) 1989; Cohen (Doc) 1989). Another study (Twardella 2007) also had three intervention arms: counselling plus nicotine replacement therapy; counselling plus a monetary incentive to the physician following study completion per successful smoke-free participant (EURO130); and a counselling plus nicotine replacement therapy plus incentive arm. The Wilson 1988 study had two intervention arms in addition to usual care: counselling and nicotine gum (as mentioned above) and a second arm of nicotine gum plus usual care (i.e., physicians were not trained in counselling). Three studies included multiple intervention methods to curtail smoking including counselling, nicotine replacement therapy, request for additional follow-up appointments and provision of self-help materials (Cummings (Priv) 1989; Cummings 1989; Gordon 2010), whilst one study combined three of those four (counselling, nicotine replacement therapy, and self-help materials, Cornuz 2002). Five studies used counselling alone (Strecher 1991; Wang 1994; Lennox 1998; Swartz 2002; Unrod 2007) and two studies used counselling with the addition of self-help materials (Kottke 1989; Hymowitz 2007).

Treatment intensity

The level of training intensity for health professionals ranged from one 40-minute session in the Unrod 2007 study, to 'four or five' day long sessions in the Joseph 2004 study. Nine studies had a training session for one day or less: Wilson 1988 (four hours), Cohen (Dent) 1989 (one hour), Cohen (Doc) 1989 (one hour), Kottke 1989 (6 hours), Lennox 1998 (one day), Sinclair 1998 (two hours), Twardella 2007 (two hours), Unrod 2007 (40 minutes) and Gordon 2010 (three hours). Four studies had two separate sessions: Strecher 1991 (two, one hour sessions scheduled two weeks apart), Wang 1994 (two sessions of unknown duration), Cornuz 2002 (two, four hour training sessions scheduled two weeks apart) and Swartz 2002 (two, 20 minute training sessions and another session of unknown duration, where residents were able to practice counselling techniques with standardised patients). Four studies had three or more sessions: Cummings (Priv) 1989 and Cummings 1989 both had three, one hour sessions over a four to five week period, Hymowitz 2007 had four, one hour sessions, four times a year and Joseph 2004 had four to five, day long sessions within six months.

Mode of intervention delivery

Three different modes of intervention delivery were used being groups sessions, one-on-one or a combination of the two. Two

studies only used one-on-one sessions (Joseph 2004; Unrod 2007), eleven studies delivered the intervention in a group setting only (Wilson 1988; Cummings 1989; Kottke 1989; Strecher 1991; Wang 1994; Lennox 1998; Sinclair 1998; Swartz 2002; Hymowitz 2007; Twardella 2007; Gordon 2010) with an eighth study using group delivery as the primary mode, however doctors who were unable to attend received a private session in their office (Cummings (Priv) 1989). Finally three studies used both modes of intervention delivery (Cohen (Dent) 1989; Cohen (Doc) 1989; Cornuz 2002), with health professionals in the two Cohen et al studies provided the option of a group or individual session.

Theoretical model - behavioural change technique

Nine studies used behavioural change theories to underpin the intervention techniques. These included the 'stages of change' (also known as the trans-theoretical) model (Kottke 1989; Strecher 1991; Wang 1994; Lennox 1998; Sinclair 1998; Cornuz 2002; Twardella 2007) and the '5A' (Ask, Assess, Advise, Assist and Arrange) approach (Unrod 2007; Gordon 2010). Three studies incorporated prompting or reminders to ask about tobacco use (Cohen (Dent) 1989; Cohen (Doc) 1989; Hymowitz 2007) and four provided feedback to the health providers, for example number of patients counselled (Cornuz 2002; Swartz 2002; Joseph 2004; Unrod 2007).

Type of professional being trained:

Two studies only focused on dentists (Cohen (Dent) 1989; Gordon 2010), one focused on pharmacists (Sinclair 1998), and the remaining fourteen studies all involved doctors. Five of these fourteen studies included doctors still undergoing training, either residents (Strecher 1991; Wang 1994; Cornuz 2002; Hymowitz 2007) or a combination of physicians and internists (Cummings 1989). Three other studies included training to other health care workers as well as doctors: Lennox 1998 also involved nurses and other health visitors; Swartz 2002 also trained nurse practitioners, physicians assistants and other health professionals; and, in addition to doctors, Joseph 2004 included nurses, psychologists and pharmacists.

Length of follow-up

Eight studies reported follow-up periods between six and nine-months post intervention (Cohen (Dent) 1989; Cohen (Doc) 1989; Strecher 1991; Wang 1994; Lennox 1998; Sinclair 1998; Unrod 2007; Gordon 2010), eleven studies presented 12 month follow-up data (Wilson 1988; Cohen (Dent) 1989; Cohen (Doc) 1989; Cummings 1989; Kottke 1989; Wang 1994; Cornuz 2002; Swartz 2002; Joseph 2004; Twardella 2007; Gordon 2010) and two studies assessed extended follow-up periods of 14 months (Lennox 1998) and four years (Hymowitz 2007). However, only

two-year post intervention data was available for Hymowitz 2007 at the time of writing.

Outcomes

Smoking abstinence was assessed in all included studies through self-report of either continuous abstinence (no smoking for an extended period of time) or point prevalence (for example, no smoking for seven days prior to the time of outcome collection). Of the eight studies that reported continuous abstinence, six (Cummings (Priv) 1989; Cummings 1989; Gordon 2010; Lennox 1998; Sinclair 1998; Wilson 1988) also reported a point prevalence measure of abstinence. Ten of the included studies used biochemical validation through either exhaled carbon monoxide (Cohen (Dent) 1989; Cohen (Doc) 1989; Strecher 1991; Cornuz 2002), serum cotinine (Kottke 1989; Twardella 2007), saliva cotinine (Wilson 1988; Unrod 2007) or a combination of exhaled carbon monoxide and serum cotinine (Cummings (Priv) 1989; Cummings 1989). A number of secondary outcomes measures were reported by some studies including: patients asked to set a quit date; patients asked to make a follow-up appointment; number of smokers counselled; number of smokers receiving self-help material; number of smokers receiving nicotine gum/replacement therapy; and number of smokers prescribed a quit date.

Two studies reported n-values as a total across both intervention and control arms (Cohen (Dent) 1989; Cohen (Doc) 1989) and six studies reported n-values as percentages, which had to be transformed into whole numbers (Wilson 1988; Cornuz 2002; Swartz 2002; Joseph 2004; Hymowitz 2007; Unrod 2007). As such there is likely to be some small variance between actual n-values and those reported in these analyses, but this is not significant. Seven studies had multiple intervention arms, which were considered similar enough to be pooled together, two in the Wilson 1988, Kottke 1989 and Wang 1994 studies and three intervention arms in the Cohen (Dent) 1989, Cohen (Doc) 1989, Strecher 1991 and Twardella 2007 studies. One study did not report the n-value for subjects at randomization, and hence this was calculated based on the number eligible for study and the number at follow-up (Strecher 1991). The Kottke 1989 study reported all outcome data as continuous variables, as such it was unable to be pooled in the meta-analyses. Smoking related outcomes in the Hymowitz 2007 study were unable to be pooled as only change scores from baseline were presented.

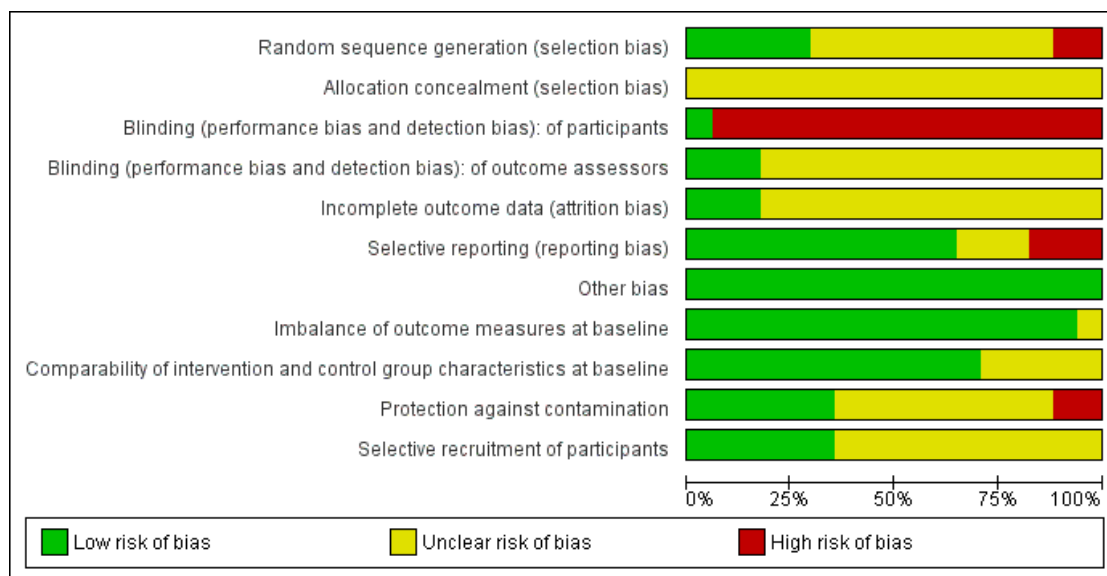
Excluded studies

Sixty-five studies (71 articles) were excluded for the following reasons: 21 included consultation process only, 18 did not include a control group, 13 failed to measure smoking related outcome data, 12 were considered to be inadequately randomized and one only reported on smokeless tobacco use. See the [Characteristics of excluded studies](#) table for more detailed information relating to each excluded study.

Risk of bias in included studies

Methodological details for the 17 included studies are provided in the 'risk of bias table' at the end of the [Characteristics of included studies](#) tables. Key methodological features are also summarised in [Figure 2](#).

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias judgement presented as percentages across all included studies



Random sequence generation (selection bias)

Five studies reported adequate methods of sequence generation (Cummings 1989; Cornuz 2002; Hymowitz 2007; Twardella 2007; Unrod 2007), two had inadequate methods (Kottke 1989; Strecher 1991) whilst the remaining ten did not provide enough information to assess risk of bias for sequence generation and were hence judged to be at unclear risk in this category. Adequate methods included the use of a random number generator or coin toss, whilst unclear methods were described as being 'random' in design, however methods were not described. The Kottke 1989 study required some physicians to be re-assigned due to inappropriate allocation methods during assignment. For the Strecher 1991 study appropriate randomization did not occur as residents were randomly assigned by clinic half-day session to one of four groups, which risks introducing bias. All 17 trials used cluster randomization, with five studies inadequately accounting for potential clustering effects in the data, requiring manual clustering adjustments (Wilson 1988; Cummings (Priv) 1989; Cummings 1989; Kottke

1989; Wang 1994). Only two studies (Kottke 1989; Hymowitz 2007) reported outcome data at the level of randomization. No authors reported that differences in the method of analysis affected the results.

Allocation concealment (selection bias)

Allocation concealment was unclear in all 17 included studies as authors did not describe methods of allocation concealment. Authors of the Lennox 1998 study report that physicians were randomly and blindly allocated to control or intervention groups, however the methods were not described. Another study mentioned that an independent research assistant concealed the result of randomization until two weeks before the intervention, when residents were provided with details about training sessions, however, methods of concealment were again not reported (Cornuz 2002).

Blinding (performance bias and detection bias) of participants

Only one study reported adequately blinding participants to the intervention (Cornuz 2002), as residents were not informed about the aim of the trial and were advised only that a survey on cardiovascular risk factors and prevention program would be conducted. Authors announced that a training program in clinical prevention that included sessions on smoking cessation and management of dyslipidaemia was being conducted. Authors also report that patients were blinded to the aim of the study and group allocation of their physician. Due to the nature of the intervention, blinding of participants was not possible for the remaining 16 studies. An attempt was made to blind physicians in the Unrod 2007 study, with physicians learning their group assignment only after signing the informed consent, however they were not blinded during the study intervention period and follow-up.

Blinding (performance bias and detection bias) of outcome assessors

Three studies reported methods blinding of outcome assessors that we judged at low risk of bias. Authors of Cummings (Priv) 1989 stated that 'outcome assessors were blinded', authors of the Joseph 2004 study report interviewers collecting patient outcomes were blinded to subject treatment status and authors in the Strecher 1991 study report that telephone interviewers, who were blinded to residents' and patients' group assignments, obtained the patient reports. The remaining 14 studies did not report any attempts to blind outcome assessors and as such are unclear for this category.

Incomplete outcome data (attrition bias)

Incomplete outcome data was adequately addressed in three studies (Cummings (Priv) 1989; Cummings 1989; Gordon 2010) and unclear in the remaining 14 studies. The Cummings (Priv) 1989 and Cummings 1989 studies reported that missing data was accounted for in analyses, whilst the Gordon 2010 study reported the use of multiple imputation procedures to account for missing data with participants lost to attrition discussed in the text. All unclear studies failed to mention if there was any missing outcome data and if so, how this was addressed when reporting results.

Selective reporting (reporting bias)

Selective reporting was evident in three studies (Hymowitz 2007; Unrod 2007; Gordon 2010), unclear in three studies (Kortke 1989; Strecher 1991; Wang 1994) and not detected in the remaining 11. Although all pre-specified outcomes were addressed in the four year follow-up for the Hymowitz 2007 study, the authors mention that outcome data for year one was omitted in order to provide a 'cleaner look' at the progress of the data. In the Unrod 2007 study, smoking abstinence from baseline to follow-

up (an outcome that would be expected to have been assessed in this study) was not reported. The Gordon 2010 authors report that secondary participant outcomes were examined with no significant differences on any variables, and that therefore they were not presented in the publication. Also, receipt of intervention was reported in text as percentages, however no information regarding this outcome was reported for the control.

Imbalance of outcome measures at baseline

One study did not report data for baseline smoking and made no mention of statistical analyses to potentially adjust for any imbalances (Wang 1994), as such the risk of bias category was assessed as unclear. All remaining studies adequately addressed imbalances of outcome measures at baseline. Thirteen studies accounted for baseline imbalances through analysis of covariance, regression analyses or other analysis techniques, whilst three studies reported outcomes at baseline to be similar across groups and as such did not require adjustment (Cummings (Priv) 1989; Lennox 1998; Sinclair 1998).

Comparability of intervention and control group characteristics at baseline

Five studies had unclear comparability between intervention and control groups at baseline (Wilson 1988; Cohen (Dent) 1989; Cohen (Doc) 1989; Cummings 1989; Twardella 2007) and the remaining twelve studies adequately addressed any differences found between groups via appropriate analysis methods.

Protection against contamination

Two studies reported contamination. In Gordon 2010, authors reported contamination due to a tax increase on cigarettes in New York, which resulted in a drop in smoking prevalence from 18.4% in 2006 to 15.8% in 2008. Authors believed that this tax increase contributed to the unusually high rate of smoking cessation in the usual care patients, thereby affecting the relative impact of the intervention. Authors of the second study, Strecher 1991, mention that "all four groups worked closely with one another at each site", leading to the possibility of contamination, however they also state that "...the effects appeared to be slight." Nine studies had unclear risk of bias for contamination with insufficient information to permit a judgement of yes or no, whilst the remaining six studies (Wilson 1988; Cummings (Priv) 1989; Cummings 1989; Kortke 1989; Lennox 1998; Cornuz 2002) reported no potential contamination during the study period.

Selective recruitment of participants

Although no studies were identified as having selectively recruited participants, this could not be completely ruled out for eleven studies, which were determined to have an unclear risk of bias for

this outcome (Wilson 1988; Cohen (Dent) 1989; Cohen (Doc) 1989; Cummings (Priv) 1989; Kottke 1989; Strecher 1991; Wang 1994; Sinclair 1998; Swartz 2002; Twardella 2007; Gordon 2010). The sampling frames in these studies were unclear and as such, generalisability is of a potential concern. The remaining six studies adequately reported recruitment methods and were determined as having a low risk of bias.

Other bias

No other biases were identified for the 17 included studies.

Effects of interventions

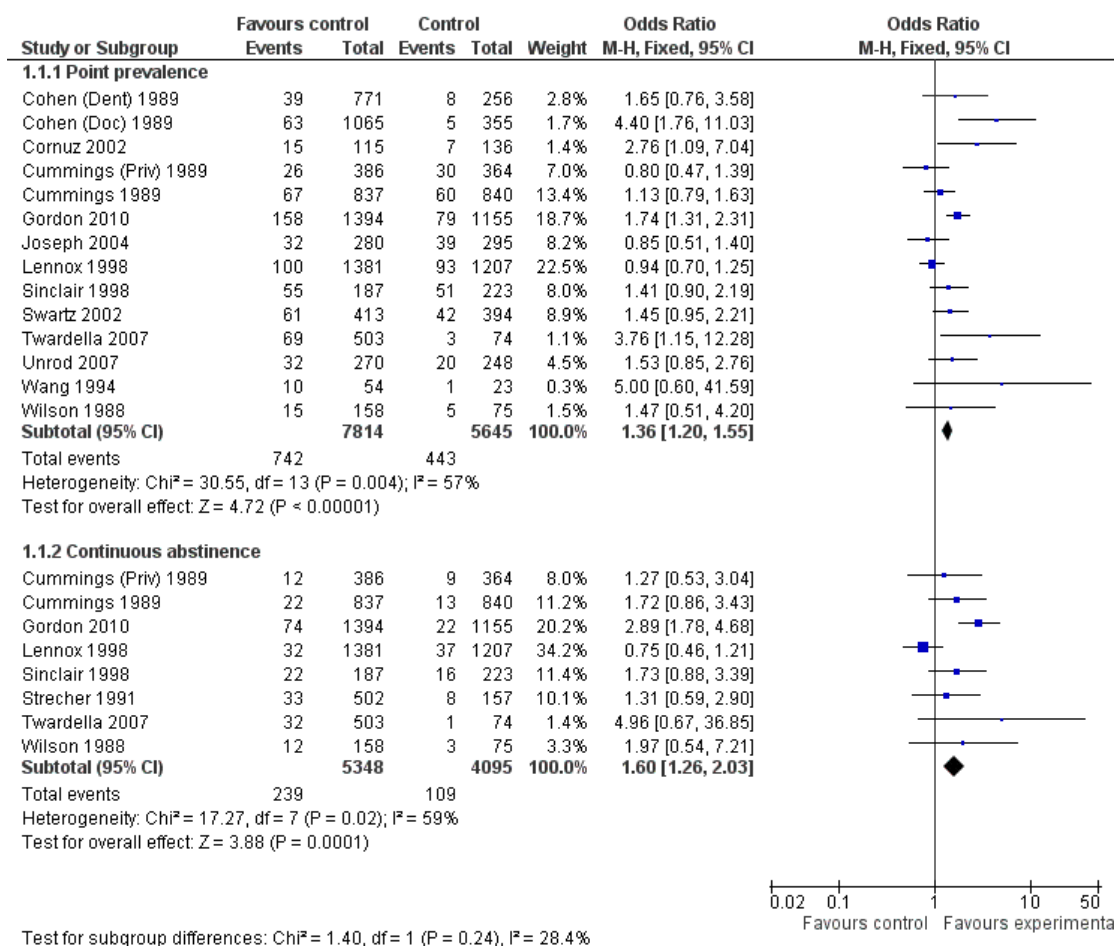
See: [Summary of findings for the main comparison Training health professionals for smoking cessation](#)

Intervention effectiveness was assessed in all seventeen included studies through smoking prevalence, as well as through multiple secondary outcomes (see [Summary of findings for the main comparison](#)). All data were analysed as per the pre-defined methodology outlined in the [Methods](#) section. For a summary of intervention effectiveness for each of these outcomes see [Table 1](#).

Overall summary of smoking behaviour

Four out of 13 studies detected significant intervention effectiveness in training health professionals to influence point prevalence of smoking in their patients at primary follow-up (Cohen (Doc) 1989; Cornuz 2002; Twardella 2007; Gordon 2010). Out of the eight studies reporting continuous abstinence at primary follow-up, only one reported a statistically significant effect in favour of the intervention (Gordon 2010). Fifteen of the 17 included studies (the exceptions being Kottke 1989 and Hymowitz 2007) could be included in a meta-analysis for the primary outcome of smoking ([Analysis 1.1](#)). Using a fixed effect model there was a statistically and clinically significant effect in favour of the intervention for point prevalence abstinence (OR 1.36, 95% CI 1.20 to 1.55, 14 trials, $I^2 = 57%$) and continuous abstinence (OR 1.60, 95% CI 1.26 to 2.03, 8 trials, $I^2 = 59%$) ([Figure 3](#)). Using only the stricter outcome of continuous abstinence for studies reporting both types of cessation, a pooled estimate for all 15 trials gave a similar estimate (OR 1.60, 95% CI 1.35 to 1.89, $I^2 = 55%$, data not displayed). Since the heterogeneity in this analysis approached the level at which we proposed a random-effects model we did a sensitivity analysis; the point estimates were similar and the wider confidence intervals continued to exclude no effect. The trial contributing most evidently to the heterogeneity, particularly for the continuous outcome, was [Lennox 1998](#) in which the point estimates for both abstinence outcomes favoured the control group.

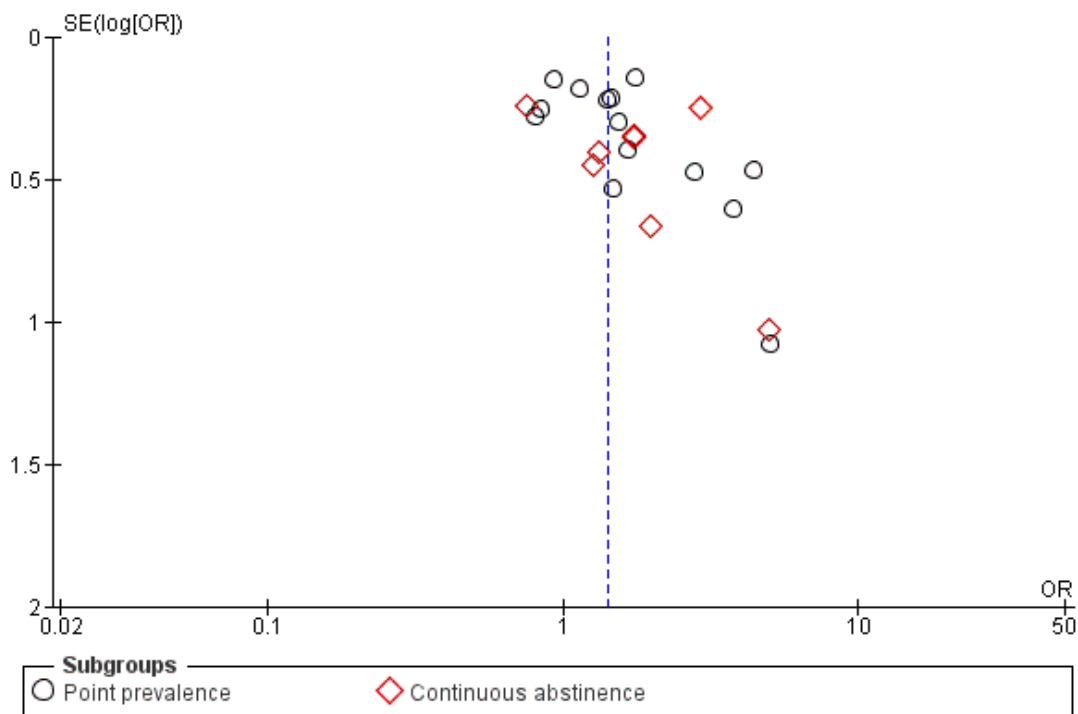
Figure 3. Forest plot of comparison: I The effect of training health professionals on patient smoking cessation



Two studies could not be included in the meta-analyses. In the [Kottke 1989](#) study at one year follow-up almost half of the participants in each group who were smoking at baseline reported quit attempts for at least 24 hours during the previous year, with a mean duration of cessation of two months. No differences between the three groups were identified. For the [Hymowitz 2007](#) study there was an increase in the special training condition of reported quitting during the past year of 3.8% (an 8.5% increase over baseline levels), however the change from baseline failed to achieve statistical significance. Among parents associated with standard training, the change was only 0.8%.

As per pre-specified methodology, a funnel plot examined the primary outcome of smoking cessation using contour lines to assess the presence of reporting biases. No publication biases were identified ([Figure 4](#)).

Figure 4. Funnel plot of comparison: I The effect of training health professionals on patient smoking cessation



Overall summary of secondary outcomes

Asked to set a quit date for stopping (quit date)

Nine studies reported the effect of training health professionals on the number of patients being asked to set a quit date, eight of which could be included in the meta-analysis producing a significant result (random effects OR 4.98, 95% CI 2.29 to 10.86, [Analysis 1.2](#)). Only three of the seven studies crossed the line of no effect ([Strecher 1991](#); [Cornuz 2002](#); [Swartz 2002](#)) but there was a very high level of heterogeneity ($I^2 = 90\%$) suggesting that not all interventions had the same impact on this outcome. Subgroup analyses suggest that some of the heterogeneity might be due to whether or not the patient intervention included an offer of NRT. The two studies ([Strecher 1991](#); [Swartz 2002](#)) that reported this outcome and did not include NRT showed no difference between groups. The other studies showed more consistent evidence that intervention increased numbers although the size of effect remained variable ([Analysis 2.1](#)). Contrary to what might have been expected, the studies where training took only a single session had higher effect sizes ([Cohen \(Dent\) 1989](#); [Cohen \(Doc\) 1989](#); [Wilson 1988](#), [Analysis 3.1](#)) compared to the five studies

using multiple sessions. Duration of training was similar for the three sub-groups being examined ([Analysis 4.1](#)) as was intervention delivery via one-on-one compared to group sessions ([Analysis 5.1](#)). There was a large amount of variability between the use of prompting and provision of feedback, however this difference was not significant ([Analysis 6.1](#)). Intervention delivery by a doctor (six studies) or dentist (one study) produced a larger effect size compared to delivery by a healthcare worker ([Swartz 2002](#)), which may also explain some of the heterogeneity ([Analysis 7.1](#)). When comparing follow-up periods, studies reporting between six and nine months ([Cohen \(Dent\) 1989](#); [Cohen \(Doc\) 1989](#); [Strecher 1991](#)) and between nine and 12 months (seven studies) produced similar effect sizes and large amounts of variability ([Analysis 8.1](#)). Studies judged to be at lower risk of bias were more likely to show evidence of an effect (seven studies) compared to studies with between three and five categories rated at high risk of bias ([Strecher 1991](#)), however the between group analysis did not suggest that this was a source of heterogeneity ([Analysis 9.1](#)).

Given a follow-up appointment

There was a significant increase in the intervention arm for pa-

tients being asked to make a follow-up appointment, as reported in seven studies available for meta-analysis (random effects OR 3.34, 95% CI 1.51 to 7.37, [Analysis 1.3](#)), although significant heterogeneity was observed ($I^2 = 92\%$). When comparing interventions using NRT with those that used counselling alone, an I^2 of 96% was observed, meaning any results from a pooled analysis would be too unreliable. As such only a visual analysis of odds ratios and confidence intervals are presented, showing similar variability between sub-groups ([Analysis 2.2](#)). Subgroup analyses for treatment intensity suggest that some of the heterogeneity might be due to whether or not the training sessions were single or multiple. Two studies that employed single sessions ([Wilson 1988](#); [Unrod 2007](#)) were more likely to show an effect (although variability was observed), compared to five studies using multiple sessions, which produced a smaller effect estimate with less variability ([Analysis 3.2](#)). When comparing the duration of the training, significant heterogeneity was once again observed between groups, with studies presenting large amounts of variability, resulting in a pooled estimate being unreliable for comparison ([Analysis 4.2](#)). There was little difference between delivery by one-on-one compared to group sessions ([Analysis 5.2](#)), and due to significant heterogeneity ($I^2 = 96\%$) the pooled comparison of prompting and provision of feedback was not possible, although a visual display shows variability is mostly due to the [Unrod 2007](#) study ([Analysis 6.2](#)). Similar to other outcomes, delivery of the intervention by a doctor (assessed in seven studies) meant that more patients were likely to have a follow-up appointment compared to intervention delivery by a healthcare worker (one study), however the [Swartz 2002](#) study was present in both sub-groups as the intervention included delivery by both a doctor and healthcare worker, as such a statistical between group comparison was not performed ([Analysis 7.2](#)). Reporting of results at different follow-up periods were similar between sub-groups, although the five studies with follow-up between nine and 12 months had similar distributions with the exception of the [Wilson 1988](#) study, which significantly favoured the intervention and had wide confidence intervals ([Analysis 8.2](#)). No between group differences were observed for quality of the studies ([Analysis 9.2](#)).

Counselled

Fourteen of the fifteen studies reporting on the number of smokers counselled were meta-analysed ([Analysis 1.4](#)). Overall, a statistically and clinically significant effect in favour of the intervention was observed (OR 2.28, 95% CI 1.58 to 3.27, $p < 0.00001$), assessed using the random effects model due to significant heterogeneity ($I^2 = 93\%$). An investigation into the causes of heterogeneity found no differences between counselling with and without nicotine replacement therapy ([Analysis 2.3](#)), however implementation via multiple sessions or single sessions did produce between group differences, with a larger effect size for single session delivery ([Analysis 3.3](#)). Duration of intervention delivery also pro-

duced significant differences with total exposure of between 40 minutes and two hours producing a larger effect size compared to durations of between two and four hours and greater than four hours ([Analysis 4.3](#)). Mode of intervention delivery (one-on-one compared to group sessions) produced very similar effect sizes ([Analysis 5.3](#)), as did the provision of feedback and prompting to aid intervention delivery by the health professional ([Analysis 6.3](#)). The type of health professional being trained may contribute to the heterogeneity with the one study evaluating dentists ([Cohen \(Dent\) 1989](#)) producing a larger effect size compared to those with doctors and other health professionals which showed a more conservative effect with narrow confidence intervals ([Analysis 7.3](#)). When examining follow-up periods, there was a slightly larger effect and more variability in the studies reporting results between six and nine months compared to results between nine and twelve months and 12 and 24 months ([Analysis 8.3](#)). No sub-group differences were observed when analysing studies based on risks of bias ([Analysis 9.3](#)).

Given self-help materials

The number of smokers receiving self-help material increased significantly in favour of the intervention for the nine studies able to be included in the meta-analysis (OR 3.52, 95% CI 1.90 to 6.52, $p < 0.0001$, [Analysis 1.5](#)). Provision of cessation materials in the [Hymowitz 2007](#) study, which could not be included in the meta-analysis, did increase significantly across both groups over the four year study period when compared to baseline values (intervention 28.8%, control 17.6%) however, this interaction was not statistically different between groups. The other study unable to be meta-analysed ([Kottke 1989](#)) also produced a statistically significant effect ($p < 0.001$). Significant heterogeneity was observed in the meta-analysis ($I^2 = 91\%$) which was explored through subgroup analyses. The type of treatment did not show a significant difference between groups, although the counselling plus nicotine replacement therapy group did have a larger effect size compared to counselling alone ([Analysis 2.4](#)). Likewise, no differences were observed for single compared to multiple session delivery ([Analysis 3.4](#)) or duration of delivery ([Analysis 4.4](#)), although the [Cornuz 2002](#) study with a total exposure over four hours did produce a very large effect with wide confidence intervals. No differences were observed for the mode of intervention delivery ([Analysis 5.4](#)) or provision of prompting or feedback to aid health professionals in the provision of self-help materials ([Analysis 6.4](#)). The one study ([Swartz 2002](#)) which included healthcare workers for intervention delivery produced less of an effect compared to the pooled result of studies using doctors ([Analysis 7.4](#)). No difference between sub-groups was observed for length of follow-up ([Analysis 8.3](#)) although studies identified as having less risk of bias did have a larger effect size compared to those with larger amounts of bias ([Analysis 9.4](#)).

Offered nicotine gum/replacement therapy

Nine studies were pooled to assess the number of smokers receiving nicotine gum/replacement therapy (Analysis 1.6). The meta-analysis did not produce evidence of an effect (OR 1.57, 95% CI 0.87 to 2.84, $p = \text{NS}$), but significant heterogeneity was detected ($I^2 = 91\%$). The Hymowitz 2007 study also assessed this outcome with few parents in either condition reporting that residents prescribed nicotine replacement therapy (intervention 7.6%, control 5.9%). An exploration into the possible sources of heterogeneity found no difference between interventions containing counselling with or without nicotine replacement therapy (Analysis 2.5), however surprising results were observed with much larger effect sizes for single session intervention delivery compared to multiple session (Analysis 3.5), which could account for some of the heterogeneity. No differences were observed between sub-groups for treatment intensity (Analysis 4.5), mode of intervention delivery (Analysis 5.5), use of feedback or prompting (Analysis 6.5), type of professional being trained (Analysis 7.5) or length of follow-up (Analysis 8.5). However studies with less risk of bias did produce larger effect sizes compared to studies with three to five sources of bias identified, which could also contribute to some of the observed heterogeneity (Analysis 9.5).

Prescribed a quit date

Only three studies reported on smokers being prescribed a quit date (Wilson 1988; Cummings 1989; Strecher 1991). Pooling these together produced a statistically and clinically significant effect in favour of the intervention (OR 14.18, 95% CI 6.57 to 30.61, $p < 0.00001$, Analysis 1.7), with minimal observed heterogeneity. As such, sub-group analyses were not necessary for this outcome.

Cost effectiveness of interventions

Cost effectiveness data was presented in one study (Cornuz 2002), with the incremental cost of the intervention reported to amount to (U.S.) \$2.58 per consultation by a smoker. When considering 'cost per life-year saved', this translated to (U.S.) \$25.40 for men and \$35.20 for women, with one-way sensitivity analyses yielding a range of \$4.00 to \$107.10 in men and \$9.70 to \$148.60 in women. The Joseph 2004 study reported that the dollar spent per 1000 primary care patients did increase in the intervention sites and decrease in control sites, however this was not significant.

Number of referrals made

No studies reported on the number of referrals made to local smoking cessation services.

Statistical analyses and cluster adjustments

All 17 studies used a cluster randomized design for practical reasons, with the unit of randomization being the health care practitioner or practice. However, in 15 of the 17 studies patients were the unit of analysis. Hymowitz 2007 and Kottke 1989 were the exceptions, reporting outcomes at the level of randomization (the doctor/resident). The majority of studies that reported outcomes at the level of patient accounted for potential clustering effects within their reported results, with four studies (three in the late 1980's Wilson 1988; Cummings (Priv) 1989; Cummings 1989 and one in the mid-1990's Wang 1994) being the exceptions. The two Cummings et al studies did perform clustering analyses, however they were not included in the published results as they were seen to have had no effect on the final outcome. As such, the data for these studies were manually adjusted for potential clustering effects as per the pre-specified methodology outlined in the Unit of analysis issues section of this review.

Sub-group analyses

Multiple sub-group analyses have been considered as per the pre-defined methodology to further explore heterogeneity. When considering these outcomes the level of statistical significance should be considered at $p \leq 0.01$, to account for potential false positive results (as per the Bonferroni adjustment described Assessment of heterogeneity), which increase with the number of potential effect modifiers being investigated. Total study confidence intervals were assessed at the 99% level for all sub-group analyses. Significant heterogeneity was determined through a combination of the I^2 statistic ($I^2 \geq 60\%$), Chi^2 statistic and visual inspection of the Forest plots, and was present for all outcomes with the exception of 'Smoking cessation at longest follow-up' and 'Number of smokers prescribed a quit date' where significant heterogeneity was not identified. In the presence of heterogeneity based on the I^2 statistic of $\geq 96\%$, the pooled estimate has been removed, as the outcomes are considered too different to be combined in meta-analysis. Likewise, when a comparison contained the same study in different sub-groups, the pooled estimate was not used.

DISCUSSION

Summary of main results

Seventeen completed studies (total 28,531 subjects) assessed the benefits of interventions to train health professionals to provide smoking cessation initiatives to their patients. Whilst some methodological variations occurred between studies in relation to intervention, delivery mode, type of health professional and duration, they were all aimed at training health professionals to help their patients stop smoking. The primary outcome of smoking cessation was presented in pooled meta-analyses as point prevalence

(14 studies) and continuous abstinence (eight studies). A statistically and clinically significant effect in favour of the intervention was observed for both of these outcomes at final follow-up (see [Summary of findings for the main comparison](#)). All secondary outcomes (with one exception) produced a statistically and clinically significant effect in favour of the intervention at final follow-up. These outcomes include asking patients to set a quit date, asking patients to make follow-up appointments, counselling of smokers, provision of self-help material and prescription of a quit date. No evidence of an effect was observed for the secondary outcome of providing patients with nicotine gum/replacement therapy. No studies were able to be meta-analysed to assess the cost effectiveness of interventions.

Overall completeness and applicability of evidence

In the context of current practice, this review should be used to provide readers with an outline of what interventions have a proven effect, and where resources need to be directed for future investigations. Studies which incorporated multiple intervention components such as provision of nicotine replacement therapy, requests for follow-up appointments and provision of self-help material were more likely to be successful than those with interventions of counselling alone. Surprisingly, health professionals who were trained using only a single session and in a group setting were just as likely if not more likely to have patients quit smoking as those being trained with multiple delivery sessions and one-on-one training (i.e., face to face with the trainer). Similarly, the duration of training for the health professional of between 40 minutes to two hours was just as effective, and in some cases more so, than a duration of greater than two hours. Studies with multiple follow-up periods and closer monitoring of outcomes by investigators (including the provision of feedback) were more successful than those of lesser intensity. Smoking cessation interventions delivered by a doctor or dentist were more likely to produce successful quit attempts than those delivered by other health care workers. To ensure methodological rigour, future studies should aim to incorporate the following into the study design:

- Report patient level outcomes (e.g., smoking cessation) as well as health professional outcomes (e.g., physician report of number of smokers counselled) rather than providing details only relating to the consultation process
- Adequate methods of randomization and allocation concealment
- Report smoking related outcome data both pre and post intervention
- Incorporate a control group which adequately matches the demographic characteristics of the intervention population.

Quality of the evidence

Study quality was a potential issue in this review with many of the studies being of unclear methodological design. It is extremely difficult to blind participants in relation to what intervention they will be receiving, as there are two levels to consider: the health professional and the patient. All 17 included studies had unclear allocation concealment whilst only five studies adequately reported methods of random sequence generation, two had a high risk of bias with the remaining ten studies being unclear. Overall, the body of evidence identified permits a moderately robust conclusion regarding the objectives of this review, with 17 included studies (28,531 participants).

Evidence presented in the summary of findings table was downgraded to take into account:

- limitations in design: methods of randomization, allocation concealment and/or blinding were not described or inadequate for the majority of studies assessing the particular outcome (-1)
- Inconsistencies: significant heterogeneity (-1)
- Imprecision: only few participants in few studies available to assess the outcome (-1)

Potential biases in the review process

A potential bias in the review process is exclusion of studies examining interventions that train health professionals in smoking cessation that are of questionable methodological design. This review does sacrifice inclusion of some relevant information, however the trade off is a meta-analysis of higher quality evidence on which future investigations can be based. Some of the pertinent information from these studies is discussed below under [Agreements and disagreements with other studies or reviews](#) though results should be interpreted with caution. Another limitation to the review is the under-reporting of the intervention for included studies. This means that some studies may have indeed included additional intervention components that, had we known they existed, would have led us to classify the study differently within the sub-groups. One key strength of the review process to address potential biases is the use of two experienced and independent review authors who assessed the studies for risk of bias, although this can do little to account for biases which occur in the methodological designs of the included studies.

Agreements and disagreements with other studies or reviews

A compilation of systematic reviews and surveys of key informants were published as a special edition in the journal 'Drug and Alcohol Review' in 2009, relating to the education and training of health professionals and students in tobacco, alcohol and other drugs ([Richmond 2009a](#)). The first published survey of 21 key informants from eight countries found a high level of consistency in

the content of the smoking cessation interventions, with 72% of programs using the 5A (Ask, Assess, Advise, Assist, Arrange) model, 64% using the stages of change (trans-theoretical) model, 84% including pharmacotherapies, with 84% having some reference to clinical practice guidelines (Zwar 2009). Only five of the seventeen included studies in our review had reference to any particular behavioural change technique, however it is quite likely that the majority of studies are based around some kind of theoretical behavioural change context, which is not reported in the publication. These results are similar to the those reported in Richmond 2009b. The authors identified a lack of interest (with other continuing education topics considered to be a higher priority) and lack of funding for interventions to be the major barriers for the uptake and sustainability of training programs (Zwar 2009). Some possible solutions were provided to address these barriers including raising awareness of the importance of smoking cessation for the health of patients and incorporating education on smoking cessation into vocational courses for specialties. Another systematic review of postgraduate smoking cessation training for physicians in 28 European countries found nine studies which met all of the inclusion criteria containing a total of 170 postgraduate training programs (Kralikova 2009). The key implications reported by the authors were that postgraduate training in smoking cessation may not be reaching physicians and was not rigorously evaluated. To combat this problem multiple authors suggest that future research needs to incorporate methods of disseminating effective educational activities with the intention of increasing participation (Kralikova 2009; Muramoto 2009). It is also imperative that health professional organisations advocate for the systematic implementation of comprehensive tobacco cessation training programs to increase the number of patients receiving tobacco cessation interventions (Botelho 2009). Another study using direct observation of physician-patient encounters found similar results and concluded that strategies are needed to assist physicians to incorporate systematic approaches that will standardise smoking cessation care (Ellerbeck 2001). In this investigation, discussions around tobacco were more common in practices that utilised standard forms for recording smoking status and during new patient visits. Interestingly, the authors also found that discussions around tobacco use occurred less often among physicians in practice for more than 10 years and with older patients (Ellerbeck 2001), which is similar to an observational study by Bertakis 2007 investigating the factors associated with physician discussion of tobacco use with patients. Considerable resistance was also observed in a cohort of physicians receiving academic detailing to promote tobacco-use cessation counselling in dental offices. Dental staff members (including receptionists, office managers, dental assistants and dental hygienists) were reluctant to participate in the interventions due to increased paperwork, having to deal with uncooperative patients, and the perception that only a few patients use tobacco anyway and that counselling does not work (Albert 2004). However, the resistance observed did decrease as follow-up visits progressed and

staff became more comfortable with the intervention and the procedures involved. This evidence suggests that through the provision of first-hand experience prior to guiding patients through the same process, physicians may feel more comfortable in implementing smoking cessation interventions into standard practice, which has the potential to be highly cost-effective. One of the included studies by Cornuz 2002 reported that training residents in smoking cessation counselling is very cost-effective and may be more efficient than the majority of currently accepted tobacco control interventions. This has also been supported by more recent systematic reviews and investigations (Maciosek 2006; Solberg 2006; Stead 2008). As such, the provision of counselling, advice and/or offers of assistance to the patient has the potential to significantly increase the number of quit attempts, which subsequently has the potential to reduce health related costs as well as morbidity and mortality associated with ongoing chronic tobacco use.

The previous version of this Cochrane review (New Reference) included eight studies with six finding no effect of intervention. The authors also stated that effects of training on process outcomes increased if prompts and reminders were used, however they concluded that there was no strong evidence that training health professionals to provide smoking cessation interventions changed smoking behaviour. With the addition of nine studies (more than half the initial number of inclusions), the findings of this review have now changed to support the training health professionals in smoking cessation interventions.

AUTHORS' CONCLUSIONS

Implications for practice

Overall, a moderately large amount of methodologically rigorous evidence has been presented to support the effectiveness of training health professionals in smoking cessation. The following program characteristics could be considered for individuals involved in future clinical practice initiatives:

- Combination of multiple intervention components including the provision of counselling, offer of follow-up appointments, setting or being prescribed a quit date and provision of self-help material
- A one-off group training session for health professionals of between one to two hours duration, providing there is adequate follow-up and monitoring of progress. This will need to include provision of follow-up feedback to health professionals and resources such as patient self-help materials, with consideration given to other intervention components as mentioned above.
- Consider organisational factors to ensure that smoking cessation messages are reliably delivered. Training can be expensive, and simply providing programs for health care

professionals, without addressing the constraints imposed by the conditions in which they practise, is unlikely to be a wise use of health care resources.

Implications for research

Multi-component investigations incorporating new pharmacological interventions for smoking cessation (such as varenicline tartrate and bupropion) or other cessation aids (such as electronic cigarettes) alongside physician training should be considered to determine if any additional benefit in long-term abstinence can be obtained. Future research needs to ensure that adequate methodological rigour is met with considerations relating to:

- Sequence generation and allocation concealment
- Demographics and comparability of the control comparison
- Reporting of smoking related outcome data
- Collection of data both pre and post intervention implementation.

So as to enable interventions to be replicated in clinical practice, it is also important that authors of future trial reports describe the

content of the training in sufficient detail, for example detailing the educational methods, strategies and theories used to train the professionals.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Cohen (Dent) 1989

Methods	<p><i>Country:</i> USA, Indianapolis area</p> <p><i>Design:</i> Randomized controlled trial; Nested; Clustered</p> <p><i>Objective:</i> To improve the effectiveness of dentists helping their patients quit smoking</p> <p><i>Methods of analysis:</i> A generalized linear model was used to analyse the results of the quit-smoking rates and a scale-factor was used to reflect the expected extra variance in quit rates caused by between-dentist variability; Chi² statistic based on changes in the deviance function for a series of nested models was used to test for main effect and interactions; Two-way analyses of variance were calculated on the weighted data for the amount of time spent in counselling patients about their smoking</p> <p><i>Clustering adjustment made:</i> Yes - Generalised linear model allowed a scale-factor to reflect the extra variance expected to be inflated due to variability between dentists</p> <p><i>Significance of cluster adjustment:</i> Not reported</p>
Participants	<p><i>Therapist description:</i> Dentists</p> <p><i>Eligible for study:</i> n= 54</p> <p><i>Randomized:</i> n= 50</p> <p><i>Completed:</i> Gum n= 9, reminder n= 10, gum & reminder n= 12, control n= 13 (total n= 44)</p> <p><i>Age:</i> Not reported</p> <p><i>Gender:</i> Not reported</p> <p><i>Patient description:</i> n= 1027 patients from American private dental practices</p> <p><i>Eligible for study:</i> n= 1027</p> <p><i>Randomized:</i> n= 1027</p> <p><i>Completed:</i> n= 647</p> <p><i>Age:</i> Mean = 37.1 (SD + 10.4) (total population only)</p> <p><i>Gender:</i> Males= 43.2% males (total population only)</p>
Interventions	<p><i>Setting:</i> American private dental practices</p> <p><i>Training of those delivering the intervention to the health professional:</i> Not reported</p> <p><i>Intervention description:</i> Three intervention groups: Training & nicotine gum, training & reminder (chart prompt), combined training with prompt & nicotine gum</p> <p><i>Control description:</i> Training alone (advice, quit date, follow-up check); Dentists provided a booklet containing the four-step care protocol and were encouraged to counsel their patients who were smokers</p> <p><i>Duration of intervention:</i> One hour</p> <p><i>Intervention delivered by:</i> General dentist</p> <p><i>Intensity:</i> One lecture</p>
Outcomes	<p><i>Pre-specified outcome data:</i> Point prevalence of cessation at 12 months; Number advised to quit; Number asked about setting a quit date</p> <p><i>Follow-up period:</i> Twelve months total: 6 months (defined as the smoking status determined at any visit that occurred at least 3 months after the initial appointment but not more than 9 months); 12 months (defined as the smoking status determined at any visit that occurred at least 9 months and 1 day and up to 15 months after the initial visit)</p>

Notes	<i>Process measures:</i> Outcomes reported in Cohen 1987; Patients not having a visit during the 6 or 12 month periods were assumed to be smokers <i>Validation:</i> Expired carbon monoxide The three intervention groups were combined for meta-analyses to produce the single 'Intervention' sample	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomization mentioned though methods not described: "...dentists and their entire panel of patients who smoked cigarettes were randomly assigned to one of four conditions."
Allocation concealment (selection bias)	Unclear risk	Methods not described
Blinding (performance bias and detection bias) of participants	High risk	Due to the nature of the intervention blinding of participants was not possible for this study
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	No mention of attempted blinding for outcome assessors
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Patients not having a visit during the 6 or 12 month periods were assumed to be smokers; No further information provided regarding missing or incomplete outcome data
Selective reporting (reporting bias)	Low risk	All expected outcomes, including those that were pre-specified were reported
Other bias	Low risk	No other biases identified
Imbalance of outcome measures at baseline	Low risk	Analysis of covariance occurred
Comparability of intervention and control group characteristics at baseline	Unclear risk	Insufficient information reported to permit judgement of yes or no; "... participating dentists varied widely in age, types of practices, previous use of tobacco effects ..."
Protection against contamination	Unclear risk	Insufficient information to permit judgement of yes or no

Cohen (Dent) 1989 (Continued)

Selective recruitment of participants	Unclear risk	n-values across different intervention groups not reported
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Cohen (Doc) 1989

Methods	<p><i>Country:</i> USA</p> <p><i>Design:</i> Randomized controlled trial; Nested; Clustered</p> <p><i>Objective:</i> Evaluation of a RCT of interventions designed to improve effectiveness of physicians and dentists in helping their patients quit smoking</p> <p><i>Methods of analysis:</i> Analysis of variance performed on percentages; Stepwise multiple regression analyses performed using the weighted number of minutes as the criterion to determine the extent to which the amount of counselling time was a function of the health professionals' initial attitudes and habits; Chi² analysis used to test main effects and interactions; Generalised linear interactive modelling (GLIM) software used</p> <p><i>Clustering adjustment made:</i> Yes - Generalised linear model allowed a scale-factor to reflect the extra variance expected to be inflated due to variability between physicians</p> <p><i>Significance of cluster adjustment:</i> Not reported</p>
Participants	<p><i>Therapist description:</i> n= 112 primary care physicians (including n= 97 physicians in training)</p> <p><i>Eligible for study:</i> Not reported</p> <p><i>Randomized:</i> Total= 97 internal medicine residents and 15 faculty general internists</p> <p><i>Completed:</i> Total= 97 internal medicine residents and 15 faculty general internists</p> <p><i>Age:</i> Not reported</p> <p><i>Gender:</i> Not reported</p> <p><i>Patient description:</i> n= 1420 patients receiving primary care, not selected by motivation to quit</p> <p><i>Eligible for study:</i> Participation refusal rate was 9.7% of all eligible patients contacted</p> <p><i>Randomized:</i> n= 1420</p> <p><i>Completed:</i> n= 1091 medical patients</p> <p><i>Age:</i> 18 to 64 years; Mean = 46.2 + 11.6 years</p> <p><i>Gender:</i> Male= 37%</p>
Interventions	<p><i>Setting:</i> General medicine (primary care) clinic of a city-county teaching hospital in the USA</p> <p><i>Training of those delivering the intervention to the health professional:</i> Registered internist</p> <p><i>Intervention description:</i> Three intervention groups: Training & nicotine gum, training & reminder (chart prompt), combined training with prompt & nicotine gum</p> <p><i>Control description:</i> Training alone (advice, quit date, follow-up check); Physicians provided a booklet containing the four-step care protocol and were encouraged to counsel their patients who were smokers</p> <p><i>Duration of intervention:</i> One-hour lecture or personalised instruction</p> <p><i>Intervention delivered by:</i> David M Smith, registered internist</p> <p><i>Intensity:</i> One, one hour lecture maximum</p>
Outcomes	<p><i>Pre-specified outcome data:</i> Point prevalence of abstinence at 12 months; Patients who did not have an appointment in the period regarded as smokers; Rates also reported giving returnees as denominator; Number advised to quit; Number asked about setting a quit</p>

Cohen (Doc) 1989 (Continued)

	date; Had their doctor talked to them about smoking <i>Follow-up period:</i> Six and 12 months (12 months defined as patients visited 9 and 15 months after the initial visit)	
Notes	<p><i>Process measures:</i> Outcomes reported in Cohen 1987; Patients not having a visit during the 6 or 12 month periods were assumed to be smokers</p> <p><i>Validation:</i> Expired carbon monoxide</p> <p>The three intervention groups were combined for meta-analyses to produce the single 'Intervention' sample</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomization mentioned however methods not described
Allocation concealment (selection bias)	Unclear risk	Methods not described
Blinding (performance bias and detection bias) of participants	High risk	Due to the nature of the intervention blinding of participants was not possible for this study
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	No mention of attempted blinding for outcome assessors
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Patients not visiting the physicians during the 6 and 12 month visits were assumed smokers; No further information provided regarding missing or incomplete outcome data
Selective reporting (reporting bias)	Low risk	All expected outcomes, including those that were pre-specified were reported
Other bias	Low risk	No other potential risks of bias identified
Imbalance of outcome measures at baseline	Low risk	Analysis of covariance occurred
Comparability of intervention and control group characteristics at baseline	Unclear risk	Insufficient information reported to permit judgement of yes or no
Protection against contamination	Unclear risk	Insufficient information reported to permit judgement of yes or no
Selective recruitment of participants	Unclear risk	Insufficient information reported to permit judgement of yes or no

Methods	<p><i>Country:</i> Geneva and Lausanne, Switzerland, Europe</p> <p><i>Design:</i> Randomized controlled trial; Clustered</p> <p><i>Objective:</i> To assess the efficacy of an educational program based on behavioural theory, active learning methods, and practice with standardized patients in helping patients abstain from smoking and changing physicians' counselling practices</p> <p><i>Methods of analysis:</i> To compare baseline characteristics of patients and physicians' practices between groups, the authors used the Chi² or Fisher exact tests for categorical data and the t-test or Wilcoxon rank-sum test for continuous data; To test the effectiveness of the training on the outcomes, the authors performed a logistic regression with generalized estimating equation to stratify by clinic and adjust for clustering on residents; Intention-to-treat analysis was performed for abstinence from smoking, in which smokers lost at follow-up were considered to be continuing smokers; Because smoking abstinence was validated in a sub sample of the study participants, the authors used simulation to perform sensitivity analysis of the likelihood of smoking cessation</p> <p><i>Clustering adjustment made:</i> Yes - to test the effectiveness of the training on the outcomes, the authors performed a logistic regression with generalized estimating equation to stratify by clinic and adjust for clustering on residents</p> <p><i>Significance of cluster adjustment:</i> Not reported</p>
Participants	<p><i>Therapist description:</i> Resident physicians; All residents were at the end of postgraduate training in general internal medicine or family medicine</p> <p><i>Eligible for study:</i> n= 35</p> <p><i>Randomized:</i> Intervention n= 17; Control n= 18</p> <p><i>Completed:</i> Intervention n= 17; Control n= 18</p> <p><i>Age:</i> Median 31 years</p> <p><i>Gender:</i> 18 females and 17 males</p> <p><i>Patient description:</i> Patients aged 16 to 75 years who consulted one of the outpatient clinics for a follow-up or an emergency visit</p> <p><i>Eligible for study:</i> n= 1456</p> <p><i>Randomized:</i> Intervention n= 115; Control n= 136</p> <p><i>Completed:</i> Intervention n= 77; Control n= 100</p> <p><i>Age:</i> Range 16 to 75 years; Mean + SD: Intervention 35.1 + 14 years; Control 36.9 + 15 years</p> <p><i>Gender:</i> Intervention = 63% male; Control= 57% male</p>
Interventions	<p><i>Setting:</i> Two general internal medicine clinics of the university hospitals of Lausanne and Geneva, Switzerland; Both sites are public service clinics that provide adult ambulatory care to approximately 25,000 outpatient visits per year</p> <p><i>Training of those delivering the intervention to the health professional:</i> Teachers are two authors, who are experienced physicians active in both clinical practice and teaching; Both were previously trained in smoking cessation counselling through a Master of Public Health course and are considered national experts in smoking cessation</p> <p><i>Intervention description:</i> The training program is based on 5 principles: 1) recent evidence-based content on tobacco use and cessation, 2) behavioural theory (stage-of-change model), 3) pharmacological therapy, 4) educational methods focusing on active skills training, and 5) tobacco control context; Session 1: Video-clips observations, interactive workshops and role plays; Session 2: practice with standardized patients; At the end of the first session, participants received a set of documents (reference manual, two algorithms of counselling strategies and pharmacological therapy, record sheet for consultations with smokers, brochures for patients and patient instructions for NRT)</p>

	<p><i>Control description:</i> Training in management of dyslipidaemia with equal contact time to the intervention; This course taught residents about the Swiss guidelines on screening for and diagnosis/management of high blood levels of cholesterol; Residents that were trained in smoking cessation attended the lesson on dyslipidaemia 4 months later, and vice versa</p> <p><i>Duration of intervention:</i> Two, 4 hour sessions scheduled 2 weeks apart</p> <p><i>Intervention delivered by:</i> Not specified though face-to-face workshops took place</p> <p><i>Intensity:</i> Two, half-day sessions; Total contact time 8 hours</p>	
Outcomes	<p><i>Pre-specified outcome data:</i> Self-reported abstinence from smoking, 1 week point prevalence of abstinence, score of overall quality of counselling based on use of 14 counselling strategies, patient willingness to quit, daily cigarette consumption, socio-demographic data, cardiovascular risk factors, smoking history, nicotine dependence, smoking intervention</p> <p><i>Follow-up period:</i> Twelve months</p>	
Notes	<p><i>Process measures:</i> None reported</p> <p><i>Validation:</i> Exhaled carbon monoxide testing at one clinic</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	An independent research assistant performed computer randomization stratified by clinic
Allocation concealment (selection bias)	Unclear risk	An independent research assistant concealed the result of randomization until 2 weeks before the intervention, when residents were provided with details about training sessions - however methods not described
Blinding (performance bias and detection bias) of participants	Low risk	"Residents were blinded to the aim of the trial and were informed only that a survey on cardiovascular risk factors and prevention would be conducted"; "We announced only that a training program in clinical prevention that included sessions on smoking cessation and management of dyslipidaemia was being conducted"; "Patients were also blinded to the aim of the study and group allocation of their physician"
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	A research assistant was blinded to group allocation for measurement of exhaled carbon monoxide; Authors also mention that allocation of residents and patient assign-

Cornuz 2002 (Continued)

		ment was blinded to research staff that collected data; No mention of attempts to blind outcome assessors
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Intention-to-treat analysis used; No further information provided regarding missing or incomplete outcome data
Selective reporting (reporting bias)	Low risk	All expected outcomes, including those that were pre-specified were reported
Other bias	Low risk	No other biases identified
Imbalance of outcome measures at baseline	Low risk	Baseline outcome data are reported and similar
Comparability of intervention and control group characteristics at baseline	Low risk	The authors mention no differences at baseline between intervention and control residents or patients
Protection against contamination	Low risk	“Residents who first trained in smoking cessation attended the session on dyslipidaemia 4 months later, and vice versa. The second session took place after the 3 month patient recruitment period had ended” - Contamination unlikely
Selective recruitment of participants	Low risk	“...to identify smokers and avoid revealing group assignments, we interviewed all patients, regardless their smoking status”

Cummings (Priv) 1989

Methods	<p><i>Country:</i> USA</p> <p><i>Design:</i> Randomized controlled trial; Nested; Clustered</p> <p><i>Objective:</i> To test if physicians who are trained to use the 'Quit for Life' (QFL) program are more effective in helping patients to quit smoking</p> <p><i>Methods of analysis:</i> Chi² test for proportions and t-tests for means; Multiple logistic regression (for proportions) and ordinary least-squares (for means) and calculated adjustment rates from the partial slopes associated with a dummy variable; Individual patients were the unit of analysis</p> <p><i>Clustering adjustment made:</i> No adjustment to presented data but separate analyses tested clustering effects</p> <p><i>Significance of cluster adjustment:</i> Clustering effects were tested in separate analyses; These adjustments had no discernible effect on significance levels and did not alter the conclusion</p>
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Participants	<p><i>Therapist description:</i> Primary care physicians in private practice <i>Eligible for study:</i> n= 844 <i>Randomized:</i> Intervention n= 31; Control n= 28 <i>Completed:</i> Intervention n= 20; Control n= 18 <i>Age:</i> Not reported <i>Gender:</i> Intervention females n= 4; Control females n= 2 <i>Patient description:</i> n= 916 smoking patients not selected by motivation to quit <i>Eligible for study:</i> Not reported <i>Randomized:</i> Intervention n= 470; Control n= 446 <i>Completed:</i> Intervention n= 360; Control n= 364 <i>Age:</i> Intervention mean = 43 years; Control mean = 45 years <i>Gender:</i> Intervention mean = 53%; Control mean = 61%</p>
Interventions	<p><i>Setting:</i> Private primary care internal medicine and family practice (primary care) in San Francisco, USA; Local hospitals at times that fit with the schedules of the participating physicians; Four who were unable to attend the second sessions received the training privately in their office <i>Training of those delivering the intervention to the health professional:</i> Not described <i>Intervention description:</i> Training (personalised advice, quit date, one follow-up visit, self help materials and nicotine gum) <i>Control description:</i> Normal care (no training) <i>Duration of intervention:</i> Three, one hour seminars <i>Intervention delivered by:</i> Internist or psychologist <i>Intensity:</i> Three, one hour seminars, second seminar one or two weeks after the first, third seminar four to twelve weeks later</p>
Outcomes	<p><i>Pre-specified outcome data:</i> Demographic characteristics; Smoking history; How much do you want to quit smoking; How confident are you that you will not be smoking one year from now; Pressure to quit from family and friends; Was smoking discussed; Did you receive a self-help booklet; Did you receive a follow-up appointment about smoking <i>Follow-up period:</i> Twelve months</p>
Notes	<p><i>Process measures:</i> None reported <i>Validation:</i> Expired carbon monoxide and serum cotinine Manual adjustment for potential clustering effects performed in the meta-analyses for primary outcome data</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Authors state patients were randomly assigned however methods not described
Allocation concealment (selection bias)	Unclear risk	Methods not described
Blinding (performance bias and detection bias) of participants	High risk	Due to the nature of the intervention blinding of participants was not possible for this

Cummings (Priv) 1989 (Continued)

		study
Blinding (performance bias and detection bias) of outcome assessors	Low risk	Authors state outcome assessors were blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Participants assumed smokers if lost to follow-up or abstinence unable to be biochemically verified; Missing outcome data accounted for in analyses
Selective reporting (reporting bias)	Low risk	All expected outcomes, including those that were pre-specified were reported
Other bias	Low risk	No other biases identified
Imbalance of outcome measures at baseline	Low risk	Imbalances adjusted for using logistic regression
Comparability of intervention and control group characteristics at baseline	Low risk	Imbalances adjusted for using logistic regression
Protection against contamination	Low risk	Members of the same group practice were assigned to the same condition to minimise cross-over
Selective recruitment of participants	Unclear risk	More control participants were recruited by practice staff than intervention subjects; Methods of recruitment not clearly described

Methods	<p><i>Country:</i> San Francisco, California, USA</p> <p><i>Design:</i> Randomized controlled trial; Clustered</p> <p><i>Objective:</i> To test whether physicians who receive a continuing education program about how to counsel smokers to quit would counsel smokers more effectively and have higher rates of long-term smoking cessation among their patients that smoke</p> <p><i>Methods of analysis:</i> Chi² for proportions and t-tests for means were used for significance measures; Binomial test for difference between paired proportions used to calculate confidence intervals for changes in attitudes and self-reported counselling practices of physicians in the experimental group before and after training; To analyse differences between the groups in patient reports about physicians counselling and rates of abstinence, large-sample difference-of-proportions and difference-of-means tests were used; To determine significance of intervention among those patients who had the greatest desire to quit, an interaction was tested between assignment to the experimental or control group and the smoker's rating of his or her desire to quit; Multiple logistic regression analysis used to determine significance for specific counselling strategies by experimental group physicians for abstinence levels</p> <p><i>Clustering adjustment made:</i> No - The individual patient was the unit of analysis for these results; However, patients were clustered by physician and physicians were clustered by work station; "...Therefore for simplicity, we present the results with the patient as the unit of analysis"</p> <p><i>Significance of cluster adjustment:</i> Not reported</p>
Participants	<p><i>Therapist description:</i> Physicians</p> <p><i>Eligible for study:</i> n= 189 internists</p> <p><i>Randomized:</i> n= 81; Control n= 41; Intervention n= 40</p> <p><i>Completed:</i> n= 81; Control n= 41; Intervention n= 40</p> <p><i>Age:</i> Not reported</p> <p><i>Gender:</i> Control: 27% female; Intervention 30% female</p> <p><i>Patient description:</i></p> <p><i>Eligible for study:</i> n= 2056; Control n= 1032; Intervention n= 1024</p> <p><i>Randomized:</i> n= 2056; Control n= 1032; Intervention n= 1024</p> <p><i>Completed:</i> n= 2012; Control n= 1008; Intervention n= 1004</p> <p><i>Age:</i> Control 45 years; Intervention 46 years</p> <p><i>Gender:</i> Control 53% female; Intervention 58% female</p>
Interventions	<p><i>Setting:</i> Four Health Maintenance Organisation (HMO) medical centres in northern California</p> <p><i>Training:</i> Three, one hour group tutorials</p> <p><i>Training of those delivering the intervention to the health professional:</i> Not stated but delivered by internist or psychologist</p> <p><i>Intervention description:</i> Training (personalised advice, quit date, one follow-up visit, self help materials and nicotine gum)</p> <p><i>Control description:</i> Normal care (no training)</p> <p><i>Duration of intervention:</i> Three sessions over a five to fourteen week period</p> <p><i>Intervention delivered by:</i> Internist or psychologist</p> <p><i>Intensity:</i> Three, one hour sessions</p>
Outcomes	<p><i>Pre-specified outcome data:</i> long-term abstinence from smoking (≥ 9 months); Number of smokers counselled; Asked to set a quit date; Asked to make a follow-up appoint-</p>

	ment; Number receiving self help materials; Number receiving nicotine gum; Number of smokers prescribed a quit date <i>Follow-up period:</i> Point prevalence abstinence at 12 months	
Notes	<i>Process measures:</i> None reported <i>Validation:</i> Expired carbon monoxide and serum cotinine Manual adjustment for potential clustering effects performed in the meta-analyses for primary outcome data	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random allocation of physicians (by computer) to intervention or control groups
Allocation concealment (selection bias)	Unclear risk	Methods not described
Blinding (performance bias and detection bias) of participants	High risk	Due to the nature of the intervention blinding of participants was not possible for this study
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	Authors report a blinded assessment of principal outcomes; Methods for blinding participants or outcome assessors were not mentioned
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data obtained for 78% of surviving patients of experimental physicians and 76% of surviving controls
Selective reporting (reporting bias)	Low risk	All expected outcomes, including those that were pre-specified were reported
Other bias	Low risk	No other biases identified
Imbalance of outcome measures at baseline	Low risk	Participants assumed smokers if lost-to-follow-up or abstinence unable to be biochemically verified; Missing outcome data accounted for in analyses
Comparability of intervention and control group characteristics at baseline	Unclear risk	Except for sex, the characteristics of smokers in the experimental and control groups were similar
Protection against contamination	Low risk	"...To minimize exchange of information, materials, and cross-over of patients between two groups of physicians, we grouped physicians into 22 units corre-

		sponding to existing medical stations, each with distinct space and separate office staff”
Selective recruitment of participants	Low risk	n-values are similar across groups; Also, all smokers who made a visit to any doctor participating in the study were eligible for participating in the study

Gordon 2010

Methods	<p><i>Country:</i> USA</p> <p><i>Design:</i> Randomized controlled trial; Nested; Clustered</p> <p><i>Objective:</i> With consideration to the oral health effects associated with chronic tobacco use, the dental visit provides a “teachable moment” during which the dental team can relate oral health and systemic problems to tobacco use and provide evidence-based brief interventions to patients who use tobacco in lower socio-economic areas</p> <p><i>Methods of analysis:</i> Analysis of variance with clinics as a random, nested factor within condition and patients nested within clinic for both outcomes, for all participants, and within each racial/ethnic group; Logistic regression used for baseline measures of tobacco use with condition included as a covariate</p> <p><i>Clustering adjustment made:</i> Yes: intra cluster correlation and analysis of variance with nesting</p> <p><i>Significance of cluster adjustment:</i> Not reported</p>
Participants	<p><i>Therapist description:</i> Federally funded public health dental clinics in lower socio-economic areas</p> <p><i>Eligible for study:</i> Not reported</p> <p><i>Randomized:</i> Intervention n= 7 practices; Control n= 7 practices</p> <p><i>Completed:</i> Intervention n= 7 practices; Control n= 7 practices</p> <p><i>Age:</i> Not reported</p> <p><i>Gender:</i> Not reported</p> <p><i>Patient description:</i> Dental patients aged 18 years and older who were seen for a non-emergency visit to the clinic and were self-identified current tobacco users (within the past 7 days)</p> <p><i>Eligible for study:</i> n= 2751 completed informed consent and baseline survey</p> <p><i>Randomized:</i> Intervention n= 1434; Control n= 1203</p> <p><i>Completed:</i> Six weeks Intervention n= 1214; Control n= 1026; 7.5 months Intervention n= 990; Control n= 885</p> <p><i>Age:</i> Total sample only: Mean = 40.5 + 12.6 years</p> <p><i>Gender:</i> Total sample only: Female= 45.8% n= 1508</p>
Interventions	<p><i>Setting:</i> Baseline survey completed in the clinic and were mailed follow-up surveys at 6 weeks and 7.5 months (lower socio-economic areas)</p> <p><i>Training of those delivering the intervention to the health professional:</i> Not reported</p> <p><i>Intervention description:</i> ‘5A approach’ (Ask, Advise, Assess, Assist and Arrange): Ask - ask all patients about their tobacco use at every visit; Advise - relating the oral effects of tobacco use to the patients’ oral health status and advising patients to quit tobacco; Assess - setting a quit date, discussing pharmacotherapy, providing free self-help materials</p>

	<p>and free nicotine replacement therapy; Arrange - arranging for follow-up by mail or phone for patients setting a quit date; Each intervention practice was provided with a supply of nicotine patches and lozenges, as well as printed patient self-help materials and information on the local tobacco quit line, which providers were asked to give to all tobacco-using patients</p> <p><i>Control description:</i> Usual care - delayed intervention control; Following the study period control clinics received the in-service workshop and received all the intervention materials</p> <p><i>Duration of intervention:</i> One workshop</p> <p><i>Intervention delivered by:</i> Dentists, dental hygienists and dental assistants</p> <p><i>Intensity:</i> One, 3 hour workshop</p>	
Outcomes	<p><i>Pre-specified outcome data:</i> Tobacco cessation, reduction in tobacco use, number of quit attempts, change in readiness to quit, number of cigarettes smoked per day, level of nicotine dependence</p> <p><i>Follow-up period:</i> 7.5 months (6 months post-enrolment plus a 6 week grace period)</p>	
Notes	<p><i>Process measures:</i> Intervention subjects only - 66.5% reported receiving the reading materials and the majority of patients reported reading them (96.7%); 16.9% reported using nicotine replacement therapy and 10.9% reported receiving quit line counselling</p> <p><i>Validation:</i> No biochemical validation</p> <p>n-values re-calculated for meta-analysis to permit intention-to-treat analysis for primary outcome data</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomization mentioned however methods not described
Allocation concealment (selection bias)	Unclear risk	Methods not described
Blinding (performance bias and detection bias) of participants	High risk	Due to the nature of the intervention blinding of participants was not possible for this study
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	No mention of attempted blinding of outcome assessors
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing data accounted for via multiple imputation procedures; Attrition in participants discussed in text
Selective reporting (reporting bias)	High risk	Secondary participant outcomes were examined however authors found no significant differences on any of these variables, consequently no data was presented in the publication; Receipt of intervention sec-

Gordon 2010 (Continued)

		ondary outcome measures were reported as percentages in text, however no information was presented for the control population
Other bias	Low risk	No other biases identified
Imbalance of outcome measures at baseline	Low risk	Imbalances at baseline were identified, however they were controlled using analysis of variance
Comparability of intervention and control group characteristics at baseline	Low risk	Logistic regression used to examine the effect of baseline measures on tobacco use with condition as a covariate in the model
Protection against contamination	High risk	Authors mention a tax increase on cigarettes in New York (2008), such that the tax on a pack of cigarettes was \$5.00; The smoking prevalence in New York City dropped from 18.4% (2006) to 15.8% (2008); Authors state this likely contributed to the unusually high rate of quitting among usual care patients observed in this study, thereby affecting the relative impact of the intervention
Selective recruitment of participants	Unclear risk	Insufficient information to permit judgment of yes or no

Hymowitz 2007

Methods	<p><i>Country:</i> USA</p> <p><i>Design:</i> Randomized controlled trial; Nested; Clustered</p> <p><i>Objective:</i> The primary aim of the study was to compare the effects of the two training conditions on resident tobacco intervention as measured by annual resident tobacco survey and OSCEs, baseline, and end-of-study patient and parent/guardian tobacco surveys, and a survey of program graduates who enter paediatric practice</p> <p><i>Methods of analysis:</i> Due to training site being the unit of randomization, analyses were based on aggregated data rather than on individuals; Likert scales were calculated as means; Two-stage mixed model relationship was used for waves of residents at baseline and 2 year follow-up</p> <p><i>Clustering adjustment made:</i> No - However data were analysed based on aggregated data to account for unit of analysis issues; Authors state that this will provide "...an unbiased estimate of the intervention effect and standard error" (also know as a 'mean analysis')</p> <p><i>Significance of cluster adjustment:</i> Not reported</p>
Participants	<p><i>Therapist description:</i> Paediatric residents undergoing training in the New York/New Jersey metropolitan area</p> <p><i>Eligible for study:</i> n= 16 residency training programs; n= 2069 Residents</p>

	<p><i>Randomized:</i> n= 16 residency training programs; 3rd year residents n= 140 in intervention arm; n= 135 in control arm</p> <p><i>Completed:</i> n= 14 residency training programs; 3rd year residents n= 136 in intervention arm; n= 99 in control arm</p> <p><i>Age:</i> Approximately 33 years of age for overall population; Intervention mean = 32.3 + 5.1 years; Control mean = 33.7 + 5.7 years</p> <p><i>Gender:</i> Intervention female= 69.1%; Control female= 59.3%</p> <p><i>Patient description: Parent/Guardian:</i> Parents of the patients visiting the primary care clinics</p> <p><i>Eligible for study:</i> n= 1770</p> <p><i>Randomized:</i> Intervention n= 849; Control n= 776</p> <p><i>Completed:</i> Intervention n= 724; Control n= 617</p> <p><i>Age:</i> Overall= 29.88 + 8.65 years</p> <p><i>Gender:</i> Female= 85.8%</p> <p><i>Patient description: Children:</i> Patients (children) visiting the primary care clinics</p> <p><i>Eligible for study:</i> n= 550</p> <p><i>Randomized:</i> Intervention n= 255; Control n= 300</p> <p><i>Completed:</i> Intervention n= 255; Control n= 300</p> <p><i>Age:</i> Intervention 14.89 + 1.84 years; Control 15 + 2.16 years</p> <p><i>Gender:</i> Intervention female= 55.3%; Control female= 60%</p>
Interventions	<p><i>Setting:</i> New York/New Jersey metropolitan area; Continuity clinic (primary care clinic) served as the venue for resident tobacco-intervention activities</p> <p><i>Training of those delivering the intervention to the health professional:</i> Not specified</p> <p><i>Intervention description:</i> Special training - 'Solutions for Smoking' was the main teaching tool; Also provided with assistance with clinics (e.g., take-home educational and behavioural-change materials available in the waiting areas, anti-tobacco posters, marking charts of smokers etc); Packets of educational and behavioural materials designed for mothers of newborns, adolescent smokers, parents who smoke etc.; Seminar series provided opportunities to distribute program materials, highlight key concepts and aspects of the background material, and utilise role-playing to help residents acquire interviewing, counselling and tobacco-intervention skills; PowerPoint presentations were used during these seminars on environmental tobacco smoke, smoking cessation and prevention of smoking onset and solutions for smoking audio/visual vignettes to demonstrate and model state-of-the-art counselling and intervention skills</p> <p><i>Control description:</i> Standard training - Background reading material that included the clinical practice guideline 'Treating Tobacco Use and Dependence' and 'American Academy of Pediatrics Statement on Tobacco'; A manual entitled 'Clinical Interventions to Prevent Tobacco Use by Children and Adolescents'; A journal article on approaches to tobacco prevention and control in clinic and office settings; Standard training sites did not receive assistance with clinic mobilisation or have access to companion intervention material; They did receive pamphlets and related material to facilitate intervention on tobacco; Seminar also conducted the same as the intervention group with the exception of vignettes to demonstrate counselling and intervention skills</p> <p><i>Duration of intervention:</i> One hour seminars, four times per year</p> <p><i>Intervention delivered by:</i> Unclear, though the manuscript mentions 'training directors'; Seminars delivered by senior investigators from the New Jersey Medical School</p> <p><i>Intensity:</i> One hour seminars, four times per year</p>

Outcomes	<i>Pre-specified outcome data:</i> Primary outcome measures included changes in resident tobacco intervention activities and skills in the area of environmental tobacco smoke, tobacco-use prevention and tobacco-use cessation; Demographic information, knowledge and attitudes about tobacco prevention and control, tobacco-intervention activities during the past year, use of specific tobacco-intervention skills and strategies, and beliefs about the efficacy of tobacco intervention in patients and parents <i>Follow-up period:</i> Four years in total; Outcome data for participants only published for 2 year follow-up	
Notes	<i>Process measures:</i> Sixty percent of residents in the special training condition reported review of 'Solutions for Smoking', although a higher proportion attended the seminar series (80%) and had access to companion intervention material in the clinic <i>Validation:</i> No biochemical validation	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomization was performed according to coin toss
Allocation concealment (selection bias)	Unclear risk	Methods not described
Blinding (performance bias and detection bias) of participants	High risk	Due to the nature of the intervention blinding of participants was not possible for this study
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	No mention of attempts to blind outcome assessors
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	One site withdrew from the study following the events of 9/11/2001 and another withdrew later; No further information provided regarding missing or incomplete outcome data
Selective reporting (reporting bias)	High risk	All pre specified outcomes were addressed in the 4 year outcome findings; However, the authors mention that outcome data for year 1 were omitted in order to provide a 'cleaner look' at the progress of the study
Other bias	Low risk	No other biases identified
Imbalance of outcome measures at baseline	Low risk	All within-condition analyses controlled for residents' gender, smoking status and ethnic status

Hymowitz 2007 (Continued)

Comparability of intervention and control group characteristics at baseline	Low risk	The two conditions differed with respect to racial composition, however analyses adjusted to account for residents' gender, smoking status and ethnic status
Protection against contamination	Unclear risk	The control and intervention residents all arrived at the medical school and attended the one hour seminar together at the same time
Selective recruitment of participants	Low risk	n-values reported and similar across groups

Joseph 2004

Methods	<p><i>Country:</i> USA</p> <p><i>Design:</i> Randomized controlled trial; Clustered</p> <p><i>Objective:</i> To test the effect of modest intensity, practical systems changes that might increase the delivery of smoking cessation treatment within VAMCs (Veterans' Medical Centres); Authors hypothesized that an intervention addressing common barriers to delivery of smoking cessation treatment at the organisation level (as opposed to provider or patient level) might be an effective strategy to improve compliance with guideline recommendations; The trial was designed to test the effectiveness of this intervention</p> <p><i>Methods of analysis:</i> McNemar odds on change to assess differences in the change between intervention groups; Pearson Chi² statistic to compute the significant of the resulting odds ratio between the intervention and control group; Differences in smoking cessation rates were determined via the Pearson Goodness-of-Fit Chi² statistic; Change scores were used for continuous variables and the relative difference in change was measured using the Wilcoxon rank sum test; Logistic regression was used for binary outcomes; SAS glimmix macro was used to incorporate the design effect and allow for the binary outcome</p> <p><i>Clustering adjustment made:</i> Yes - SAS glimmix macros used to incorporate the design effects</p> <p><i>Significance of cluster adjustment:</i> Not reported</p>
Participants	<p><i>Therapist description:</i> Physicians, nurses, psychologists and pharmacists were present at the training meeting</p> <p><i>Eligible for study:</i> n= 164 VAMCs (Veteran Medical Centres) nationwide</p> <p><i>Randomized:</i> Intervention n= 10; Control n= 10</p> <p><i>Completed:</i> Intervention n= 10; Control n= 10</p> <p><i>Age:</i> Not reported</p> <p><i>Gender:</i> Not reported</p> <p><i>Patient description:</i> A random selection of patients who had seen their primary care provider (at VAMCs) within 6 weeks were phoned for baseline surveys; Current smokers were identified and underwent 1 year follow-up also via phone</p> <p><i>Eligible for study:</i> Cohort n= 5793; Eligible n= 5367</p> <p><i>Randomized:</i> Intervention n= 2112; Control n= 2142</p> <p><i>Completed:</i> Intervention n= 641; Control n= 783</p> <p><i>Age:</i> Baseline - Intervention 64.6 years; Control 63.1 years; Follow-up - Intervention 64.</p>

	9 years; Control 63.8 years <i>Gender:</i> Baseline (male) - Intervention 96.1%; Control 95.3%; Follow-up - Intervention 95.8%; Control 98.0%	
Interventions	<p><i>Setting:</i> Veterans Affairs Medical Centers (VAMCs)</p> <p><i>Training of those delivering the intervention to the health professional:</i> Registered nurse who was trained in smoking cessation methods and had considerable administrative experience within Veteran Affairs</p> <p><i>Intervention description:</i> Intervention sites received 5 copies of the AHCPR Smoking Cessation Guideline for distribution; Plus a multi-component intervention designed to increase implementation of 3 specific Guideline recommendations: 1) documentation of tobacco use status in the medical record 2) delivery of intervention to all smokers and 3) liberal use of smoking cessation medications; The organisational support included a training meeting, site visits and a study interventionist at the coordinating site in Minneapolis; Removal of formulary restrictions were encouraged for smoking cessation aids as were the requirements for attendance at a cessation class to access pharmacotherapies; Bupropion SR was suggested as an addition to formulary; However approaches were individualised for each site</p> <p><i>Control description:</i> Control sites also received 5 copies of the AHCPR Smoking Cessation Guideline for distribution</p> <p><i>Duration of intervention:</i> Authors state intervention lasted through a 6 month period, however level of exposure for participants not specified</p> <p><i>Intervention delivered by:</i> Registered nurse face-to-face through 2 to 3 site visits within the first 6 months to communicate with directors of primary care, pharmacy service chiefs, smoking cessation coordinators and primary care nurses, as well as the 2 day training meeting</p> <p><i>Intensity:</i> One, 2 day training meeting held in Minneapolis for the site-based principal investigator; 2 to 3 day visit to each site by the interventionist within the first 6 months</p>	
Outcomes	<p><i>Pre-specified outcome data:</i> General health, smoking history/status, nicotine dependence, services provided at the last primary care visit, mood, alcohol use and demographics, provision of counselling, referred to a smoking cessation clinic, provided advice or medications and cessation discussed (documented in medical records)</p> <p><i>Follow-up period:</i> Twelve months</p>	
Notes	<p><i>Process measures:</i> None reported</p> <p><i>Validation:</i> No biochemical validation</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomization mentioned, however methods not described
Allocation concealment (selection bias)	Unclear risk	Methods not described

Joseph 2004 (Continued)

Blinding (performance bias and detection bias) of participants	High risk	Due to the nature of the intervention blinding of participants was not possible for this study
Blinding (performance bias and detection bias) of outcome assessors	Low risk	Interviewers were blinded to subjects' site treatment status
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition appears to be higher in the intervention arm than the control arm based on n-values; No further information provided regarding missing or incomplete outcome data
Selective reporting (reporting bias)	Low risk	All expected outcomes, including those that were pre-specified were reported
Other bias	Low risk	No other biases identified
Imbalance of outcome measures at baseline	Low risk	A logistics regression analysis was used to account for imbalances in outcome measures at baseline
Comparability of intervention and control group characteristics at baseline	Low risk	No significant differences between subject characteristics were identified
Protection against contamination	Unclear risk	Insufficient information to permit judgement of yes or no
Selective recruitment of participants	Low risk	Baseline n-values appear similar, methods for recruitment of participants are the same across groups

Methods	<p><i>Country:</i> USA</p> <p><i>Design:</i> Randomized controlled trial; Clustered</p> <p><i>Objective:</i> "...the task of Doctors Helping Smokers was to be the development and testing of a program to help physicians incorporate currently identified smoking cessation intervention into their practice routine." Hypothesis: that physicians trained in a workshop would be more effective in helping their smoking patients quit than would similar volunteer physicians who received only patient education materials or a group of physicians that received no assistance</p> <p><i>Methods of analysis:</i> Data presented as proportions were analysed with the Chi² analysis; Data reported as means and SDs were analysed with analysis of variance; Life-table analysis used to examine relapse patterns of the patients who attempted to quit smoking</p> <p><i>Clustering adjustment made:</i> Physicians unit of analysis; Multivariate regression used to adjust for confounding effects of differences among the groups of doctors and their patients</p> <p><i>Significance of cluster adjustment:</i> Not reported</p>
Participants	<p><i>Therapist description:</i> n= 109 family practitioners</p> <p><i>Eligible for study; n-value:</i> 1110; n= 109 physicians returned postcards</p> <p><i>Randomized; n-value:</i> Workshop group n= 27; No-assistance group n= 17; Materials group n= 22</p> <p><i>Completed; n-value:</i> Workshop group n= 27; No-assistance group n= 17; Materials group n= 22</p> <p><i>Age:</i> Workshop group 37.9 + 9.7; No-assistance group 39.5 + 7.7; Materials group 44.3 + 11.7</p> <p><i>Gender:</i> Workshop group female=22.2%; No-assistance group female=9.1%; Materials group female=11.8%</p> <p><i>Patient description:</i> n= 1653 primary care smoking patients not selected by motivation to quit</p> <p><i>Eligible for study; n-value:</i> Not reported</p> <p><i>Randomized; n-value:</i> 6053 total (89.4% of patients whose names were submitted by the physicians)</p> <p><i>Completed; n-value:</i> 87% of the n= 6053 were available for follow-up; 86.8%, 87.5% and 86.8% for the workshop, materials and no-assistance groups respectively</p> <p><i>Age:</i> 18 to 70 years; Mean= slightly over 40</p> <p><i>Gender:</i> 2/3 female</p>
Interventions	<p><i>Setting:</i> Private family practice (primary care) in Minnesota, USA; Workshop site not described though likely centralised</p> <p><i>Training of those delivering the intervention to the health professional:</i> Not described</p> <p><i>Intervention description:</i> Two intervention groups: Materials group - physicians given self-help manuals to distribute; Workshop group - self-help manuals plus 6 hour group workshop</p> <p><i>Control description:</i> Normal care</p> <p><i>Duration of intervention:</i> Workshop group: 6-hour workshop given on two occasions. Workshop started in the morning with two presentations of 30-minutes about the effects of smoking, chronic disease and organisation for smoking cessation interventions; 1-hour presentation on doctor-patient intervention skills; 1-hour introduction to smoking cessation techniques; Two 1-hour small-group workshop sessions on counselling sessions and planning for smoking cessation interventions and 30-minutes for summary and discussion; Materials group: 100 copies of Quit-and-Win, a smoking cessation manual</p>

Kottke 1989 (Continued)

	<i>Intervention delivered by:</i> Not described <i>Intensity:</i> Workshop: 6-hr workshop given on 2 occasions; Materials group: None; No assistance: None	
Outcomes	<i>Pre-specified outcome data:</i> Physicians: Characteristics, knowledge, skills, confidence and beliefs about smoking cessation in relation to their performance during the trial Patients: demographics, smoking habits, health status, details about visit with physician, prevalence of smoking in their social environment and support received from spouse or others who were emotionally important to them; Four questions about extent to which they felt in control of their life, the confidence they felt about handling personal problems, extent that “things were going [their] way,” and the extent to which difficulties were piling up; Serum cotinine levels <i>Follow-up period:</i> 12months	
Notes	<i>Process measures:</i> None <i>Validation:</i> Serum cotinine Not able to be meta-analysed due to unit of analysis being the practitioners instead of the individuals	
<i>Risk of bias</i>		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Some physicians were re-assigned to groups due to inappropriate allocation methods during assignment
Allocation concealment (selection bias)	Unclear risk	Methods not described
Blinding (performance bias and detection bias) of participants	High risk	Due to the nature of the intervention it is not possible to blind participants
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	No mention of attempted blinding for outcome assessors
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Participants lost-to-follow-up were assumed smokers; No information on how missing data from questionnaires were handled
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of yes or no
Other bias	Low risk	No other potential threats to validity identified
Imbalance of outcome measures at baseline	Low risk	Analysis of covariance conducted

Kottke 1989 (Continued)

Comparability of intervention and control group characteristics at baseline	Low risk	Characteristics of physicians reported and comparable; Multivariate regression analysis conducted to adjust for confounding factors
Protection against contamination	Low risk	Physicians within the same practice were all within the same arm of the study
Selective recruitment of participants	Unclear risk	Insufficient reporting to permit judgement of yes or no

Lennox 1998

Methods	<p><i>Country:</i> United Kingdom</p> <p><i>Design:</i> Randomized controlled trial; Nested; Clustered</p> <p><i>Objective:</i> To assess the impact of the training intervention on both health professionals and smoking subjects</p> <p><i>Methods of analysis:</i> Comparison of binary outcomes were analysed using the Chi² test; Logistic and multiple regression analyses were carried out where appropriate for these outcome measures; Comparisons of continuous outcomes were analysed using t-tests and multiple linear regression; Confounders were adjusted including age, sex and deprivation score for the regression analysis as well as for indicators for the intervention group</p> <p><i>Clustering adjustment made:</i> Yes - GLMM (Generalised linear mixed model) approach used for regression techniques which added the general practice as a random factor nested within the treatment groups to the other fixed-effect factors</p> <p><i>Significance of cluster adjustment:</i> Regression techniques used to explore clustering effects for variables significant in individual level analyses; No significant difference in point prevalence of abstinence after adjustment</p>
Participants	<p><i>Therapist description:</i> n= 16 general practices with training for doctors, nurses and health visitors</p> <p><i>Eligible for study:</i> n= 26 practices</p> <p><i>Randomized:</i> n= 16 practices</p> <p><i>Completed:</i> n= 16 practices</p> <p><i>Age:</i> Not reported</p> <p><i>Gender:</i> Not reported</p> <p><i>Patient description:</i> Smoking patients of the practices identified from questionnaires to random sample</p> <p><i>Eligible for study:</i> Not reported</p> <p><i>Randomized:</i> Number of patients surveyed: Intervention n= 6631; Control n= 6631; Number of patients responding: Intervention n= 5022; Control n= 5217; Number of smokers identified: Intervention n= 1381; Control n= 1207</p> <p><i>Completed:</i> Eight months - Intervention n= 941; Control n= 864; 14 months - Intervention n= 898; Control n= 795</p> <p><i>Age:</i> Not reported</p> <p><i>Gender:</i> Not reported</p>

Interventions	<p><i>Setting:</i> Primary care medical practices in Aberdeen, UK <i>Training of those delivering the intervention to the health professional:</i> Two authors conducted the training, one a senior health promotion officer experienced in group work with primary health care teams and the other a GP <i>Intervention description:</i> One day training workshop based on stages of change model <i>Control description:</i> Usual care control group <i>Duration of intervention:</i> Six identical one day training workshops were held within a three week period based on stages of change model <i>Intervention delivered by:</i> Two authors, one a senior health promotion officer experienced in group work with primary health care teams and the other a GP <i>Intensity:</i> One day training workshop</p>	
Outcomes	<p><i>Pre-specified outcome data:</i> Changes in attitudes, self-reported behaviour, change in readiness to change, cessation attempt made, point prevalence, continuous abstinence <i>Follow-up period:</i> 8 and 14 months post workshop for patient questionnaires</p>	
Notes	<p><i>Process measures:</i> Some subjects did not attend their practice during the study and therefore were not exposed to the effects of the training <i>Validation:</i> No biochemical validation n-values re-calculated for meta-analysis to permit intention-to-treat analysis for primary outcome data</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Physicians were randomly allocated to control or intervention however method not described; Patients were randomly selected via a computer-generated randomization program for every 1 in 6 drawn from the patient lists
Allocation concealment (selection bias)	Unclear risk	Physicians were randomly and blindly allocated to control or intervention however methods not described
Blinding (performance bias and detection bias) of participants	High risk	Due to the nature of the intervention blinding of participants was not possible for this study
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	No mention of attempted blinding for outcome assessors
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No further information provided regarding missing or incomplete outcome data

Lennox 1998 (Continued)

Selective reporting (reporting bias)	Low risk	All expected outcomes, including those that were pre-specified were reported
Other bias	Low risk	No other biases identified
Imbalance of outcome measures at baseline	Low risk	No significant differences between groups
Comparability of intervention and control group characteristics at baseline	Low risk	No significant differences between groups however intervention subjects less affluent than controls which was adjusted for in regression analyses
Protection against contamination	Low risk	Practices containing staff who attended pilot workshops or staff whom worked for more than one participating practice were excluded
Selective recruitment of participants	Low risk	Patients were randomly selected from practices using a computer-generated randomization program; n-values are similar across groups

Sinclair 1998

Methods	<p><i>Country:</i> Scotland <i>Design:</i> Randomized controlled trial <i>Objective:</i> To evaluate a training workshop for community pharmacy personnel to improve their counselling in smoking cessation based on the stage-of-change model <i>Methods of analysis:</i> To demonstrate the differences between intervention and control groups, parametric tests (t-tests for quantitative variables) and non-parametric tests (Mann-Whitney tests for quantitative variables) were used. Multiple logistic regression was carried out for the binary outcomes of point prevalence at one month, and continuous abstinence at four and nine months, and to assess the effect of potential confounders <i>Clustering adjustment made:</i> Yes; authors mention that the effect of cluster randomization was assessed by firstly calculating the degree of intra-cluster correlation for each of the binary outcomes of abstinence. Secondly, regression techniques, adding the pharmacy as a random factor nested within the treatment groups to the other fixed effect factors, were considered leading to a generalised linear mixed model. The authors mention that intra-cluster correlations for the outcomes at each time point were calculated. The estimated values were less than 0.0001 and therefore negligible <i>Significance of cluster adjustment:</i> No; authors mention that trends in outcome were not affected by potential confounders or adjustment for clustering <i>Setting:</i> Residents and physicians in family medicine, Taiwan <i>Training:</i> Two lessons</p>
Participants	<p><i>Therapist description:</i> <i>Eligible for study; n-value:</i> n= 76 pharmacies <i>Randomized; n-value:</i> Intervention n= 32 pharmacies; Control n= 30 pharmacies</p>

Sinclair 1998 (Continued)

	<p><i>Completed; n-value:</i> Intervention n= 32 pharmacies (specify: n= 94 (54 assistants, 40 pharmacists); Control n= 29 pharmacies <i>Age:</i> Not described <i>Gender:</i> Intervention: 54 female assistants; 25 female pharmacists; Control: not described <i>Patient description:</i> <i>Eligible for study; n-value:</i> n= 775 smokers <i>Randomized; n-value:</i> Intervention n= 224; Control n= 268 <i>Completed; n-value:</i> Intervention n= 159; Control n= 188 <i>Age:</i> Intervention 41.7 (17-74); Control 41.5 (17-77) <i>Gender:</i> Intervention 61.2% men; Control 62.7% men</p>	
Interventions	<p><i>Setting:</i> Eight workshops were scheduled with a choice of dates, times and location (Aberdeen or Elgin - the major population centres which are located 70 miles apart at apposite ends of the study area) <i>Training of those delivering the intervention to the health professional:</i> Not described <i>Intervention description:</i> Training in stages of change approach to smoking cessation <i>Control description:</i> Usual care <i>Duration of intervention:</i> Two-hour workshop <i>Intervention delivered by:</i> Not described <i>Intensity:</i> One workshop</p>	
Outcomes	<p><i>Pre-specified outcome data:</i> Self-reported point prevalence smoking cessation rates at one month; Self-reported continuous abstinence from zero to four months and from zero to nine months; The pharmacy support process (registration, counselling and client record) <i>Follow-up period:</i> 1, 4, 9 months; Point prevalence of abstinence at 12 months No process outcomes</p>	
Notes	<p><i>Validation:</i> none n-values re-calculated for meta-analysis to permit intention-to-treat analysis for primary outcome data</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Pharmacy recruits were stratified by type ... and ranked according to the pharmacists' level of motivation ... They were then randomized to either the intervention or control group by sequential allocation"
Allocation concealment (selection bias)	Unclear risk	Methods not described
Blinding (performance bias and detection bias) of participants	High risk	Authors state "Pharmacists and pharmacy assistants were aware of group by virtue of intervention design"

Sinclair 1998 (Continued)

Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	Methods for blinding participants for outcome assessors were not mentioned
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information to permit judgement of yes or no
Selective reporting (reporting bias)	Low risk	All outcomes were reported
Other bias	Low risk	No other sources of bias were identified
Imbalance of outcome measures at baseline	Low risk	The potential confounders of age, sex, socio-economic status, and nicotine dependence showed no difference between intervention and controls
Comparability of intervention and control group characteristics at baseline	Low risk	There was no significant difference between the characteristics of the intervention and control customers
Protection against contamination	Unclear risk	To minimise inter-group contamination, both leaflets requested customers to return to that same pharmacy for any further advice and for subsequent purchase(s) of anti-smoking products
Selective recruitment of participants	Unclear risk	During the 12-month customer recruitment period, all smokers who sought advice on stopping smoking or those who bought an OTC anti-smoking product in preparation for a new attempt to stop smoking were eligible for inclusion

Strecher 1991

Methods	<p><i>Country:</i> USA <i>Design:</i> Randomized Controlled Trial; Factorial design; Nested; Cluster <i>Objective:</i> The study evaluated the effectiveness of training and prompting under realistic conditions, including: the use of simple and generalisable interventions; training conducted by existing faculty; and evaluation at several sites with residents from three primary care specialties <i>Methods of analysis:</i> Contingency tables with Chi² tests, t-tests, and analysis of variance (ANCOVA) were used to investigate the pre-test equivalencies of the four groups and all outcomes for selected other variables; ANCOVA compared the effects of the two interventions, alone and in combination, whilst controlling for pre-test scores and physician speciality <i>Clustering adjustment made:</i> No <i>Significance of cluster adjustment:</i> N/A (Physician speciality adjusted for but not individual physician clustering effects)</p>
Participants	<p><i>Therapist description:</i> 250 residents in internal medicine, family practice and paediatrics <i>Eligible for study:</i> n= 261 <i>Randomized;</i> n= 250; Tut (Tutelage) and Pro (Prompt) n= 66; Tut only n= 66; Pro only n= 60; Control n= 58 <i>Completed;</i> n= 234; Tut and Pro n= 62; Tut only n= 63; Pro only n= 55; Control n= 54 <i>Age:</i> Not reported <i>Gender:</i> Not reported <i>Patient description:</i> 937 patients from American primary care medical practice <i>Eligible for study;</i> n= 937; Tut and Pro n= 250; Tut only n= 243; Pro only n= 228; Control n= 225 <i>Randomized;</i> n= 843 <i>Completed;</i> n= 659; Tut and Pro n= 184; Tut only n= 156; Pro only n= 162; Control n= 157 <i>Age:</i> 17 to 75 years; Mean age = 45 years <i>Gender:</i> 63% female</p>
Interventions	<p><i>Setting:</i> American primary care residency programs (physicians in training) <i>Training of those delivering the intervention to the health professional:</i> Not specified though one of the authors in each instance conducted the tutorial <i>Intervention description:</i> Three intervention groups: Tutelage only (minimal contact counselling); Prompt only (chart-reminder and advice sheet); Tutelage and Prompt <i>Control description:</i> Normal care <i>Duration of intervention:</i> Only held once, two sessions in total - the first included slide presentations the second group discussions <i>Intervention delivered by:</i> One of the authors, usually a clinic director or a faculty member conducted the tutorial <i>Intensity:</i> Tutorial: two sessions - initial one-hour long, second session two weeks later</p>
Outcomes	<p><i>Pre-specified outcome data:</i> Self-administered questionnaires requesting self-reports on smoking-cessation counselling frequency, content, attitude and training; Patients were asked about smoking habits and physicians advice to stop smoking <i>Follow-up period:</i> 6-months</p>

Notes	<p><i>Process measures:</i> None <i>Validation:</i> Expired CO; Biochemical verification was obtained where possible The three intervention groups were combined for meta-analyses to produce the single 'Intervention' sample; n-values re-calculated for meta-analysis to permit intention-to-treat analysis for primary outcome data</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Authors state "After the pre-test, residents were randomly assigned by clinic half-day session to one of four groups"
Allocation concealment (selection bias)	Unclear risk	Methods not described
Blinding (performance bias and detection bias) of participants	High risk	Due to the nature of the intervention it was not possible to blind participants
Blinding (performance bias and detection bias) of outcome assessors	Low risk	Authors state "...telephone interviewers, who were blinded to residents' and patients' group assignments, obtained patient reports..."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No mention of data containing any missing variables; Missing outcome data not described
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of yes or no
Other bias	Low risk	No other sources of bias were identified
Imbalance of outcome measures at baseline	Low risk	All groups were reported as similar for baseline outcomes; Analysis of variance also conducted
Comparability of intervention and control group characteristics at baseline	Low risk	All groups were reported as similar for baseline characteristics; Analyses to test pre-test equivalence were conducted
Protection against contamination	High risk	Authors state contamination occurred as all four groups worked closely with one another at each site though they also state that "...the effects appeared to be slight."

Selective recruitment of participants	Unclear risk	Insufficient information to permit judgement of yes or no
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Swartz 2002

Methods	<p><i>Country:</i> USA</p> <p><i>Design:</i> Randomized controlled trial; Clustered</p> <p><i>Objective:</i> Primary goal of this study was to determine if in-person feedback intervention, compared to mailed feedback, would lead to a higher use of tobacco treatments by patients who smoke</p> <p><i>Method of Analysis:</i> Odds ratios, 95% confidence intervals and p-values were calculated to evaluate intervention effects on patient and provider behaviour; Unadjusted models and models adjusted for age, insurance at baseline, practice speciality and region of the state were calculated using logistic regression; All analyses were completed with SAS statistical software</p> <p><i>Clustering adjustments made:</i> Yes - survey logistic procedures</p> <p><i>Significance of clustering:</i> Not reported</p>
Participants	<p><i>Therapist description:</i> Primary care providers with practices of at least 75% internal medicine or family medicine clinicians providers combined with Medicaid and HMO panel size of at least 200 adults; n= 176 were physicians, n= 26 nurse practitioners, n= 20 physician assistants, n= 3 unknown classification</p> <p><i>Eligible for study:</i> n= 150 practices; n= 230 providers within the 50 practices recruited were eligible</p> <p><i>Randomized:</i> n= 50 practices; n= 225 providers</p> <p><i>Completed:</i> n= 50 practices; n= 179 providers</p> <p><i>Age:</i> Not reported</p> <p><i>Gender:</i> Not reported</p> <p><i>Patient description :</i> Patients were adults receiving primary care by a study practice aged 18 years and older who were seen within the prior year</p> <p><i>Eligible for study:</i> n= 17318 identified as receiving primary care by a study practice; n= 11547 eligible</p> <p><i>Randomized:</i> n= 7461 completed baseline survey; n= 1238 patients identified as smokers at baseline</p> <p><i>Completed:</i> n= 807 reporting provider visit in the year proceeding follow-up; n= 516 smokers with baseline and follow-up surveys reporting one serious quit attempt</p> <p><i>Age:</i> Intervention mean age= 41.9 years; Control mean age= 42.9 years</p> <p><i>Gender:</i> Intervention male= 26.4%; Control male= 23.2%</p>
Interventions	<p><i>Setting:</i> Maine Medicaid and Maine HMO, USA</p> <p><i>Training of those delivering the intervention to the health professional:</i> Not reported</p> <p><i>Intervention description:</i> Experimental study practices received two educational office sessions, with data feedback presented during the first visit; Second visit reinforced the guidelines and discussed office systems to improve tobacco treatment</p> <p><i>Control description:</i> Control practices received information and feedback data by mail</p> <p><i>Duration of intervention:</i> For the intervention: Two educational office sessions, the second occurred five months after the first</p> <p><i>Intervention delivered by:</i> One nurse practitioner well-versed in motivational interviewing</p>

	and tobacco guidelines <i>Intensity:</i> Twenty minute slide presentation followed by feedback and discussions for the first visit; Second visit discussions time not stated	
Outcomes	<i>Pre-specified outcome data:</i> Reports of provider asking about tobacco, advice to quit, spending time talking about smoking or quitting, discussing tobacco treatment medications, and discussing counselling services or programs; Smokers were asked about serious attempts at quitting for 24 hours or longer, use of medication or counselling to aid quitting, and use of any tobacco in the previous week (7 day point prevalence) <i>Follow-up Period:</i> Fifteen to 18 months later which corresponded to 12 months following the practice intervention	
Notes	<i>Process measures:</i> None reported <i>Validation:</i> No biochemical validation	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomization mentioned however methods not described
Allocation concealment (selection bias)	Unclear risk	Methods not described
Blinding (performance bias and detection bias) of participants	High risk	Due to the nature of the intervention blinding of participants was not possible for this study
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	No mention of attempted blinding of outcome assessors
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No further information provided regarding missing or incomplete outcome data
Selective reporting (reporting bias)	Low risk	All expected outcomes, including those that were pre-specified were reported
Other bias	Low risk	No other biases identified
Imbalance of outcome measures at baseline	Low risk	Differences in intervention effect were adjusted for baseline outcomes
Comparability of intervention and control group characteristics at baseline	Low risk	Data were adjusted for age, gender and insurance to account for patient differences
Protection against contamination	Unclear risk	Insufficient information to permit judgement of yes or no

Selective recruitment of participants	Unclear risk	Methods of recruitment not described
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Twardella 2007

Methods	<p><i>Country:</i> Germany</p> <p><i>Design:</i> Randomized controlled trial; Nested; Clustered; Factorial design 2x2</p> <p><i>Objective:</i> The aim of this study was to examine whether and to what extent structural changes could enhance promotion of smoking cessation in general practice. In particular, we aimed to investigate the effect of the following strategies on smoking cessation rates: (1) specific training of general practitioners in methods of promoting smoking cessation and a financial incentive to general practitioners for each recruited patient who successfully quits and (2) specific training of general practitioners in promotion of smoking cessation and the cost-free prescription of drugs proved effective in supporting smoking cessation</p> <p><i>Methods of analysis:</i> Primary end-point data were assessed on an intention-to-treat basis; Smoking abstinence at 12 months was assessed using a mixed logistic regression model accounting for cluster randomization including a random effect for medical practice in the model; Baseline imbalances between intervention arms were adjusted using multivariate analyses; The effect of drug use during follow-up, as recorded by general practitioners, was evaluated in a bivariate mixed logistic regression model</p> <p><i>Clustering adjustment made:</i> Yes - mixed logistic regression model, using PROC NLMIXED in "SAS V8.1" (including a random effect for medical practice)</p> <p><i>Significance of cluster adjustment:</i> Not reported</p>
Participants	<p><i>Therapist description:</i> General practitioners in the Rhine-Neckar region located in south-west Germany</p> <p><i>Eligible for study:</i> n= 174 met the inclusion criteria</p> <p><i>Randomized:</i> Total= 94 general practitioners from n= 82 practices; Usual care: n= 21 therapists (20 practices); Training + incentive: n= 24 therapists (21 practices); Training + medication: n= 23 therapists (21 practices); Training, incentive + medication: n= 26 therapists (20 practices)</p> <p><i>Completed:</i> n= 59 practices; Usual care: n= 14 practices; Training + incentive: n= 16 practices; Training + medication: n= 11 practices; Training, incentive + medication: n= 18 practices</p> <p><i>Age:</i> Not reported</p> <p><i>Gender:</i> Not Reported</p> <p><i>Patient description:</i> Patients visiting the practices and who smoked at least 10 cigarettes per day and aged between 36 to 75 years, were recruited by participating general practitioners, irrespective of intention to quit smoking and conditional on written informed consent</p> <p><i>Eligible for study:</i> n= 587</p> <p><i>Randomized:</i> n= 587; Usual care: n= 76; Training + incentive: n= 146; Training + medication: n= 144; Training, incentive + medication: n= 221</p> <p><i>Completed:</i> n= 488; Usual care: n= 61; Training + incentive: n= 123; Training + medication: n= 121; Training, incentive + medication: n= 183</p> <p><i>Age:</i> Range 36 to 75 years;<45 years: Usual care n= 30; Training + incentive n= 55; Training + medication n= 59; Training, incentive + medication n= 95; 45 to 54 years: Usual care n= 24; Training + incentive n= 63; Training + medication n= 44; Training, incentive + medication n= 86; > 55 years: Usual care n= 22; Training + incentive n= 28;</p>

	<p>Training + medication n= 41; Training, incentive + medication n= 40 <i>Gender:</i> Female: Usual care n= 38; Training + incentive n= 74; Training + medication n= 71; Training, incentive + medication n= 121</p>	
Interventions	<p><i>Setting:</i> Not reported <i>Training of those delivering the intervention to the health professional:</i> Not reported <i>Intervention description:</i> Three intervention groups: Training + incentive - Two hour cost-free group tutorial for general practitioners in methods of promoting smoking cessation including stages of change model, approaches for counselling in general practice and potential of pharmacological support; Financial remuneration of EURO130 after study completion per smoke-free participant; Training + medication - Same group tutorial as above plus general practitioners could offer cost-free prescription of drugs proved effective in supporting smoking cessation; Training, incentive + medication - All of the above <i>Control description:</i> Usual care <i>Duration of intervention:</i> A single 2 hour tutorial available at two session times <i>Intervention delivered by:</i> Not reported <i>Intensity:</i> Two-hour workshop</p>	
Outcomes	<p><i>Pre-specified outcome data:</i> Primary outcome measure - Self-reported point prevalence of smoking abstinence obtained at 12 months follow-up Second outcome measure - Continuous smoking abstinence for at least 6 months (183 days) at 12 months follow-up; Frequency of the use of methods to support smoking cessation among patients during the follow-up period as reported by general practitioners <i>Follow-up period:</i> Twelve months</p>	
Notes	<p><i>Process measures:</i> None reported <i>Validation:</i> Serum cotinine <i>Other:</i> Definition of abstinence - Participants were categorised as 'at least 6 months abstinent' if they were smoke free at 12 months follow-up, validated by serum cotinine, and, according to self-report, had stopped smoking at least 6 months before the date of follow-up The three intervention groups were combined for meta-analyses to produce the single 'Intervention' sample</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomization performed centrally at the German Centre for Research on Aging using PROC PLAN in SAS
Allocation concealment (selection bias)	Unclear risk	Methods not described
Blinding (performance bias and detection bias) of participants	High risk	Due to the nature of the intervention blinding of participants was not possible for this study

Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	Authors report serum cotinine levels determined in a blinded fashion, though methods not described; No mention of blinding for assessors of the other outcomes
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Two participants died during follow-up and five participants could not be located; Three participants in whom smoking abstinence could not be validated as a result of current use of nicotine replacement therapy were excluded; No further information provided regarding missing or incomplete outcome data
Selective reporting (reporting bias)	Low risk	All expected outcomes, including those that were pre-specified were reported
Other bias	Low risk	No other biases identified
Imbalance of outcome measures at baseline	Low risk	Patients did substantially differ at baseline regarding the stage of change for smoking cessation; A multivariate analysis was conducted in which the authors adjusted for all baseline factors that were unequally distributed between intervention arms, as assessed by Mantel-Haenszel Chi ² statistic
Comparability of intervention and control group characteristics at baseline	Unclear risk	“We found no significant differences between the four groups of GPs with respect to the number of GPs per practice (p= 0.13), location (p= 0.62), sex (p= 0.38), age (p= 0.19) or smoking status (p= 0.21)”; 13 GPs withdrew and 13 GPs had no referrals of eligible patients, leaving a total of 68 GPs, unequally divided across the different arms
Protection against contamination	Unclear risk	Insufficient information to permit judgement of yes or no
Selective recruitment of participants	Unclear risk	Authors state that a possibility exists for selective recruitment, however statistical adjustments for this at follow-up still produce a significant result; n-values are different between the three intervention groups in comparison to the usual care arm

Methods	<p><i>Country:</i> USA</p> <p><i>Design:</i> Randomized controlled trial; Nested; Clustered</p> <p><i>Objective:</i> To bolster the rate at which physicians delivered smoking cessation services and to increase patients' quit rates</p> <p><i>Methods of analysis:</i> Descriptive statistics for characterisation of sample at baseline; Pearson's Chi² test and independent sample t-test to measure differences between groups; Hierarchic generalised linear model analysis of variance controlling for baseline variables used to measure physician performance; Abstinence analysed via generalised linear model</p> <p><i>Clustering adjustment made:</i> Yes - Mixed linear modelling with physician as clustering variable used for smoking related outcomes</p> <p><i>Significance of cluster adjustment:</i> Not reported</p>
Participants	<p><i>Therapist description:</i> Primary care physicians recruited from the four largest metropolitan boroughs, Bronx, Brooklyn, Manhattan and Queens</p> <p><i>Eligible for study:</i> n= 579</p> <p><i>Randomized:</i> Intervention n= 35; Control n= 35</p> <p><i>Completed:</i> Intervention n= 35; Control n= 35</p> <p><i>Age:</i> Mean = 51.1 + 8.1 years (total population only)</p> <p><i>Gender:</i> Males= 74% (total population only)</p> <p><i>Patient description:</i> Patients in primary care physician waiting rooms who were identified as smokers</p> <p><i>Eligible for study:</i> n= 5826</p> <p><i>Randomized:</i> Intervention n= 270; Control n= 248</p> <p><i>Completed:</i> Intervention n= 237; Control n= 228</p> <p><i>Age:</i> Intervention mean= 43.5 + 14.7 years; Control mean= 42.8 + 14.2 years</p> <p><i>Gender:</i> Intervention 58% male; Control 64% male</p>
Interventions	<p><i>Setting:</i> Training conducted during a 40 minute visit to the physicians office</p> <p><i>Training of those delivering the intervention to the health professional:</i> Not reported</p> <p><i>Intervention description:</i> Physician training in brief smoking cessation counselling based on the 5As Clinical Practice Guideline algorithm; Patients and physicians provided with a one page report containing smoking-related information and recommendations based on the information provided during the patient assessment</p> <p><i>Control description:</i> Physicians in the control condition were not given any training and were instructed to continue their usual smoking cessation practices; Patients completed the same assessments but did not receive the report (being the one page report characterising patients smoking habits)</p> <p><i>Duration of intervention:</i> One session only</p> <p><i>Intervention delivered by:</i> Health educator</p> <p><i>Intensity:</i> One, 40 minute session</p>
Outcomes	<p><i>Pre-specified outcome data:</i> Patients asked - Did your doctor... ask whether you smoke, ask whether you are ready to quit, advise you to quit smoking, help you to quit smoking, help you set goals about quitting, give you written materials about quitting, refer you to a quit smoking program, talk to you about quit-smoking medications, make a follow-up appointment to discuss smoking</p> <p>Primary outcome measure - 7 day point prevalence abstinence; Longest quit attempt (in days); Total number of 25 hour quit attempts, stage-of-change progression</p> <p><i>Follow-up period:</i> Six months</p>

Notes	<i>Process measures:</i> None reported <i>Validation:</i> For sub-group of participants - Saliva-cotinine test; 14 of 16 samples confirmed abstinence (88%) n-values re-calculated for meta-analysis to permit intention-to-treat analysis for primary outcome data	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number generator
Allocation concealment (selection bias)	Unclear risk	Methods not described
Blinding (performance bias and detection bias) of participants	High risk	Physicians learned their group assignment after signing the informed consent; Due to the nature of the intervention blinding of participants was not possible for this study
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	No mention of attempts to blind outcome assessors
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	62 subjects were withdrawn due to computer malfunction, scheduling and time constraints; No further information provided regarding missing or incomplete outcome data
Selective reporting (reporting bias)	High risk	Smoking abstinence from baseline to follow-up has not been reported, which is an outcome that would be expected to have been assessed for such a study
Other bias	Low risk	No other biases identified
Imbalance of outcome measures at baseline	Low risk	Patient intervention and control groups differed on the amount of daily smoking with the intervention group having more smokers with >25 year smoking history which was subsequently controlled in all smoking outcome analyses
Comparability of intervention and control group characteristics at baseline	Low risk	Both physician and patient characteristics were reported and no differences were found

Unrod 2007 (Continued)

Protection against contamination	Unclear risk	Geographic location of intervention and control physicians not described
Selective recruitment of participants	Low risk	Project staff offered participation to all identified smokers

Wang 1994

Methods	<p><i>Country:</i> Taiwan <i>Design:</i> Randomized Controlled Trial <i>Objective:</i> To assess the stages-of-change model in cigarette smoking and practice guidelines for practicing cigarette smoking cessation counselling in a short training program, designed to make physicians more willing to help their patients to quit smoking and increase success rates <i>Methods of analysis:</i> All data were analysed using either the Chi² or Fisher's exact tests <i>Clustering adjustment made:</i> No <i>Significance of cluster adjustment:</i> Not applicable</p>
Participants	<p><i>Therapist description:</i> Residents and physicians in family medicine <i>Eligible for study;</i> n-value not reported <i>Randomized;</i> n-value: Group one: lessons n= 9, Group two: posters n= 9, Group three: usual care n= 9 <i>Completed;</i> n-value: Group one: lessons n= 9, Group two: posters n= 9, Group three: usual care n= 9 <i>Age:</i> Not reported <i>Gender:</i> Not reported <i>Patient description:</i> <i>Eligible for study;</i> n-value not reported <i>Randomized;</i> n-value: n= 93, Group one: n= 39, Group two: n= 26, Group three: n= 28 <i>Completed;</i> n-value: n= 82, Group one: n= 35, Group two: n= 24, Group three: n= 23 <i>Age:</i> Group one: <40 n= 14, 40-59 n= 17, > 60 n= 8; Group two: <40 n= 14, 40-59 n= 8, > 60 n= 4; Group three: <40 n= 7, 40-59 n= 12, > 60 n= 9 <i>Gender:</i> Group one: male n= 38 female n= 1; Group two: male n= 24 female n= 2; Group three: male n= 27 female n= 1 Therapists: 27 physicians Patients: 93 patients</p>
Interventions	<p><i>Setting:</i> Not reported <i>Training of those delivering the intervention to the health professional:</i> Not reported <i>Intervention description:</i> Two intervention groups: Training - stages of change model and practice guidelines; Poster - used as a reminder to give advice <i>Control description:</i> Usual care <i>Duration of intervention:</i> Group one: two lessons; Group two: provided with poster only; Group three: no intervention <i>Intervention delivered by:</i> Not reported <i>Intensity:</i> Group one: two lessons; Group two: provided with poster only; Group three: no intervention</p>

Outcomes	<i>Pre-specified outcome data:</i> Demographic data, cigarette-smoking habits and health beliefs <i>Follow-up period:</i> 6-months; Point prevalence of abstinence at 12 months No process outcomes	
Notes	<i>Validation:</i> None <i>Process measures:</i> None reported Manual adjustment for potential clustering effects performed in the meta-analyses for primary outcome data; The two intervention groups were combined for meta-analyses to produce the single 'Intervention' sample; n-values re-calculated for meta-analysis to permit intention-to-treat analysis for primary outcome data	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Physicians were randomized "...to one of three groups by number of years in practice." No other information provided
Allocation concealment (selection bias)	Unclear risk	Methods not described
Blinding (performance bias and detection bias) of participants	High risk	Due to the nature of the intervention it was not possible to blind participants
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	No mention of blinding for outcome assessors
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No mention of missing outcome data or how any missing variables were handled
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of yes or no
Other bias	Low risk	No other biases identified
Imbalance of outcome measures at baseline	Unclear risk	Data not reported for baseline smoking; No mention of analyses of covariance
Comparability of intervention and control group characteristics at baseline	Low risk	Authors reported no significant differences between patient demographic characteristics
Protection against contamination	Unclear risk	Insufficient information to permit judgement of yes or no

Selective recruitment of participants	Unclear risk	Methods of recruitment not described; n-values are different between groups
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Wilson 1988

Methods	<p><i>Country:</i> Canada</p> <p><i>Design:</i> Randomized controlled trial; Nested; Clustered</p> <p><i>Objective:</i> To investigate the effects of a smoking cessation workshop on physician practices and on patients' smoking behaviour</p> <p><i>Methods of analysis:</i> Analysis of covariance - Obtained by averaging patient values within the practice; Analysis of differences between groups - If there was no difference between the usual care and gum only groups (untrained cohorts) these would be combined and compared with the gum plus (trained cohort); Regression analysis performed on practice unit, adjusting for the effects of predictor variables and treatment</p> <p><i>Clustering adjustment made:</i> No - None reported</p> <p><i>Significance of cluster adjustment:</i> Not reported</p>
Participants	<p><i>Therapist description:</i> Physicians</p> <p><i>Eligible for study:</i> n= 460 Family physicians</p> <p><i>Randomized:</i> n= 90 Physicians</p> <p><i>Completed:</i> n= 83 Physicians; Usual care n= 27; Gum only n= 29; Gum plus n= 27</p> <p><i>Age:</i> Usual care: Mean = 41.64 years; Gum only: Mean = 41.77 years; Gum plus: Mean = 40.57 years</p> <p><i>Gender:</i> Usual care: Male 92.6%; Gum only: Male 93.1%; Gum plus: Male 81.5%</p> <p><i>Patient description:</i></p> <p><i>Eligible for study:</i> Not stated as n-value; Participation consent rates were: Usual care 91%; Gum only 83%; Gum plus 76%</p> <p><i>Randomized:</i> Not reported</p> <p><i>Completed:</i> Usual care n= 601; Gum only n= 726; Gum plus n= 606 (total n= 1933)</p> <p><i>Age:</i> <25 years: Usual care 22%; Gum only 19%; Gum plus 17%; 25 to 44 years: Usual care 50%; Gum only 54%; Gum plus 56%; ≥ 45 years: Usual care 27%; Gum only 27%; Gum plus 27%</p> <p><i>Gender:</i> Male: Usual care 39%; Gum only 42%; Gum plus 33%</p>
Interventions	<p><i>Setting:</i> Clinical practice setting - Participation during routine physician consultation; Based in Ontario, Hamilton</p> <p><i>Training of those delivering the intervention to the health professional:</i> Not described; CME Protocol</p> <p><i>Intervention description:</i> Two intervention groups: Gum only - Physicians instructed to approach patients in their usual manner about quitting smoking and to offer nicotine gum as an aid to quitting; Gum Plus Training - Gum in addition to training</p> <p><i>Control description:</i> Usual care</p> <p><i>Duration of intervention:</i> One, 4 hour training workshop to Gum plus physician cohort</p> <p><i>Intervention delivered by:</i> Not described</p> <p><i>Intensity:</i> Control - Not explicitly reported; Gum only - Not explicitly reported; Gum plus - One, 4 hour workshop for physicians; For patients - Use of gum, 1 to 6 follow-up visits and quit dates</p>

Outcomes	<i>Pre-specified outcome data:</i> Three-month self reported sustained abstinence prior to bio-chemically validated cessation at 12 months; Smoking behaviour, cessation attempts and nicotine gum use measured by telephone interviews; Physicians performance measured by patient flow sheets and patient telephone exit interviews <i>Follow-up period:</i> Point prevalence of abstinence at 12 months	
Notes	<i>Process measures:</i> None reported <i>Validation:</i> Salivary cotinine The two intervention groups were combined for meta-analyses to produce the single 'Intervention' sample; Manual adjustment for potential clustering effects performed in the meta-analyses for primary outcome data	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomization mentioned as 'allocated by practice to one of the three treatment groups' however methods not described
Allocation concealment (selection bias)	Unclear risk	Methods not described
Blinding (performance bias and detection bias) of participants	High risk	Due to the nature of the intervention blinding of participants was not possible for this study
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	No mention of attempted blinding for outcome assessors
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	A total of 87 patients (4.5%) who may have been non-smokers were classified as cigarette smokers for the purpose of the analysis; No further information provided regarding missing or incomplete outcome data
Selective reporting (reporting bias)	Low risk	All expected outcomes, including those that were pre-specified were reported
Other bias	Low risk	No other biases identified
Imbalance of outcome measures at baseline	Low risk	Adequately described in text and adjusted for using analysis of variance
Comparability of intervention and control group characteristics at baseline	Unclear risk	Carried out a comparison of demographic characteristics of the cohorts; Baseline characteristics not fully reported

Wilson 1988 (Continued)

Protection against contamination	Low risk	Clinical practice level randomization suitable for this type of study; No indication of contamination from external sources during study period; All participants were family physicians within a 40 mile radius of the McMaster University in Hamilton, Ontario
Selective recruitment of participants	Unclear risk	Physician n-values across different groups not reported; Participation consent rates were 91%, 83% and 76%, respectively, in the usual care, gum only, and gum plus groups

HMO: Health Maintenance Organization; OTC: over the counter

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Albert 2006	No patient smoking related outcomes reported separately for intervention and control groups
Allen 1998	Unit of randomization was patients not health care providers; No patient level outcome data reported
Andrews 1999	No smoking related outcomes reported as interventions for smokeless tobacco only
Andrews 2001	Consultation process only - No smoking related outcomes reported
Ballbe 2008	Sample not randomly allocated - consultation process only
Bernstein 2009	Sample not randomly allocated - consultation process only
Bobo 1997	Consultation process only
Campbell 1997	Consultation process only - No smoking related outcomes reported
Caplan 2011	No control group
Carney 1995	Consultation process only - No smoking related outcomes reported
Cockburn 1992	Study compared academic detailing, courier delivery and direct mailing of a new smoking cessation program for use in primary care; Did not include any measure of the extent to which physicians changed their counselling, or the number of smokers who stopped smoking in the 3 groups

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Depue 2002	No control group
Dietrich 1992	Consultation process only - No smoking related outcomes reported
Dunkley 1997	Sample not randomly allocated - midwives selected into intervention and control groups
Etter 2000	No smoking related outcomes reported
Etter 2006	No smoking related outcomes reported
Giuntini 2001	No smoking related outcomes reported
Goldberg 1994	Training not randomized
Gordon 2005a	Sample not randomly allocated - historical control only
Gordon 2005b	Investigation of smokeless tobacco cessation only
Graham 2011	Consultation process only - No smoking related outcomes reported
Guo 2010	No control group
Haresaku 2010	No control group and no patient related smoking outcomes reported
Keller 2000	Consultation process only - No smoking related outcomes reported
Kerr 2011	Consultation process only - No smoking related outcomes reported
Leong 2008	No smoking related outcomes reported - only patient movement across stages of change model
Lindsay 1997	Consultation process only - No smoking related outcomes reported
Little 2009	Consultation process only - No smoking related outcomes reported
Manfredi 2011	No control group
Martin 2010	Consultation process only - No smoking related outcomes reported
Matten 2011	No control group
McEwen 2002	Consultation process only - No smoking related outcomes reported
McEwen 2006	Consultation process only - No long-term smoking related outcomes reported
McIntosh 2004	Consultation process only - No smoking related outcomes reported

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McRobbie 2008	Consultation process only - No long-term smoking related outcomes reported
Meyer 2008	Sample not randomly allocated - unit of randomization weeks 1, 2, and 3 within the 'randomly selected' practices
Moore 2005	Consultation process only - No smoking related outcomes reported
Morgan 1996	Both groups of physicians received training; Delayed intervention group asked to give usual care
Moss 2009	No control group
Ockene 1991	Physicians not randomly allocated to training; Patients were randomly allocated to different types of physician counselling with or without nicotine gum
Patwardhan 2010	Consultation process only - No smoking related outcomes reported
Pereira 2006	No patient related smoking outcome data available
Prokhorov 2010	No outcome data available on matched cohort - follow-up data only presented for cross-sectional sample of patients
Pronk 2006	No control group and no patient outcome data presented
Rankin 2010	Sample not randomly allocated and no patient outcome data presented
Richmond 1998	No control group: All physicians trained to provide Smokescreen intervention; Intervention consisted of telephone calls to ask about use of program; Patient smoking outcomes not given separately for intervention groups
Roche 1996	No control group: Comparison of different methods of training, with no patient quit rate outcomes
Royce 1995	No control group
Russos 1999	Consultation process only - No smoking related outcomes reported
Schmelz 2010	No control group and no patient related smoking outcomes reported
Schnoll 2003	Level of randomization not healthcare practitioner or practice; Level of randomization is patient
Secker Walker 1992	The study involved training residents in obstetrics and family practice to give advice about stopping smoking during pre-natal care; However, training was not the variable that was randomized
Sheffer 2009	No control group and no patient related smoking outcomes reported
Sheffer 2011	No control group
Sohn 2010	No control group and no patient related smoking outcomes reported

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Steinemann 2005	Consultation process only - No smoking related outcomes reported
Stolz 2012	No true control group and no patient related smoking outcomes reported
Targhetta 2011	Sample not randomly allocated
Von Garnier 2010	Historical control group only
Walsh 2010	No patient smoking related outcomes reported
Ward 1996	No smoking related outcome data
Wisborg 1998	Sample not randomly allocated - Midwives working on Thursdays were considered to be the intervention group
Young 2002	Consultation process only - No smoking related outcomes reported

DATA AND ANALYSES

Comparison 1. The effect of training health professionals on patient smoking cessation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Smoking cessation at longest follow-up	15		Odds Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Point prevalence	14	13459	Odds Ratio (M-H, Fixed, 95% CI)	1.36 [1.20, 1.55]
1.2 Continuous abstinence	8	9443	Odds Ratio (M-H, Fixed, 95% CI)	1.60 [1.26, 2.03]
2 Patient asked to set a quit date	8	4332	Odds Ratio (M-H, Random, 95% CI)	4.98 [2.29, 10.86]
3 Patient asked to make a follow-up appointment	7	3114	Odds Ratio (M-H, Random, 95% CI)	3.34 [1.51, 7.37]
4 Number of smokers counselled	14	8531	Odds Ratio (M-H, Random, 95% CI)	2.28 [1.58, 3.27]
5 Number of smokers receiving self-help material	9	4925	Odds Ratio (M-H, Random, 95% CI)	3.52 [1.90, 6.52]
6 Number of smokers receiving nicotine gum/replacement therapy	9	5073	Odds Ratio (M-H, Random, 95% CI)	1.57 [0.87, 2.84]
7 Number of smokers prescribed a quit date	3	1172	Odds Ratio (M-H, Fixed, 95% CI)	14.18 [6.57, 30.61]

Comparison 2. Sub-group: treatment type

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Patient asked to set a quit date	8	4332	Odds Ratio (M-H, Random, 95% CI)	4.98 [1.79, 13.88]
1.1 Counselling plus NRT	6	3322	Odds Ratio (M-H, Random, 95% CI)	7.45 [3.30, 16.85]
1.2 Counselling alone	2	1010	Odds Ratio (M-H, Random, 95% CI)	1.22 [0.78, 1.92]
2 Patient asked to make a follow-up appointment	7		Odds Ratio (M-H, Random, 95% CI)	Totals not selected
2.1 Counselling plus NRT	4		Odds Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
2.2 Counselling alone	3		Odds Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
3 Number of smokers counselled	14	8531	Odds Ratio (M-H, Random, 95% CI)	2.28 [1.41, 3.67]
3.1 Counselling plus NRT	9	5768	Odds Ratio (M-H, Random, 95% CI)	2.66 [1.33, 5.32]
3.2 Counselling alone	5	2763	Odds Ratio (M-H, Random, 95% CI)	1.71 [1.09, 2.68]
4 Number of smokers receiving self-help material	9	4925	Odds Ratio (M-H, Random, 95% CI)	3.52 [1.56, 7.91]
4.1 Counselling plus NRT	5	3165	Odds Ratio (M-H, Random, 95% CI)	5.50 [2.45, 12.36]
4.2 Counselling alone	4	1760	Odds Ratio (M-H, Random, 95% CI)	1.91 [0.56, 6.48]
5 Number of smokers receiving nicotine gum/replacement therapy	9	5073	Odds Ratio (M-H, Random, 95% CI)	1.57 [0.72, 3.42]
5.1 Counselling plus NRT	6	4122	Odds Ratio (M-H, Random, 95% CI)	1.78 [0.65, 4.91]
5.2 Counselling alone	3	951	Odds Ratio (M-H, Random, 95% CI)	1.00 [0.66, 1.50]

Comparison 3. Sub-group: treatment intensity - Number of sessions

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Patient asked to set a quit date	8	4332	Odds Ratio (M-H, Random, 95% CI)	4.98 [1.79, 13.88]
1.1 Single session	3	1969	Odds Ratio (M-H, Random, 95% CI)	14.45 [3.98, 52.48]
1.2 Multiple sessions	5	2363	Odds Ratio (M-H, Random, 95% CI)	2.79 [1.03, 7.55]
2 Patient asked to make a follow-up appointment	7	3114	Odds Ratio (M-H, Random, 95% CI)	3.34 [1.18, 9.46]
2.1 Single session	2	751	Odds Ratio (M-H, Random, 95% CI)	13.33 [2.95, 60.24]
2.2 Multiple sessions	5	2363	Odds Ratio (M-H, Random, 95% CI)	1.88 [0.94, 3.74]
3 Number of smokers counselled	14	8531	Odds Ratio (M-H, Random, 95% CI)	2.28 [1.41, 3.67]
3.1 Single session	7	4213	Odds Ratio (M-H, Random, 95% CI)	3.39 [1.56, 7.37]
3.2 Multiple sessions	7	4318	Odds Ratio (M-H, Random, 95% CI)	1.50 [1.14, 1.98]
4 Number of smokers receiving self-help material	9	4925	Odds Ratio (M-H, Random, 95% CI)	3.52 [1.56, 7.91]
4.1 Single session	3	1182	Odds Ratio (M-H, Random, 95% CI)	6.93 [1.42, 33.76]
4.2 Multiple sessions	6	3743	Odds Ratio (M-H, Random, 95% CI)	2.58 [1.01, 6.60]
5 Number of smokers receiving nicotine gum/replacement therapy	9	5073	Odds Ratio (M-H, Random, 95% CI)	1.57 [0.72, 3.42]
5.1 Single session	3	2445	Odds Ratio (M-H, Random, 95% CI)	4.33 [3.18, 5.89]
5.2 Multiple sessions	6	2628	Odds Ratio (M-H, Random, 95% CI)	0.97 [0.74, 1.27]

Comparison 4. Sub-group: treatment intensity - Total exposure

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Patient asked to set a quit date	8	4332	Odds Ratio (M-H, Random, 95% CI)	4.98 [1.79, 13.88]
1.1 Duration 40 minutes to 2 hours	5	2979	Odds Ratio (M-H, Random, 95% CI)	5.63 [0.71, 44.43]
1.2 Duration >2 to 4 hours	2	1102	Odds Ratio (M-H, Random, 95% CI)	4.70 [3.08, 7.16]
1.3 Duration >4 hours	1	251	Odds Ratio (M-H, Random, 95% CI)	3.76 [0.65, 21.65]
2 Patient asked to make a follow-up appointment	6		Odds Ratio (M-H, Random, 95% CI)	Totals not selected
2.1 Duration 40 minutes to 2 hours	4		Odds Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
2.2 Duration >2 to 4 hours	2		Odds Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
3 Number of smokers counselled	14	8531	Odds Ratio (M-H, Random, 95% CI)	2.28 [1.41, 3.67]
3.1 Duration 40 minutes to 2 hours	8	4220	Odds Ratio (M-H, Random, 95% CI)	3.25 [1.67, 6.33]
3.2 Duration >2 to 4 hours	3	2482	Odds Ratio (M-H, Random, 95% CI)	1.57 [0.86, 2.86]
3.3 Duration >4 hours	3	1829	Odds Ratio (M-H, Random, 95% CI)	1.29 [0.99, 1.68]
4 Number of smokers receiving self-help material	9	4925	Odds Ratio (M-H, Random, 95% CI)	3.52 [1.56, 7.91]

4.1 Duration 40 minutes to 2 hours	5	2192	Odds Ratio (M-H, Random, 95% CI)	3.16 [0.77, 13.07]
4.2 Duration >2 to 4 hours	3	2482	Odds Ratio (M-H, Random, 95% CI)	3.54 [1.84, 6.83]
4.3 Duration >4 hours	1	251	Odds Ratio (M-H, Random, 95% CI)	21.82 [1.50, 317.23]
5 Number of smokers receiving nicotine gum/replacement therapy	9	5073	Odds Ratio (M-H, Random, 95% CI)	1.57 [0.72, 3.42]
5.1 Duration 40 minutes to 2 hours	5	3164	Odds Ratio (M-H, Random, 95% CI)	2.33 [0.73, 7.43]
5.2 Duration >2 to 4 hours	3	1334	Odds Ratio (M-H, Random, 95% CI)	0.87 [0.52, 1.45]
5.3 Duration >4 hours	1	575	Odds Ratio (M-H, Random, 95% CI)	1.14 [0.67, 1.95]

Comparison 5. Sub-group: mode of intervention delivery

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Patient asked to set a quit date	8		Odds Ratio (M-H, Random, 95% CI)	Subtotals only
1.1 One-on-one	4	2353	Odds Ratio (M-H, Random, 95% CI)	7.52 [2.17, 26.12]
1.2 Group sessions	8	4332	Odds Ratio (M-H, Random, 95% CI)	4.98 [1.79, 13.88]
2 Patient asked to make a follow-up appointment	7		Odds Ratio (M-H, Random, 95% CI)	Subtotals only
2.1 One-on-one	3	1135	Odds Ratio (M-H, Random, 95% CI)	3.60 [0.86, 15.08]
2.2 Group sessions	6	2596	Odds Ratio (M-H, Random, 95% CI)	2.74 [1.06, 7.08]
3 Number of smokers counselled	14		Odds Ratio (M-H, Random, 95% CI)	Subtotals only
3.1 One-on-one	6	3762	Odds Ratio (M-H, Random, 95% CI)	2.76 [1.27, 6.01]
3.2 Group sessions	12	7438	Odds Ratio (M-H, Random, 95% CI)	2.47 [1.41, 4.30]
4 Number of smokers receiving self-help material	9		Odds Ratio (M-H, Random, 95% CI)	Subtotals only
4.1 One-on-one	3	1451	Odds Ratio (M-H, Random, 95% CI)	6.09 [3.93, 9.44]
4.2 Group sessions	8	4407	Odds Ratio (M-H, Random, 95% CI)	3.22 [1.36, 7.65]
5 Number of smokers receiving nicotine gum/replacement therapy	9		Odds Ratio (IV, Random, 95% CI)	Subtotals only
5.1 One-on-one	2	941	Odds Ratio (IV, Random, 95% CI)	0.88 [0.41, 1.87]
5.2 Group sessions	8	4498	Odds Ratio (IV, Random, 95% CI)	1.65 [0.68, 4.01]

Comparison 6. Sub-group: behavioural change technique used

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Patient asked to set a quit date	5	2997	Odds Ratio (M-H, Random, 95% CI)	4.19 [0.63, 28.09]
1.1 Prompting	3	1939	Odds Ratio (M-H, Random, 95% CI)	6.99 [0.90, 54.02]
1.2 Provide feedback	2	1058	Odds Ratio (M-H, Random, 95% CI)	1.76 [0.43, 7.17]
2 Patient asked to make a follow-up appointment	4		Odds Ratio (M-H, Random, 95% CI)	Totals not selected

2.1 Prompting	1		Odds Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
2.2 Provide feedback	3		Odds Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
3 Number of smokers counselled	8	4322	Odds Ratio (M-H, Random, 95% CI)	2.32 [1.13, 4.74]
3.1 Prompting	4	2171	Odds Ratio (M-H, Random, 95% CI)	3.27 [1.23, 8.68]
3.2 Provide feedback	4	2151	Odds Ratio (M-H, Random, 95% CI)	1.67 [0.99, 2.85]
4 Number of smokers receiving self-help material	5	2011	Odds Ratio (M-H, Random, 95% CI)	2.51 [0.74, 8.58]
4.1 Prompting	2	435	Odds Ratio (M-H, Random, 95% CI)	1.48 [0.64, 3.42]
4.2 Provide feedback	3	1576	Odds Ratio (M-H, Random, 95% CI)	4.33 [0.51, 36.60]
5 Number of smokers receiving nicotine gum/replacement therapy	4	1526	Odds Ratio (M-H, Fixed, 95% CI)	1.05 [0.76, 1.45]
5.1 Provide feedback	2	1091	Odds Ratio (M-H, Fixed, 95% CI)	1.00 [0.71, 1.41]
5.2 Prompting	2	435	Odds Ratio (M-H, Fixed, 95% CI)	1.47 [0.57, 3.76]

Comparison 7. Sub-group: type of professional being trained

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Patient asked to set a quit date	8	4332	Odds Ratio (M-H, Random, 95% CI)	4.98 [1.79, 13.88]
1.1 Doctor	6	2878	Odds Ratio (M-H, Random, 95% CI)	6.35 [2.49, 16.19]
1.2 Dentist	1	647	Odds Ratio (M-H, Random, 95% CI)	6.43 [1.91, 21.56]
1.3 Healthcare worker	1	807	Odds Ratio (M-H, Random, 95% CI)	1.19 [0.74, 1.91]
2 Patient asked to make a follow-up appointment	7		Odds Ratio (M-H, Random, 95% CI)	Subtotals only
2.1 Doctor	7	3114	Odds Ratio (M-H, Random, 95% CI)	3.34 [1.18, 9.46]
2.2 Healthcare worker	1	807	Odds Ratio (M-H, Random, 95% CI)	1.06 [0.73, 1.54]
3 Number of smokers counselled	14	10916	Odds Ratio (IV, Random, 95% CI)	2.05 [1.38, 3.05]
3.1 Doctor	12	7592	Odds Ratio (IV, Random, 95% CI)	2.09 [1.25, 3.49]
3.2 Dentist	1	647	Odds Ratio (IV, Random, 95% CI)	4.33 [2.64, 7.10]
3.3 Healthcare worker	4	2677	Odds Ratio (IV, Random, 95% CI)	1.55 [0.99, 2.42]
4 Number of smokers receiving self-help material	9		Odds Ratio (IV, Random, 95% CI)	Subtotals only
4.1 Doctor	9	4925	Odds Ratio (IV, Random, 95% CI)	3.51 [1.57, 7.85]
4.2 Healthcare worker	1	807	Odds Ratio (IV, Random, 95% CI)	1.07 [0.73, 1.55]
5 Number of smokers receiving nicotine gum/replacement therapy	9		Odds Ratio (IV, Random, 95% CI)	Subtotals only
5.1 Doctor	8	4581	Odds Ratio (IV, Random, 95% CI)	1.44 [0.63, 3.30]
5.2 Healthcare worker	3	1583	Odds Ratio (IV, Random, 95% CI)	1.27 [0.64, 2.53]

Comparison 8. Sub-group: length of follow-up

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Patient asked to set a quit date	8		Odds Ratio (IV, Random, 95% CI)	Subtotals only
1.1 From 6 months up to and including 9 months	3	1939	Odds Ratio (IV, Random, 95% CI)	7.02 [0.98, 50.34]
1.2 From greater than 9 months up to and including 12 months	7	4129	Odds Ratio (IV, Random, 95% CI)	5.67 [1.96, 16.42]
2 Patient asked to make a follow-up appointment	7	3114	Odds Ratio (IV, Random, 95% CI)	3.34 [1.19, 9.34]
2.1 From 6 months up to and including 9 months	2	721	Odds Ratio (IV, Random, 95% CI)	3.82 [0.48, 30.51]
2.2 From greater than 9 months up to and including 12 months	5	2393	Odds Ratio (IV, Random, 95% CI)	3.10 [0.98, 9.75]
3 Number of smokers counselled	14		Odds Ratio (IV, Random, 95% CI)	Subtotals only
3.1 From 6 months up to and including 9 months	6	3752	Odds Ratio (IV, Random, 95% CI)	3.13 [1.38, 7.09]
3.2 From greater than 9 months up to and including 12 months	10	6575	Odds Ratio (IV, Random, 95% CI)	2.50 [1.34, 4.64]
3.3 From greater than 12 months up to 24 months	2	1235	Odds Ratio (IV, Random, 95% CI)	1.30 [0.91, 1.86]
4 Number of smokers receiving self-help material	9	4925	Odds Ratio (IV, Random, 95% CI)	3.51 [1.57, 7.85]
4.1 From 6 months up to and including 9 months	2	721	Odds Ratio (IV, Random, 95% CI)	2.59 [0.22, 30.56]
4.2 From greater than 9 months up to and including 12 months	6	3972	Odds Ratio (IV, Random, 95% CI)	4.42 [1.53, 12.70]
4.3 From greater than 12 months up to 24 months	1	232	Odds Ratio (IV, Random, 95% CI)	1.88 [0.80, 4.42]
5 Number of smokers receiving nicotine gum/replacement therapy	9	5073	Odds Ratio (IV, Random, 95% CI)	1.57 [0.72, 3.41]
5.1 From 6 months up to and including 9 months	2	695	Odds Ratio (IV, Random, 95% CI)	2.27 [0.75, 6.85]
5.2 From greater than 9 months up to and including 12 months	6	4146	Odds Ratio (IV, Random, 95% CI)	1.44 [0.54, 3.81]
5.3 From greater than 12 months up to 24 months	1	232	Odds Ratio (IV, Random, 95% CI)	1.43 [0.34, 5.99]

Comparison 9. Sub-group: risk of bias in the studies

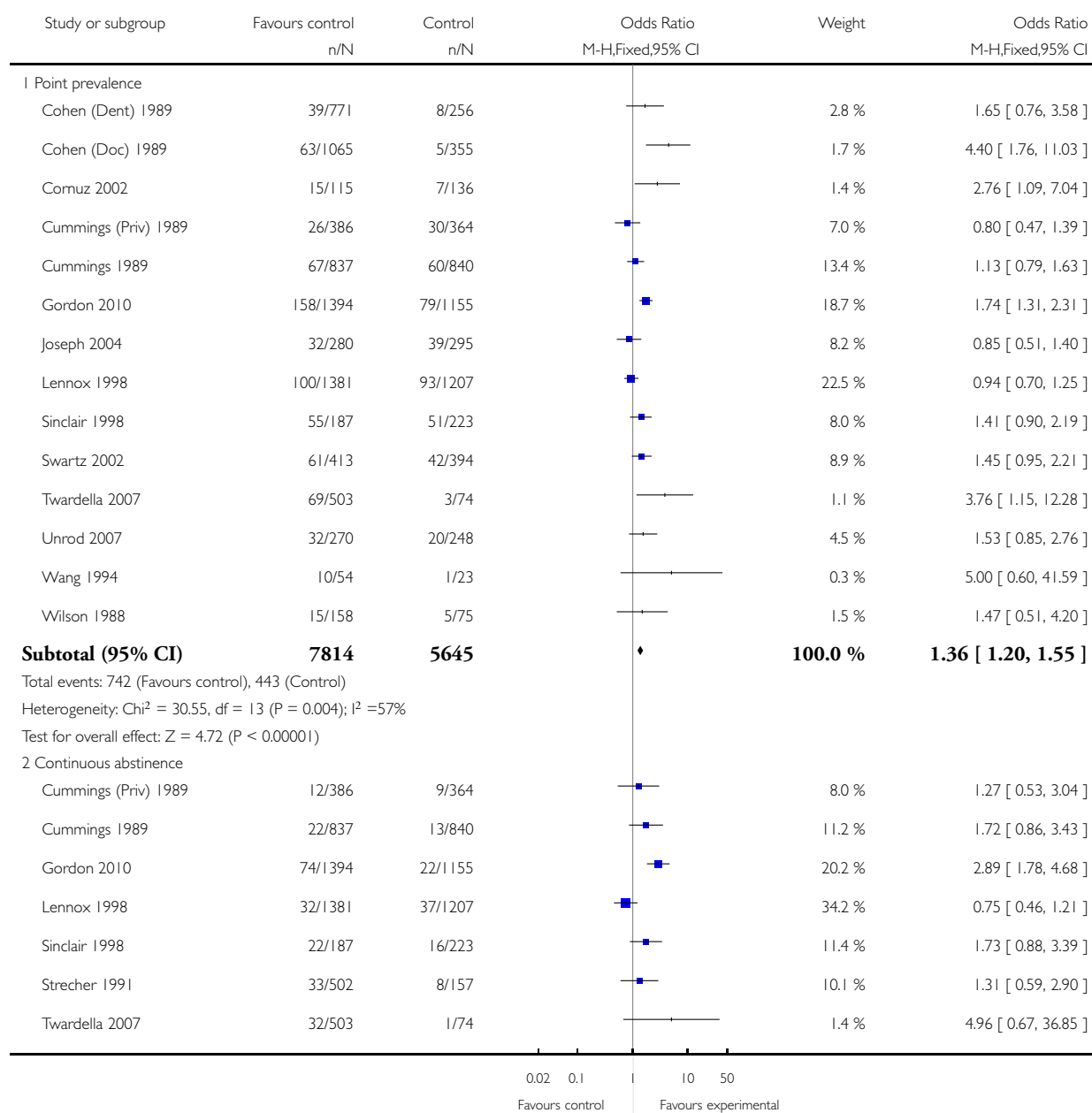
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Patient asked to set a quit date	8	4332	Odds Ratio (IV, Random, 95% CI)	4.97 [1.85, 13.30]
1.1 Up to and including 2 domains	7	4129	Odds Ratio (IV, Random, 95% CI)	5.67 [1.96, 16.42]
1.2 From 3 to 5 domains	1	203	Odds Ratio (IV, Random, 95% CI)	1.68 [0.31, 9.00]
2 Patient asked to make a follow-up appointment	7	3114	Odds Ratio (IV, Random, 95% CI)	3.34 [1.19, 9.34]
2.1 Up to and including 2 domains	6	2911	Odds Ratio (IV, Random, 95% CI)	3.79 [1.14, 12.55]
2.2 From 3 to 5 domains	1	203	Odds Ratio (IV, Random, 95% CI)	1.68 [0.69, 4.06]
3 Number of smokers counselled	14	8531	Odds Ratio (IV, Random, 95% CI)	2.28 [1.41, 3.67]
3.1 Up to and including 2 domains	11	7804	Odds Ratio (IV, Random, 95% CI)	2.32 [1.34, 4.02]
3.2 From 3 to 5 domains	2	435	Odds Ratio (IV, Random, 95% CI)	1.64 [0.87, 3.10]
3.3 From 6 to 8 domains	1	292	Odds Ratio (IV, Random, 95% CI)	3.42 [1.61, 7.28]
4 Number of smokers receiving self-help material	9	5157	Odds Ratio (IV, Random, 95% CI)	3.26 [1.57, 6.77]
4.1 Up to and including 2 domains	8	4722	Odds Ratio (IV, Random, 95% CI)	4.08 [1.75, 9.55]
4.2 From 3 to 5 domains	2	435	Odds Ratio (IV, Random, 95% CI)	1.48 [0.64, 3.42]
5 Number of smokers receiving nicotine gum/replacement therapy	9	5073	Odds Ratio (IV, Random, 95% CI)	1.57 [0.72, 3.41]
5.1 Up to and including 2 domains	6	4146	Odds Ratio (IV, Random, 95% CI)	1.44 [0.54, 3.81]
5.2 From 3 to 5 domains	2	435	Odds Ratio (IV, Random, 95% CI)	1.47 [0.57, 3.76]
5.3 From 6 to 8 domains	1	492	Odds Ratio (IV, Random, 95% CI)	3.53 [0.95, 13.09]

Analysis 1.1. Comparison 1 The effect of training health professionals on patient smoking cessation, Outcome 1 Smoking cessation at longest follow-up.

Review: Training health professionals in smoking cessation

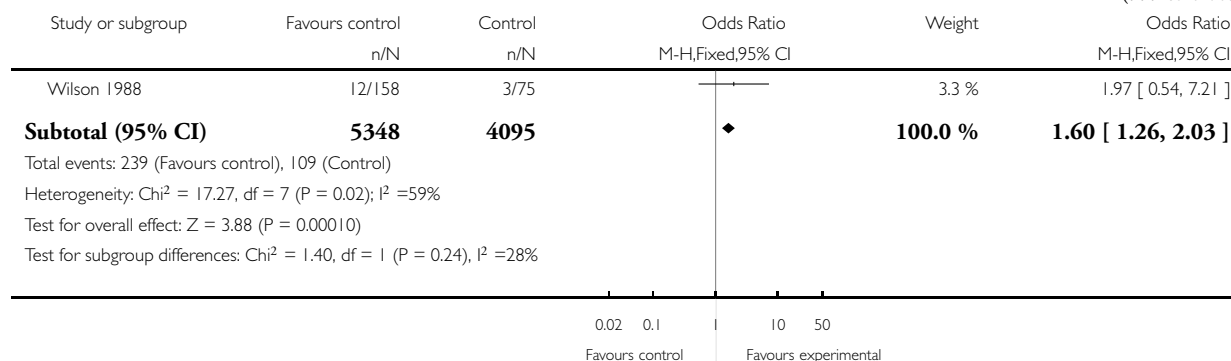
Comparison: 1 The effect of training health professionals on patient smoking cessation

Outcome: 1 Smoking cessation at longest follow-up



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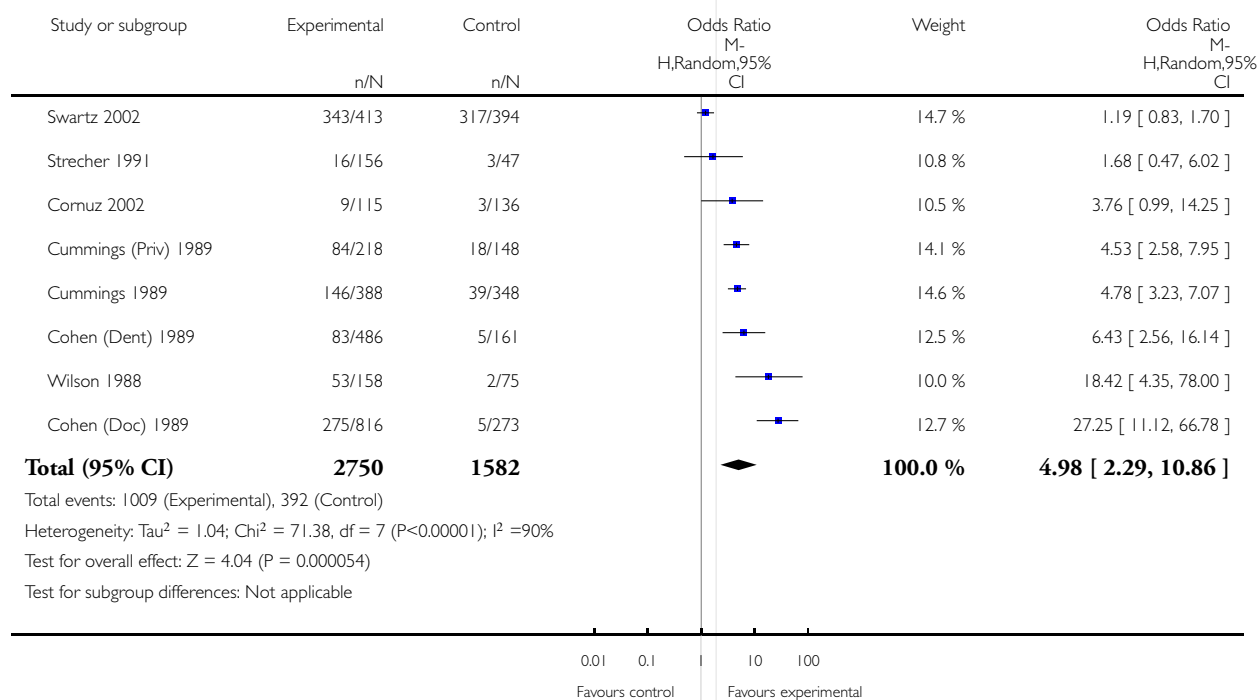


Analysis 1.2. Comparison 1 The effect of training health professionals on patient smoking cessation, Outcome 2 Patient asked to set a quit date.

Review: Training health professionals in smoking cessation

Comparison: 1 The effect of training health professionals on patient smoking cessation

Outcome: 2 Patient asked to set a quit date

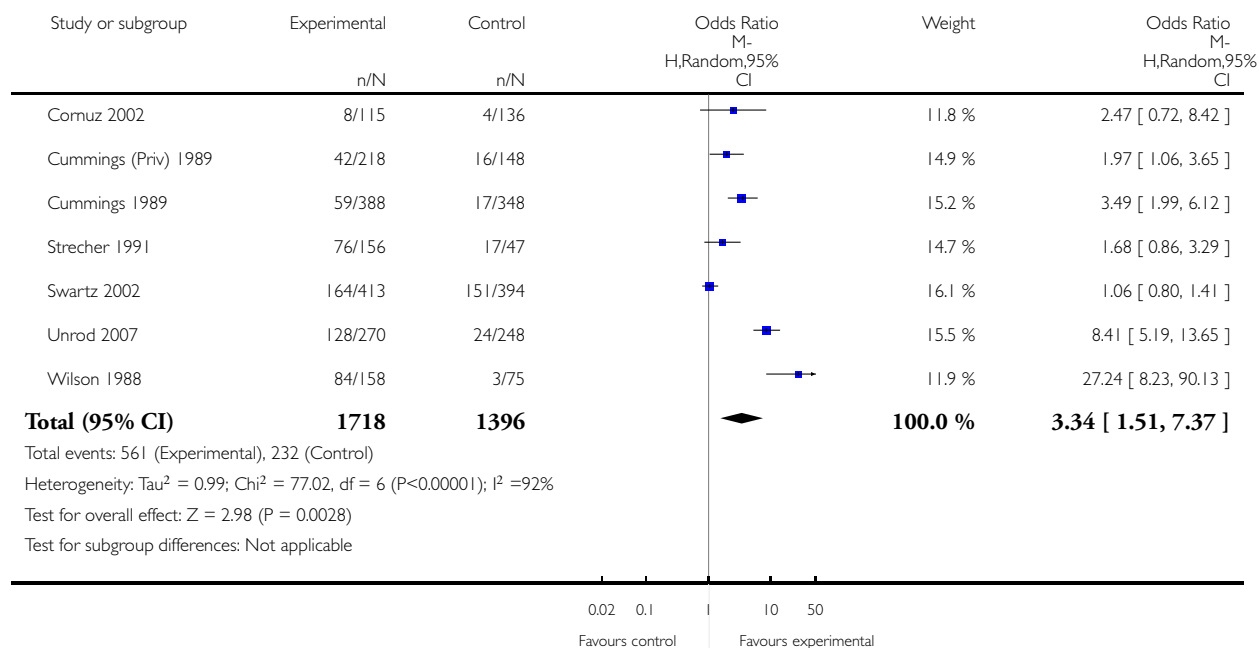


Analysis 1.3. Comparison 1 The effect of training health professionals on patient smoking cessation, Outcome 3 Patient asked to make a follow-up appointment.

Review: Training health professionals in smoking cessation

Comparison: 1 The effect of training health professionals on patient smoking cessation

Outcome: 3 Patient asked to make a follow-up appointment

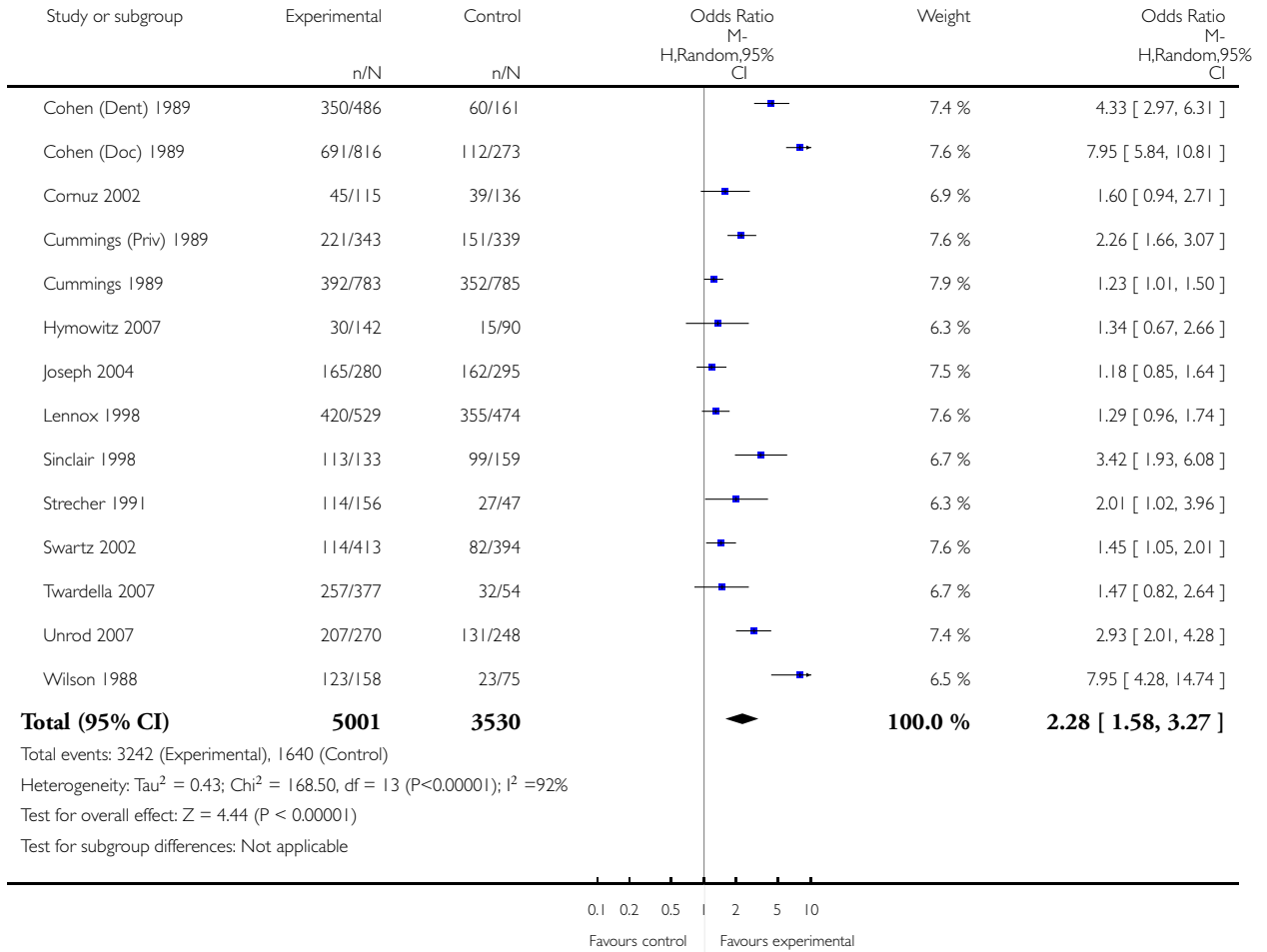


Analysis 1.4. Comparison 1 The effect of training health professionals on patient smoking cessation, Outcome 4 Number of smokers counselled.

Review: Training health professionals in smoking cessation

Comparison: 1 The effect of training health professionals on patient smoking cessation

Outcome: 4 Number of smokers counselled

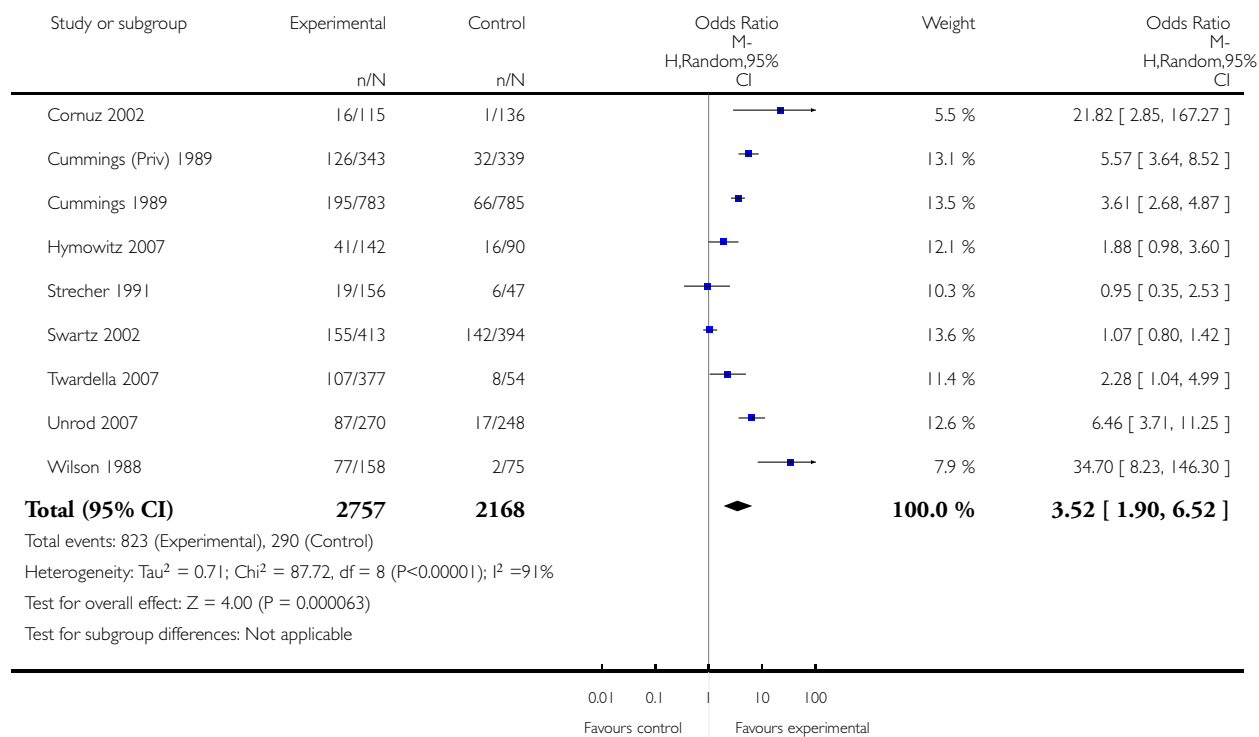


Analysis 1.5. Comparison 1 The effect of training health professionals on patient smoking cessation, Outcome 5 Number of smokers receiving self-help material.

Review: Training health professionals in smoking cessation

Comparison: 1 The effect of training health professionals on patient smoking cessation

Outcome: 5 Number of smokers receiving self-help material

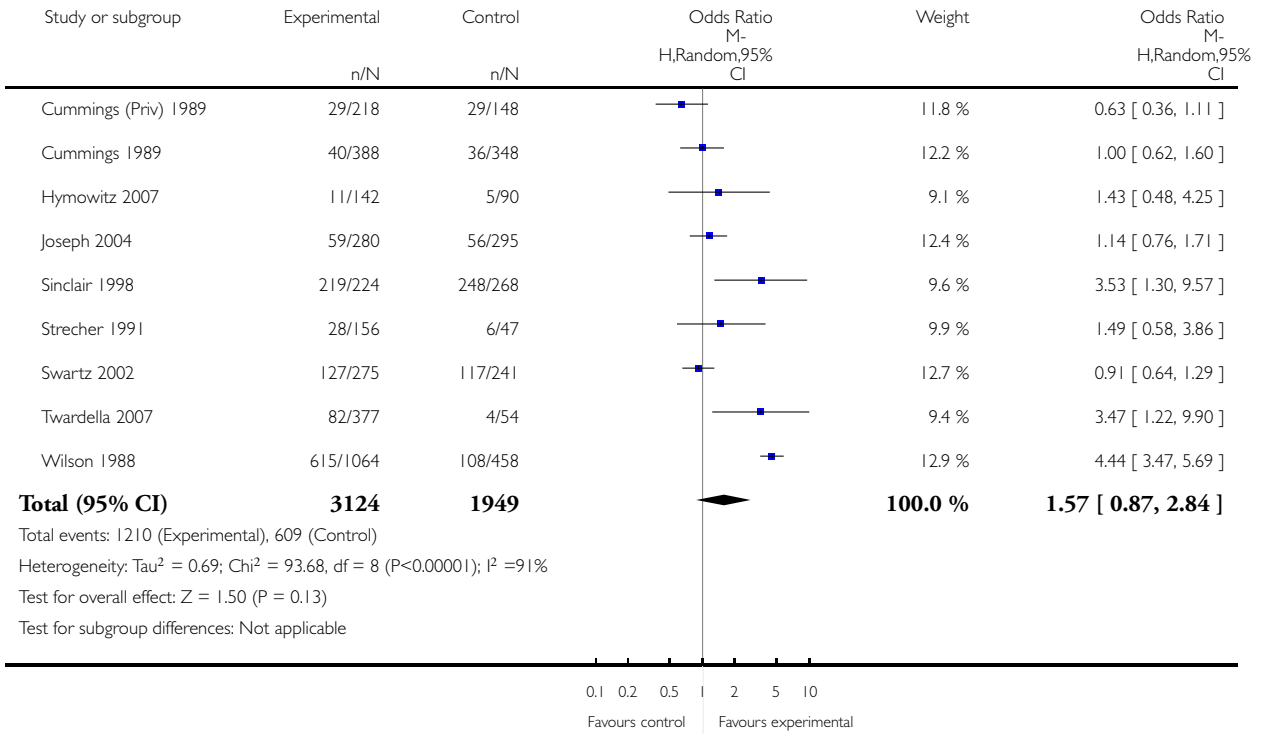


Analysis 1.6. Comparison 1 The effect of training health professionals on patient smoking cessation, Outcome 6 Number of smokers receiving nicotine gum/replacement therapy.

Review: Training health professionals in smoking cessation

Comparison: 1 The effect of training health professionals on patient smoking cessation

Outcome: 6 Number of smokers receiving nicotine gum/replacement therapy

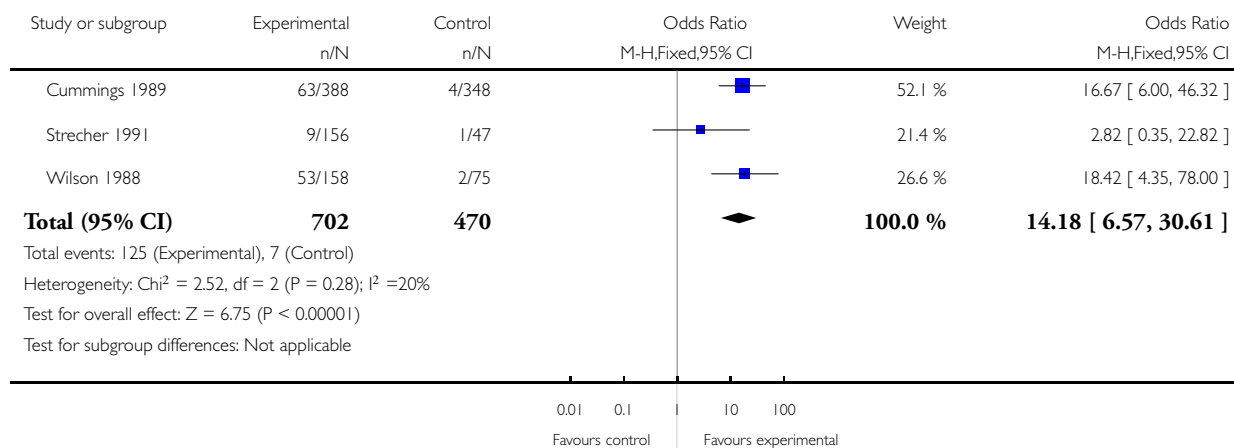


Analysis 1.7. Comparison 1 The effect of training health professionals on patient smoking cessation, Outcome 7 Number of smokers prescribed a quit date.

Review: Training health professionals in smoking cessation

Comparison: 1 The effect of training health professionals on patient smoking cessation

Outcome: 7 Number of smokers prescribed a quit date

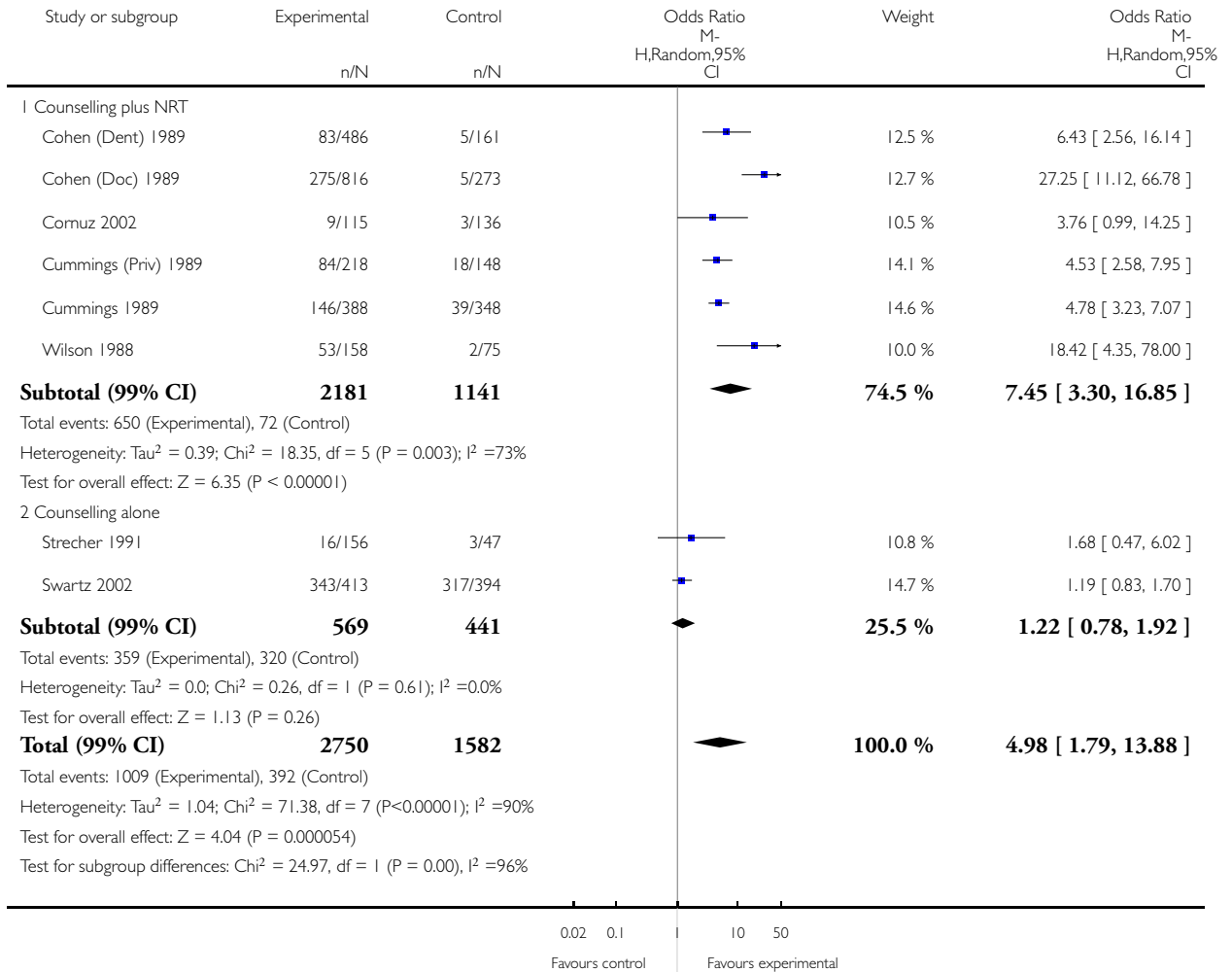


Analysis 2.1. Comparison 2 Sub-group: treatment type, Outcome 1 Patient asked to set a quit date.

Review: Training health professionals in smoking cessation

Comparison: 2 Sub-group: treatment type

Outcome: 1 Patient asked to set a quit date

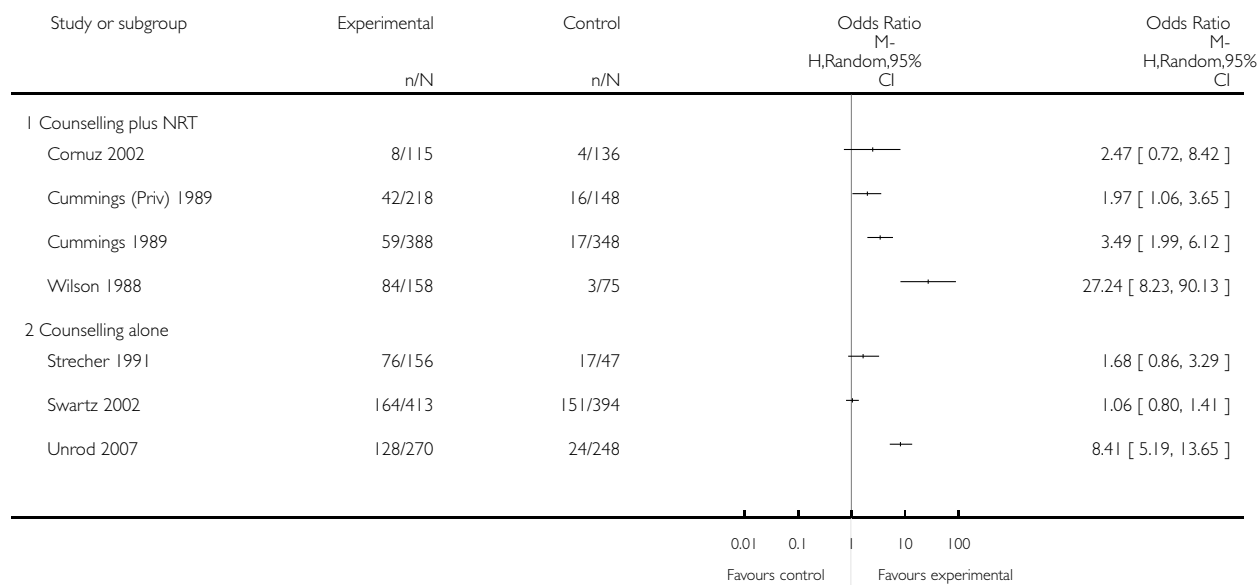


Analysis 2.2. Comparison 2 Sub-group: treatment type, Outcome 2 Patient asked to make a follow-up appointment.

Review: Training health professionals in smoking cessation

Comparison: 2 Sub-group: treatment type

Outcome: 2 Patient asked to make a follow-up appointment

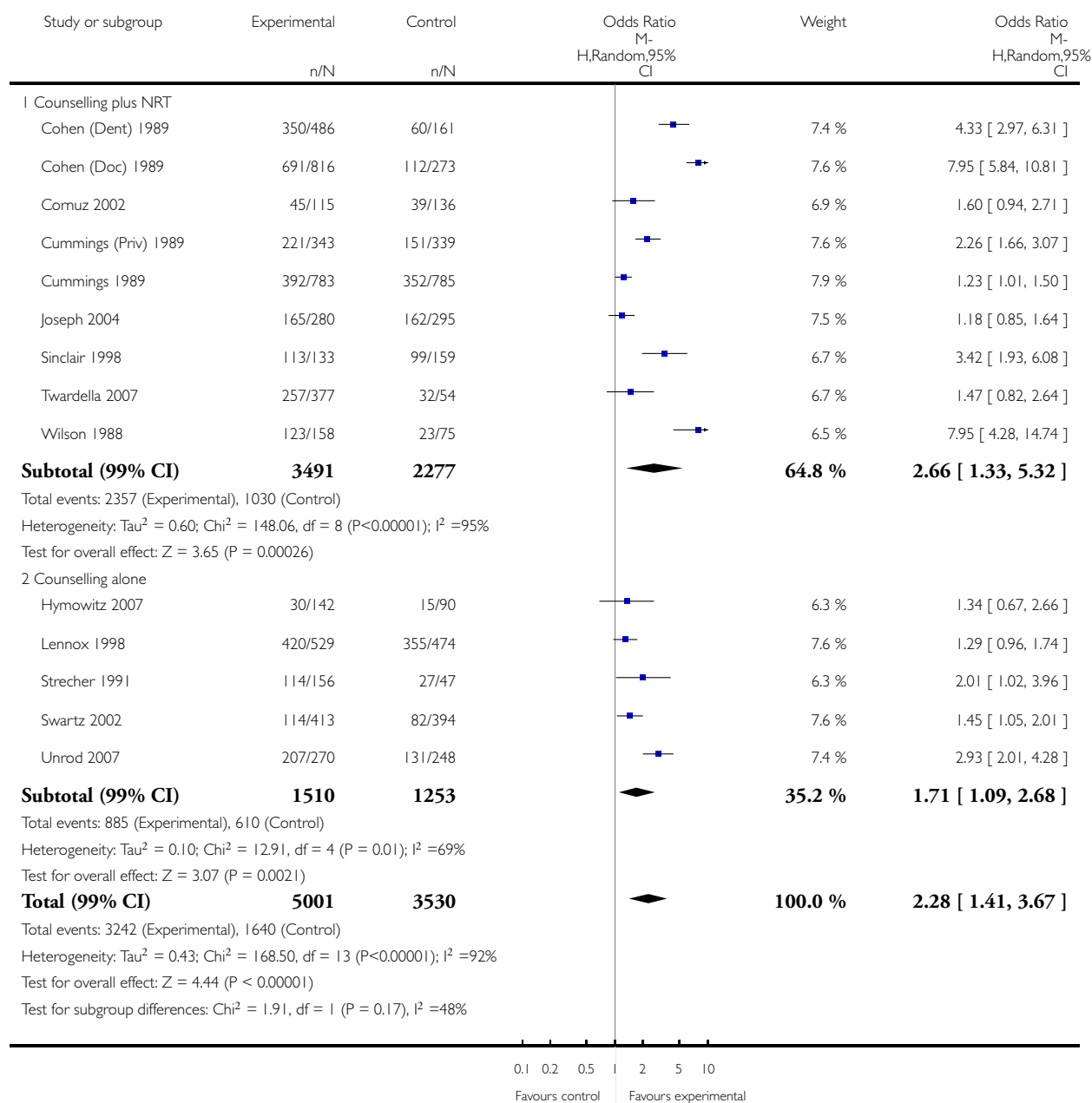


Analysis 2.3. Comparison 2 Sub-group: treatment type, Outcome 3 Number of smokers counselled.

Review: Training health professionals in smoking cessation

Comparison: 2 Sub-group: treatment type

Outcome: 3 Number of smokers counselled

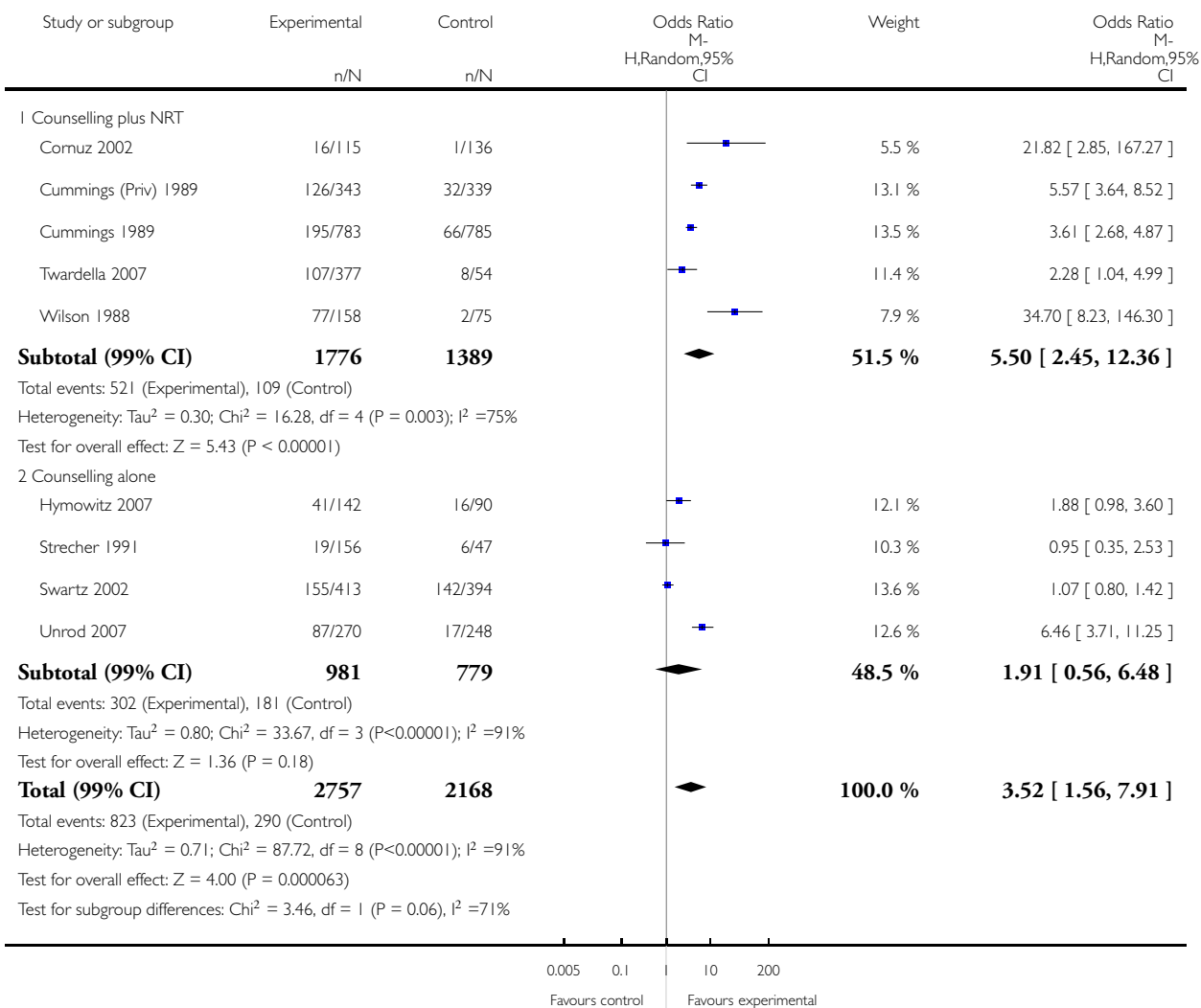


Analysis 2.4. Comparison 2 Sub-group: treatment type, Outcome 4 Number of smokers receiving self-help material.

Review: Training health professionals in smoking cessation

Comparison: 2 Sub-group: treatment type

Outcome: 4 Number of smokers receiving self-help material

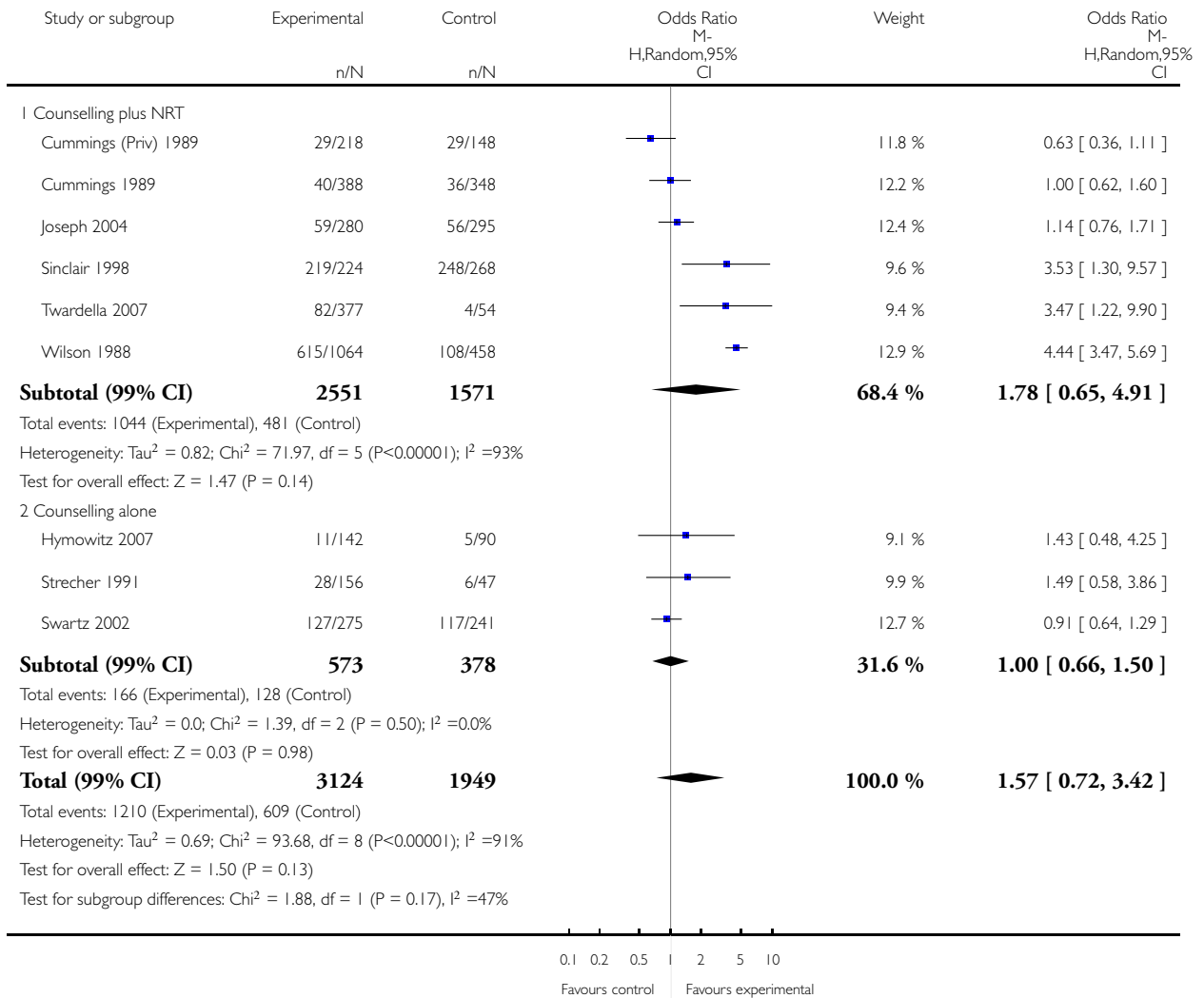


Analysis 2.5. Comparison 2 Sub-group: treatment type, Outcome 5 Number of smokers receiving nicotine gum/replacement therapy.

Review: Training health professionals in smoking cessation

Comparison: 2 Sub-group: treatment type

Outcome: 5 Number of smokers receiving nicotine gum/replacement therapy

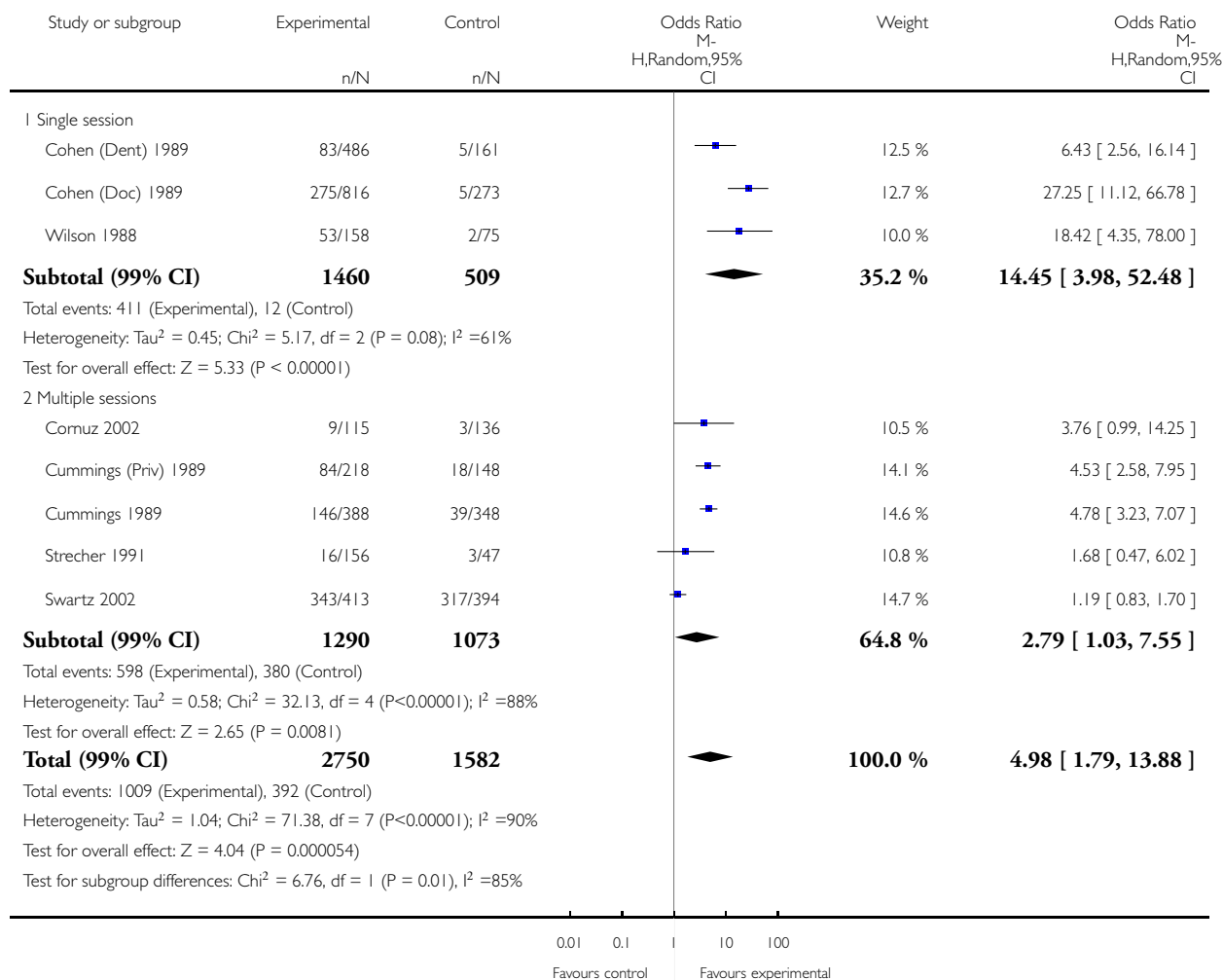


Analysis 3.1. Comparison 3 Sub-group: treatment intensity - Number of sessions, Outcome 1 Patient asked to set a quit date.

Review: Training health professionals in smoking cessation

Comparison: 3 Sub-group: treatment intensity - Number of sessions

Outcome: 1 Patient asked to set a quit date

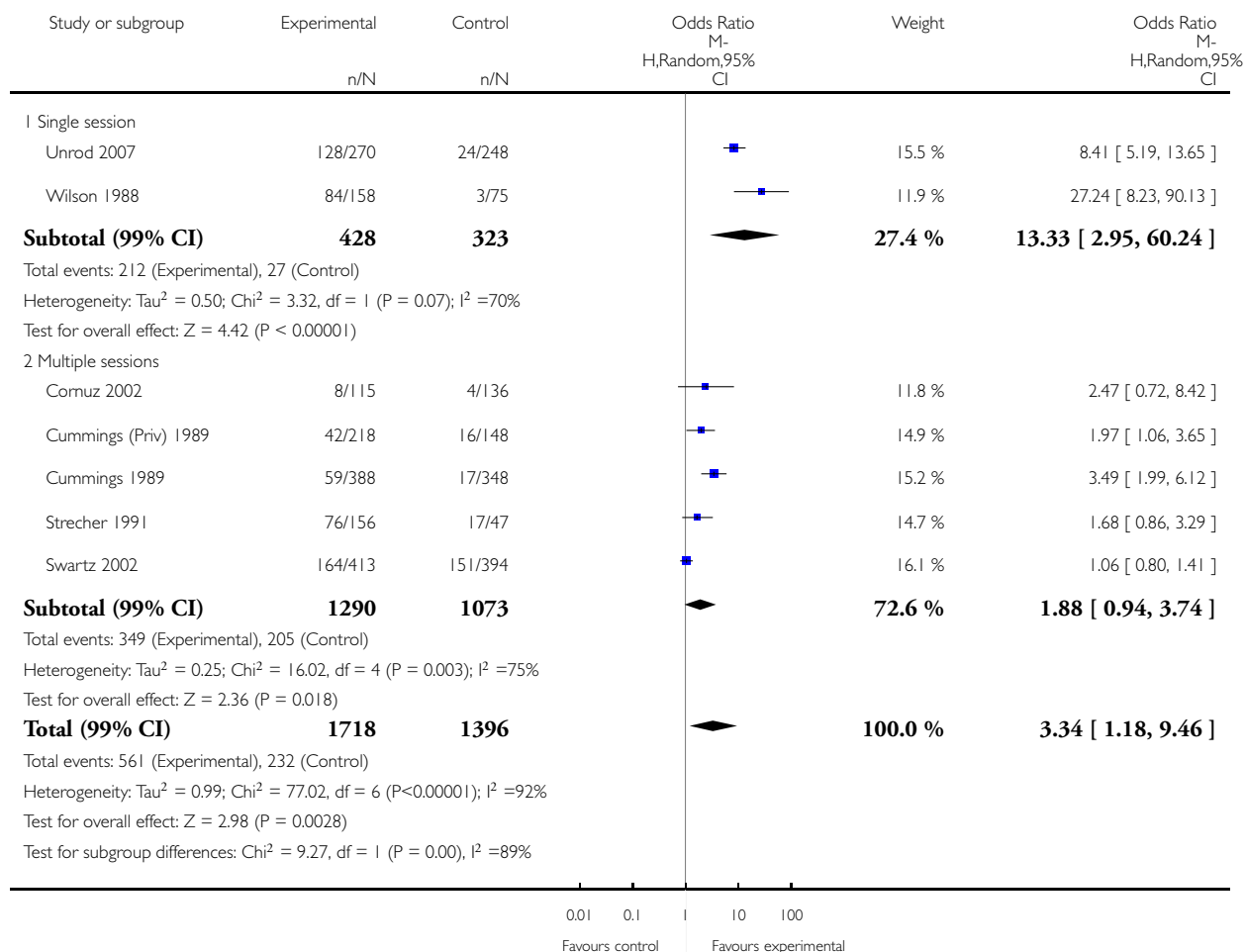


Analysis 3.2. Comparison 3 Sub-group: treatment intensity - Number of sessions, Outcome 2 Patient asked to make a follow-up appointment.

Review: Training health professionals in smoking cessation

Comparison: 3 Sub-group: treatment intensity - Number of sessions

Outcome: 2 Patient asked to make a follow-up appointment

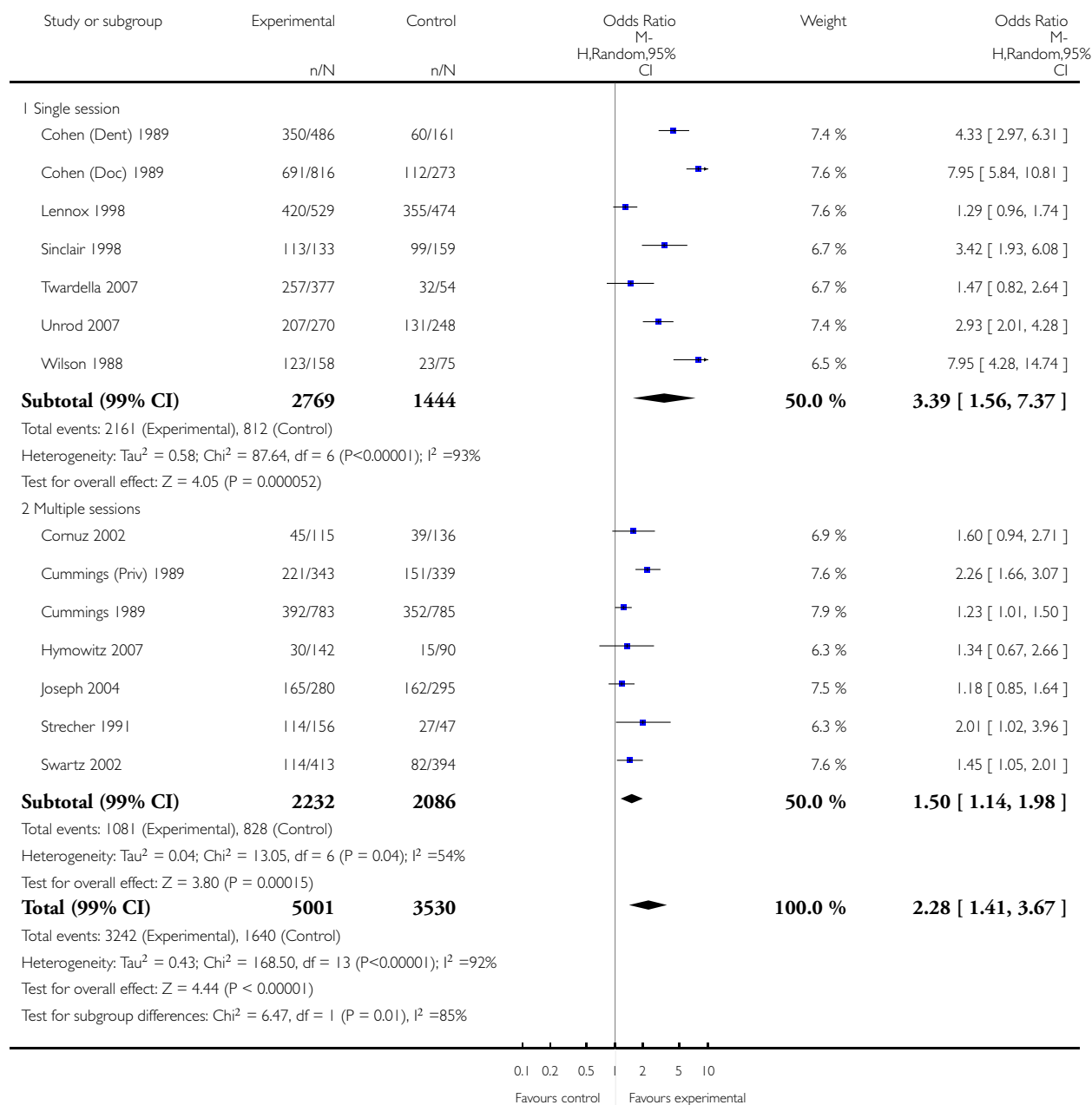


Analysis 3.3. Comparison 3 Sub-group: treatment intensity - Number of sessions, Outcome 3 Number of smokers counselled.

Review: Training health professionals in smoking cessation

Comparison: 3 Sub-group: treatment intensity - Number of sessions

Outcome: 3 Number of smokers counselled

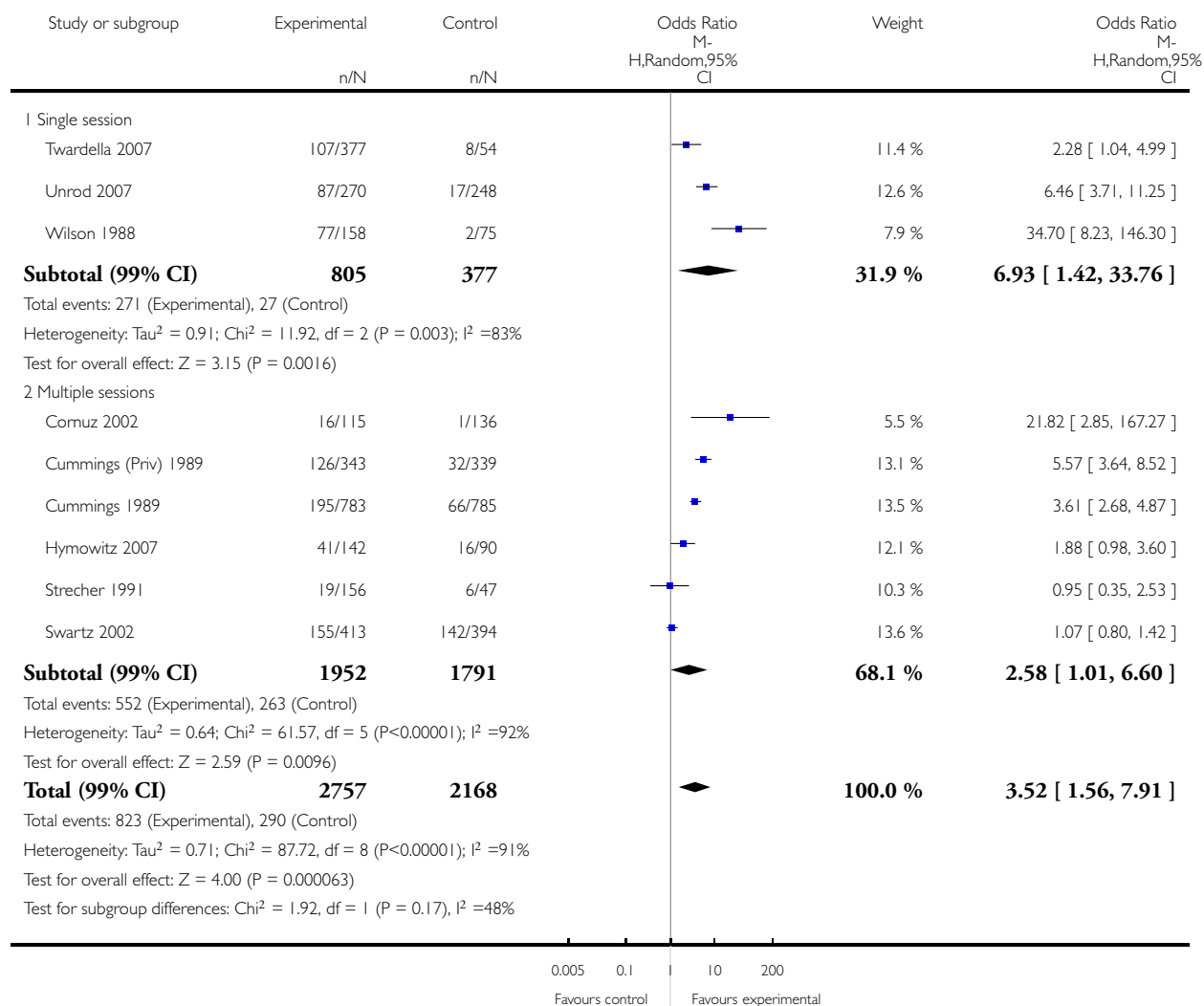


Analysis 3.4. Comparison 3 Sub-group: treatment intensity - Number of sessions, Outcome 4 Number of smokers receiving self-help material.

Review: Training health professionals in smoking cessation

Comparison: 3 Sub-group: treatment intensity - Number of sessions

Outcome: 4 Number of smokers receiving self-help material

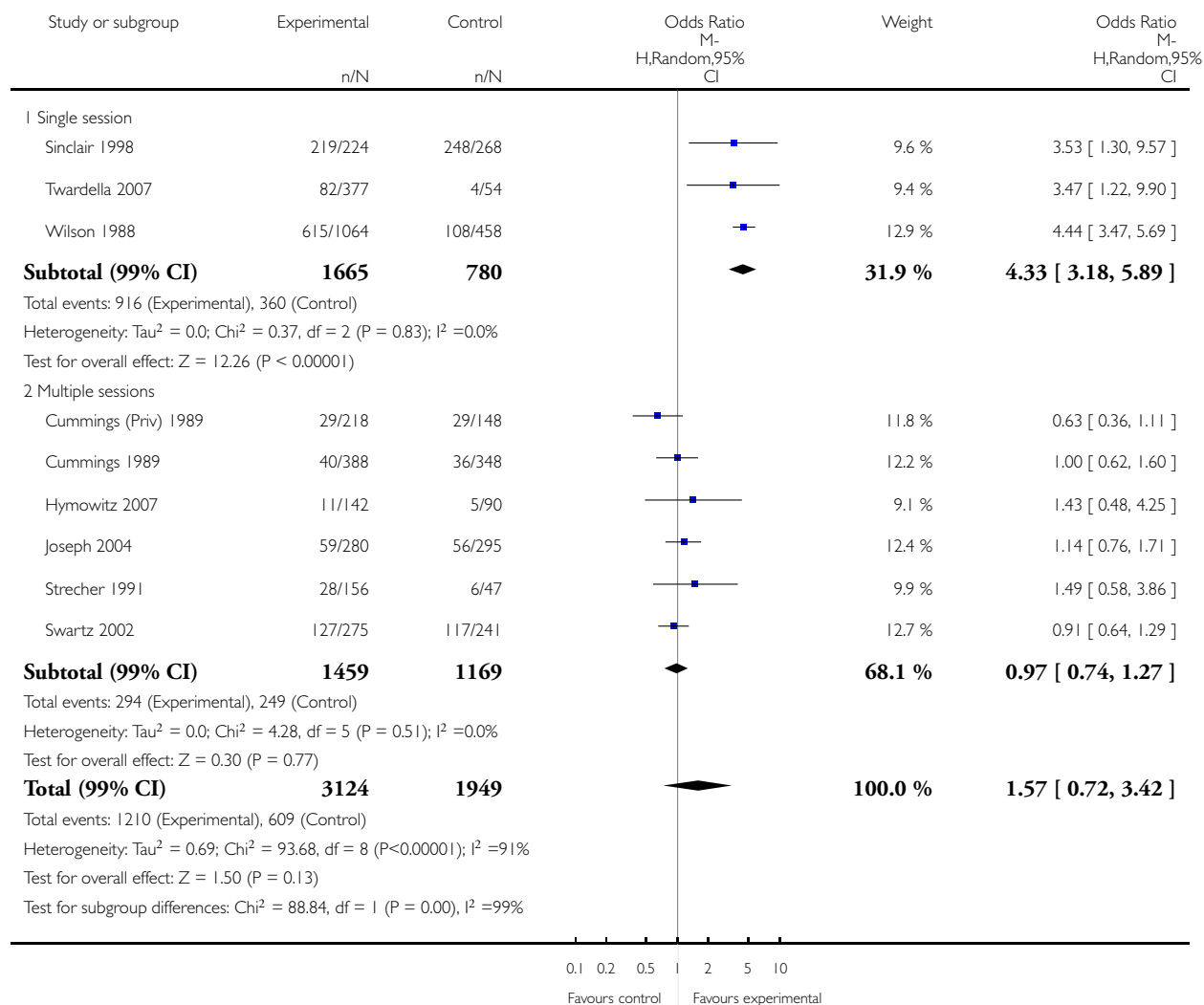


Analysis 3.5. Comparison 3 Sub-group: treatment intensity - Number of sessions, Outcome 5 Number of smokers receiving nicotine gum/replacement therapy.

Review: Training health professionals in smoking cessation

Comparison: 3 Sub-group: treatment intensity - Number of sessions

Outcome: 5 Number of smokers receiving nicotine gum/replacement therapy

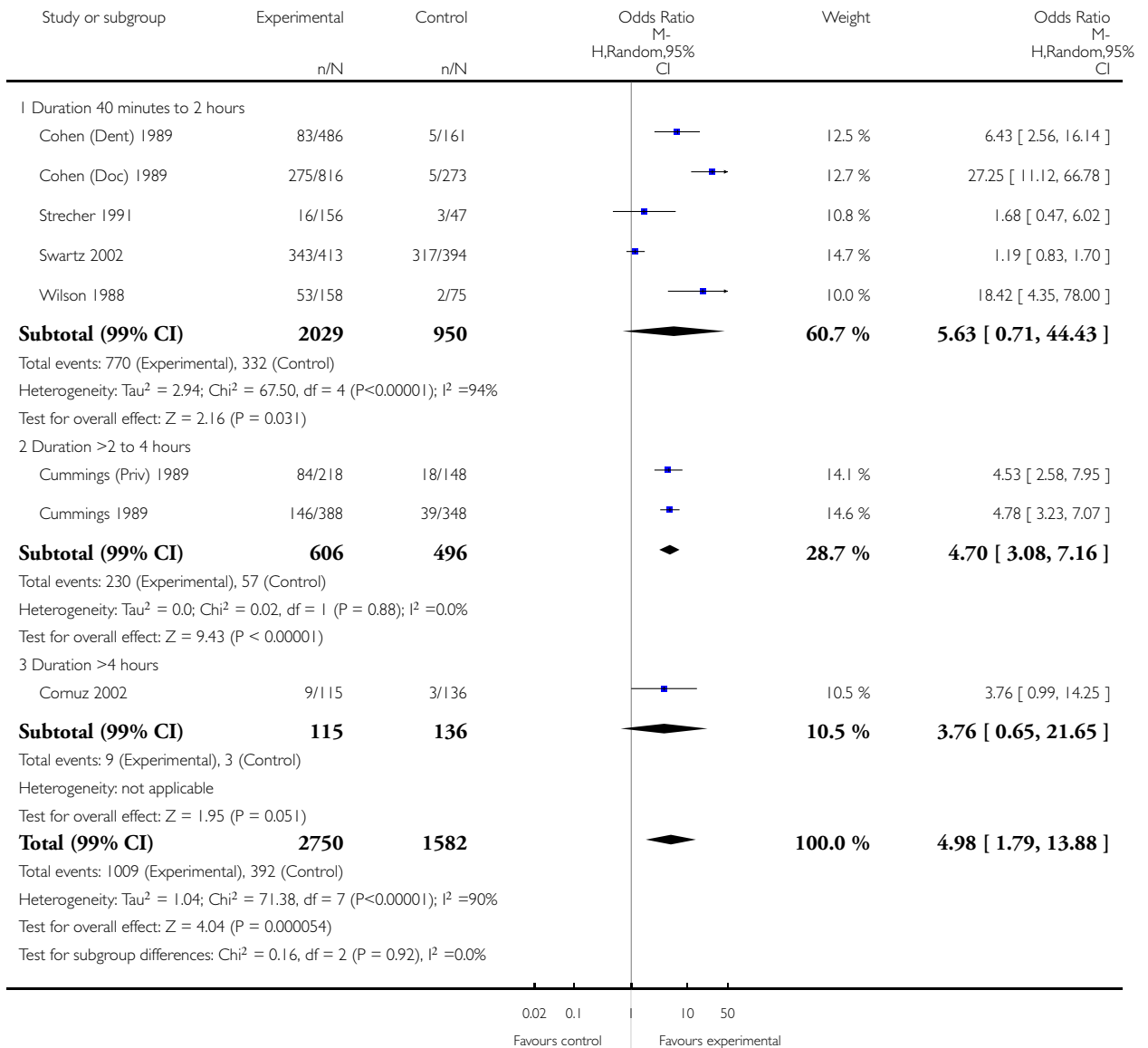


Analysis 4.1. Comparison 4 Sub-group: treatment intensity - Total exposure, Outcome 1 Patient asked to set a quit date.

Review: Training health professionals in smoking cessation

Comparison: 4 Sub-group: treatment intensity - Total exposure

Outcome: 1 Patient asked to set a quit date

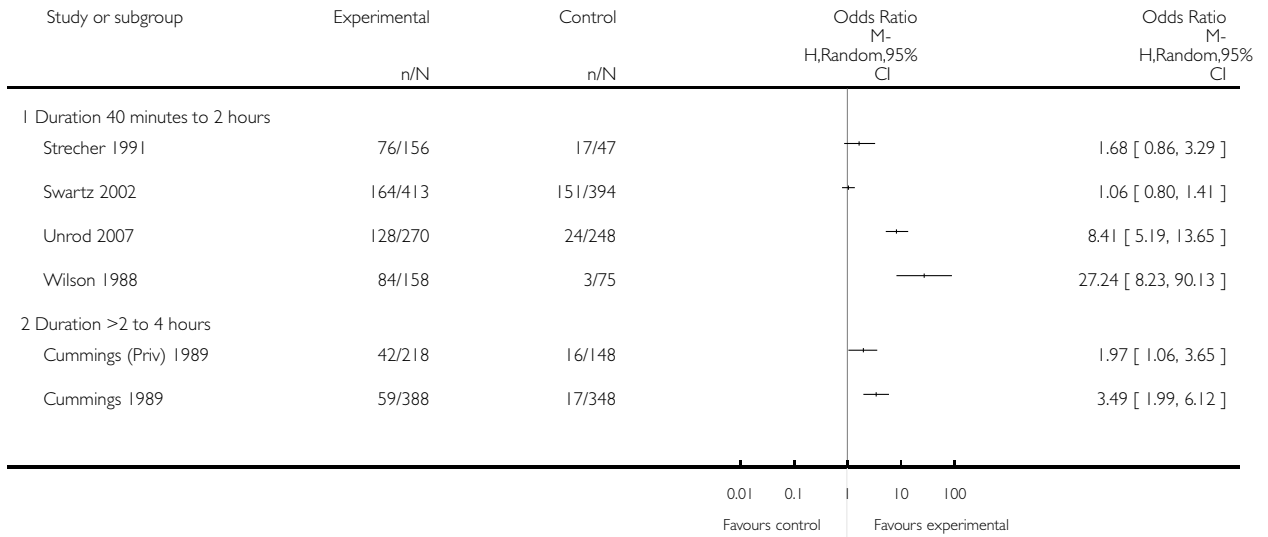


Analysis 4.2. Comparison 4 Sub-group: treatment intensity - Total exposure, Outcome 2 Patient asked to make a follow-up appointment.

Review: Training health professionals in smoking cessation

Comparison: 4 Sub-group: treatment intensity - Total exposure

Outcome: 2 Patient asked to make a follow-up appointment

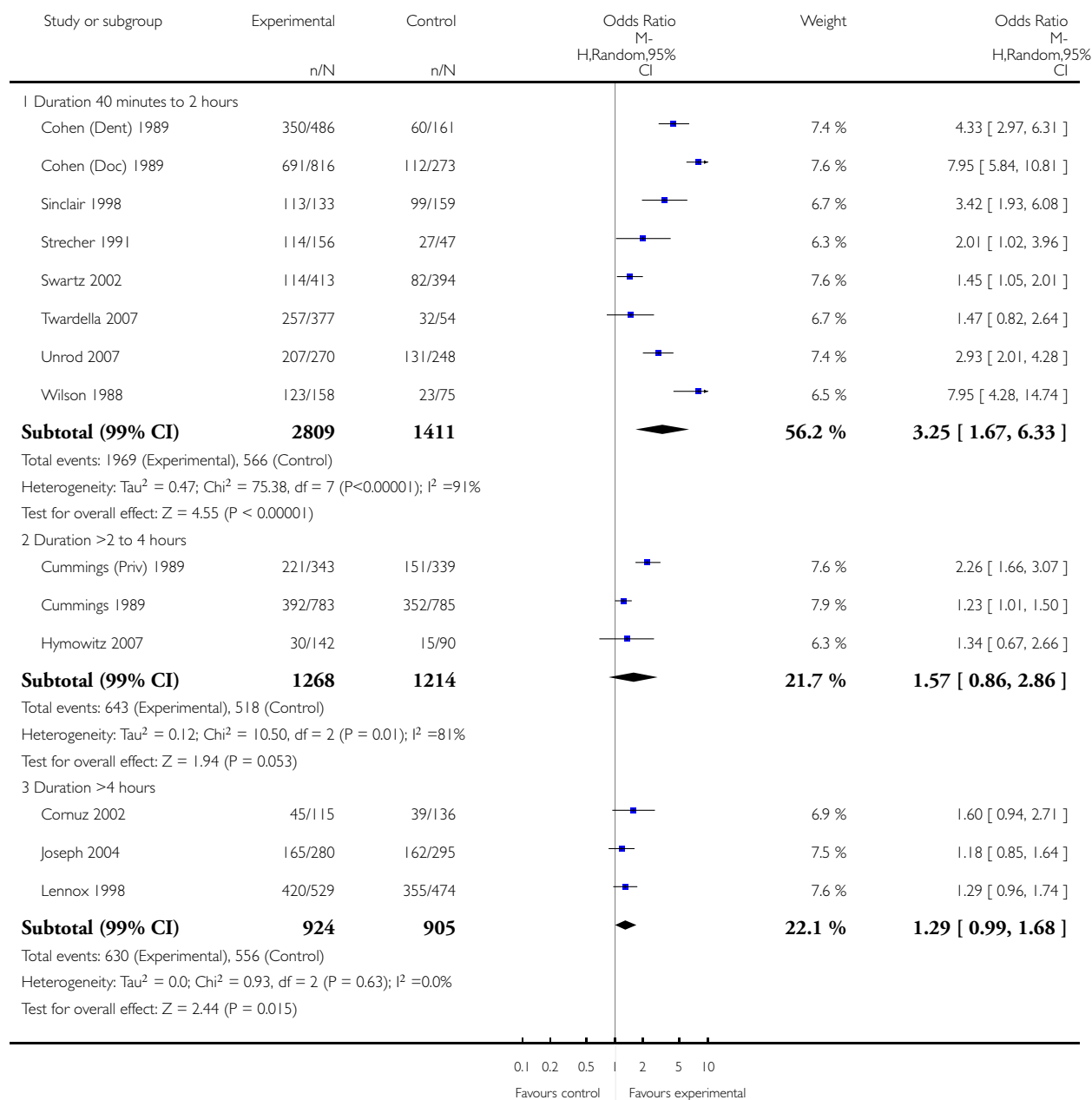


Analysis 4.3. Comparison 4 Sub-group: treatment intensity - Total exposure, Outcome 3 Number of smokers counselled.

Review: Training health professionals in smoking cessation

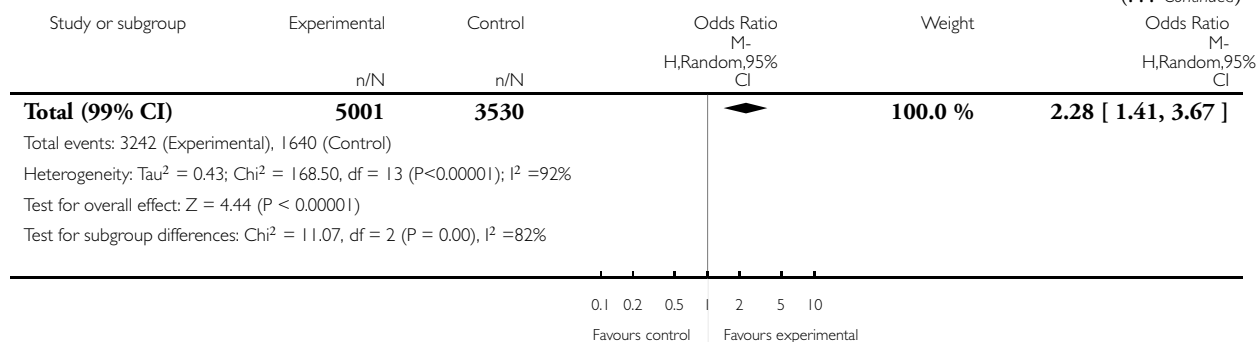
Comparison: 4 Sub-group: treatment intensity - Total exposure

Outcome: 3 Number of smokers counselled



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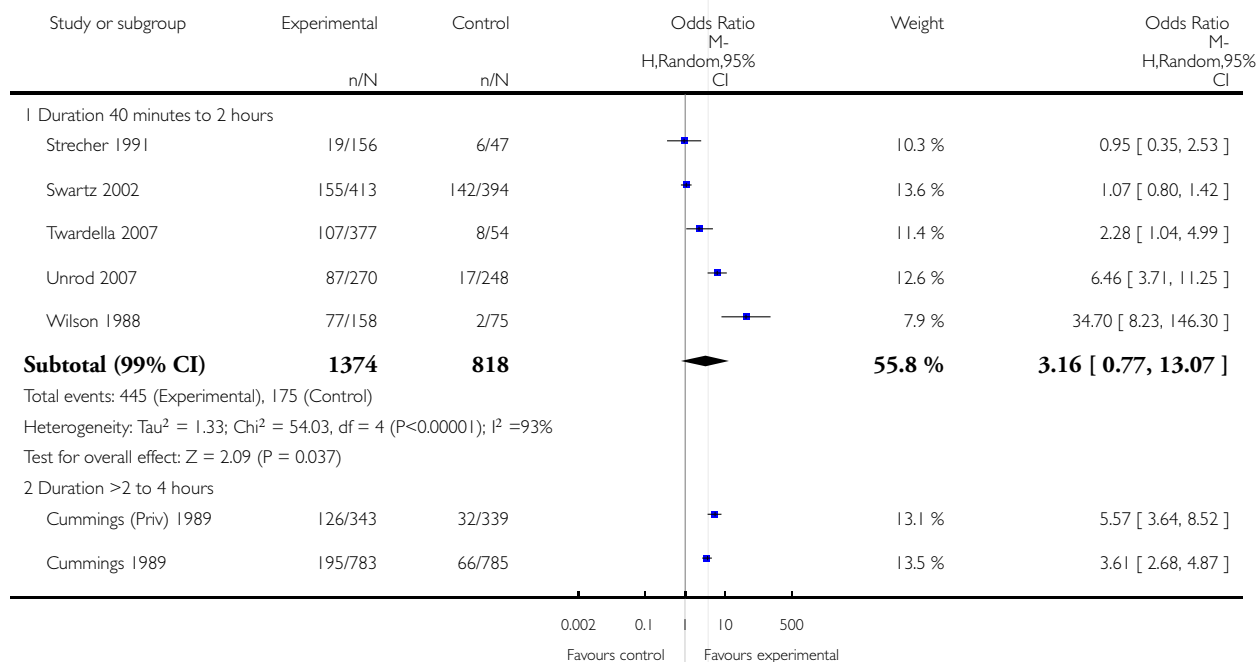


Analysis 4.4. Comparison 4 Sub-group: treatment intensity - Total exposure, Outcome 4 Number of smokers receiving self-help material.

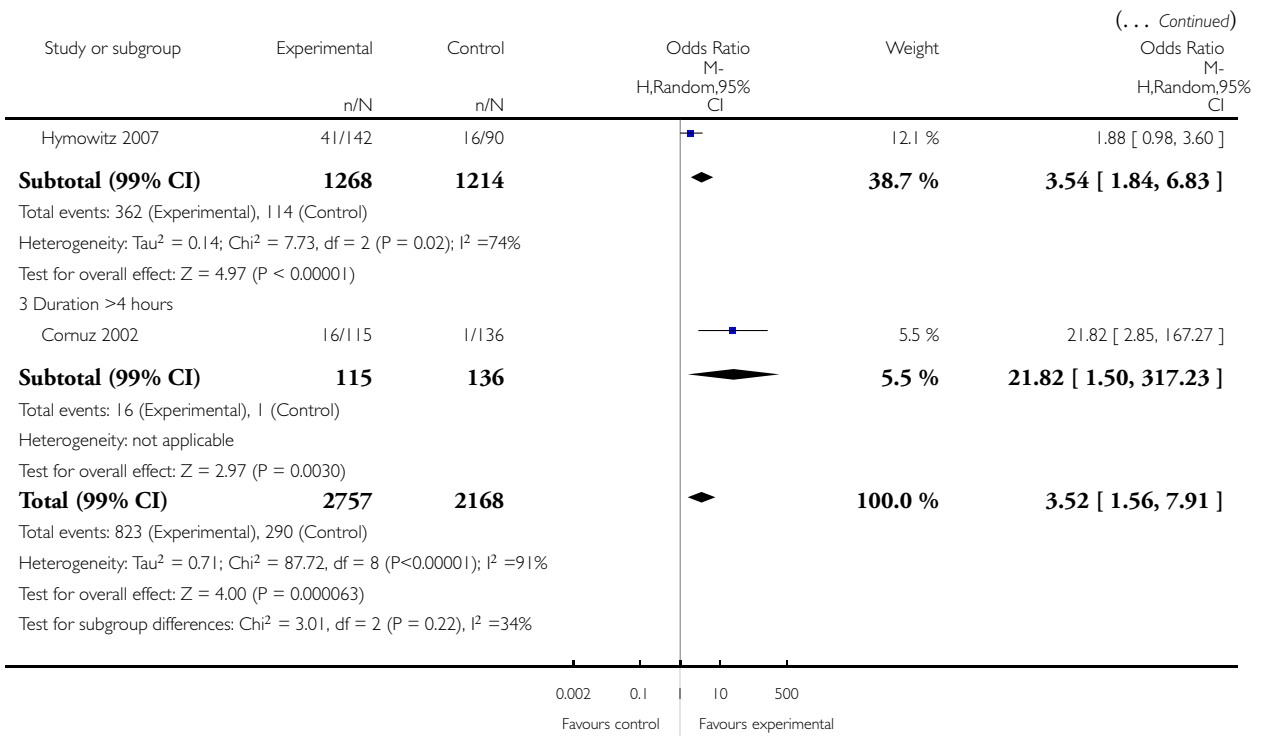
Review: Training health professionals in smoking cessation

Comparison: 4 Sub-group: treatment intensity - Total exposure

Outcome: 4 Number of smokers receiving self-help material



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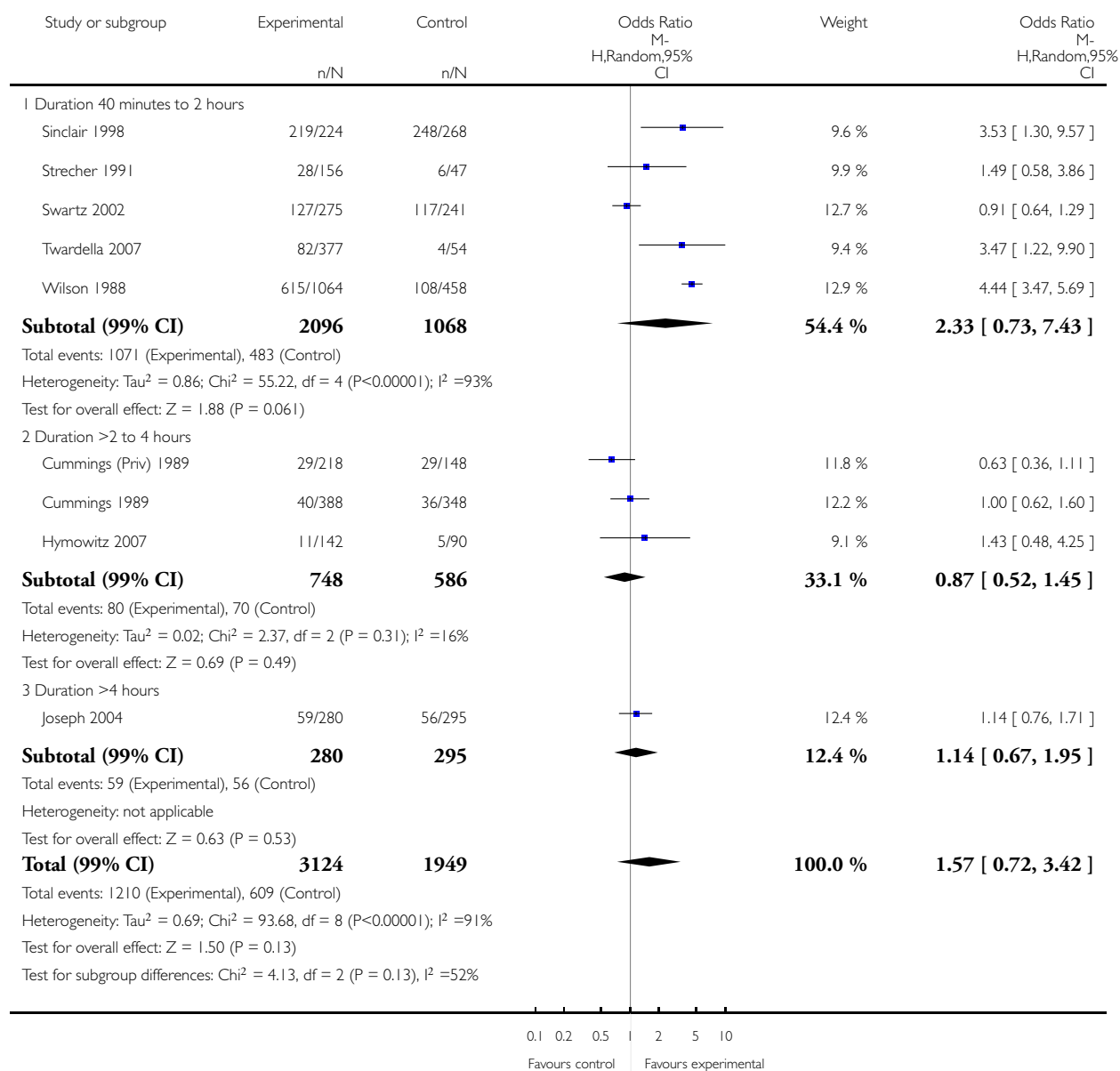


Analysis 4.5. Comparison 4 Sub-group: treatment intensity - Total exposure, Outcome 5 Number of smokers receiving nicotine gum/replacement therapy.

Review: Training health professionals in smoking cessation

Comparison: 4 Sub-group: treatment intensity - Total exposure

Outcome: 5 Number of smokers receiving nicotine gum/replacement therapy

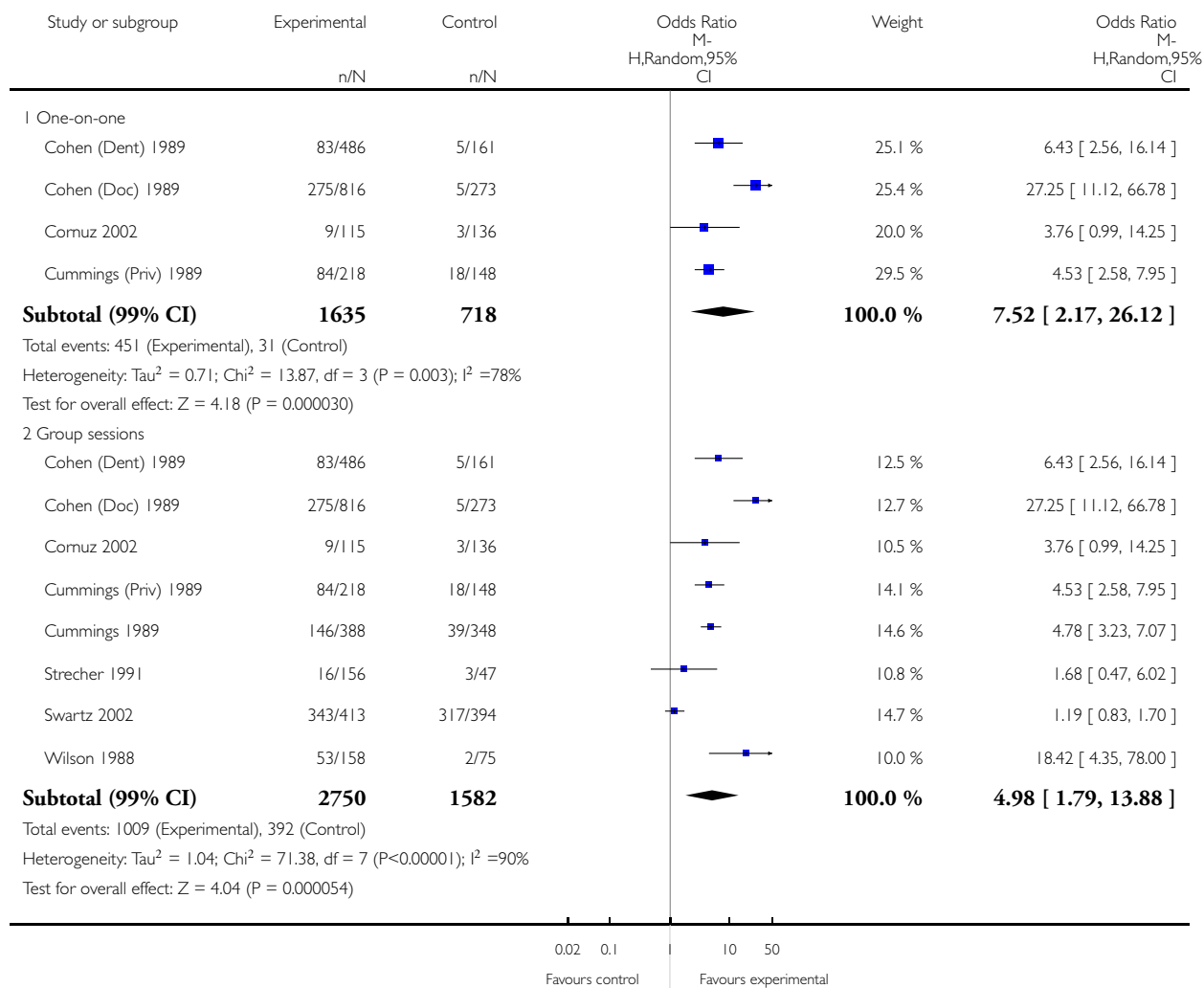


Analysis 5.1. Comparison 5 Sub-group: mode of intervention delivery, Outcome 1 Patient asked to set a quit date.

Review: Training health professionals in smoking cessation

Comparison: 5 Sub-group: mode of intervention delivery

Outcome: 1 Patient asked to set a quit date

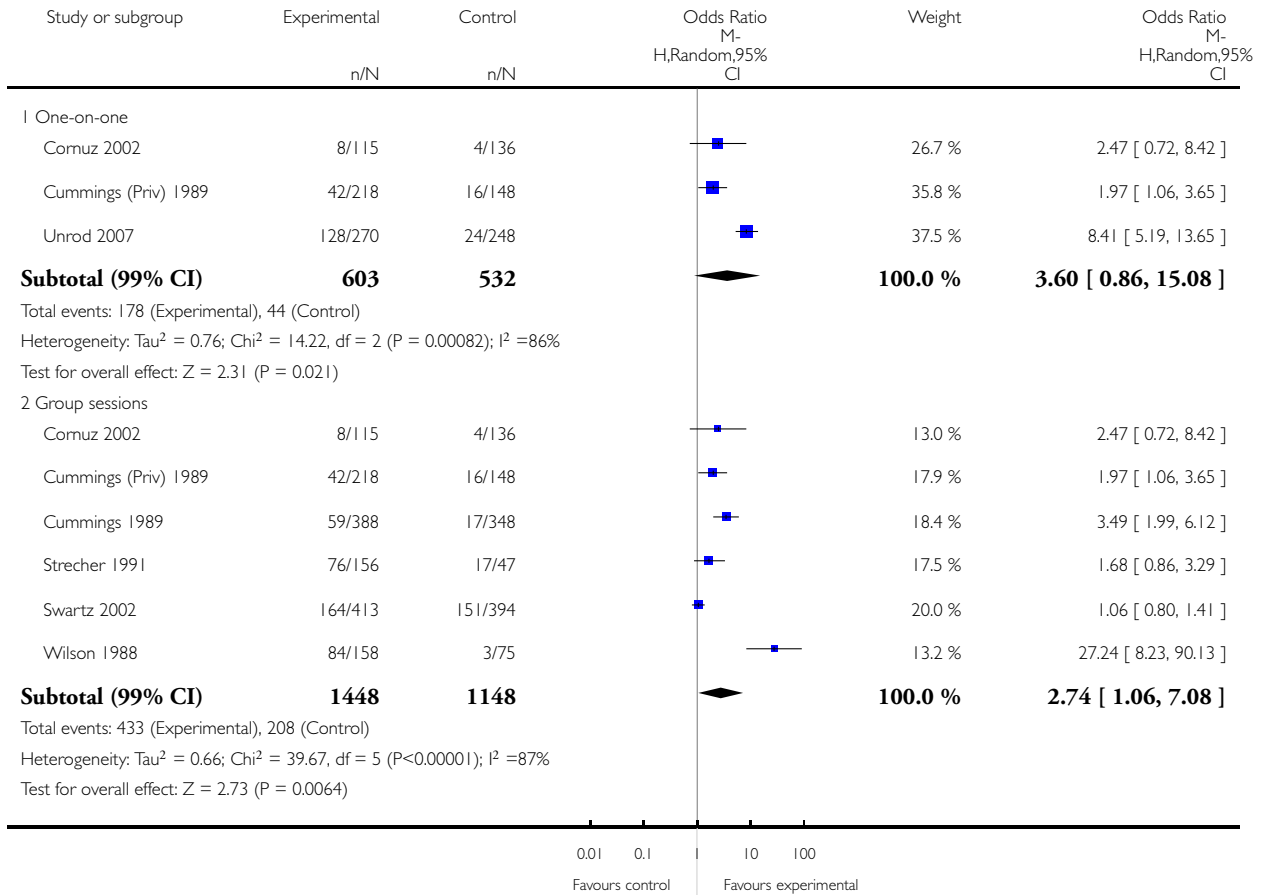


Analysis 5.2. Comparison 5 Sub-group: mode of intervention delivery, Outcome 2 Patient asked to make a follow-up appointment.

Review: Training health professionals in smoking cessation

Comparison: 5 Sub-group: mode of intervention delivery

Outcome: 2 Patient asked to make a follow-up appointment

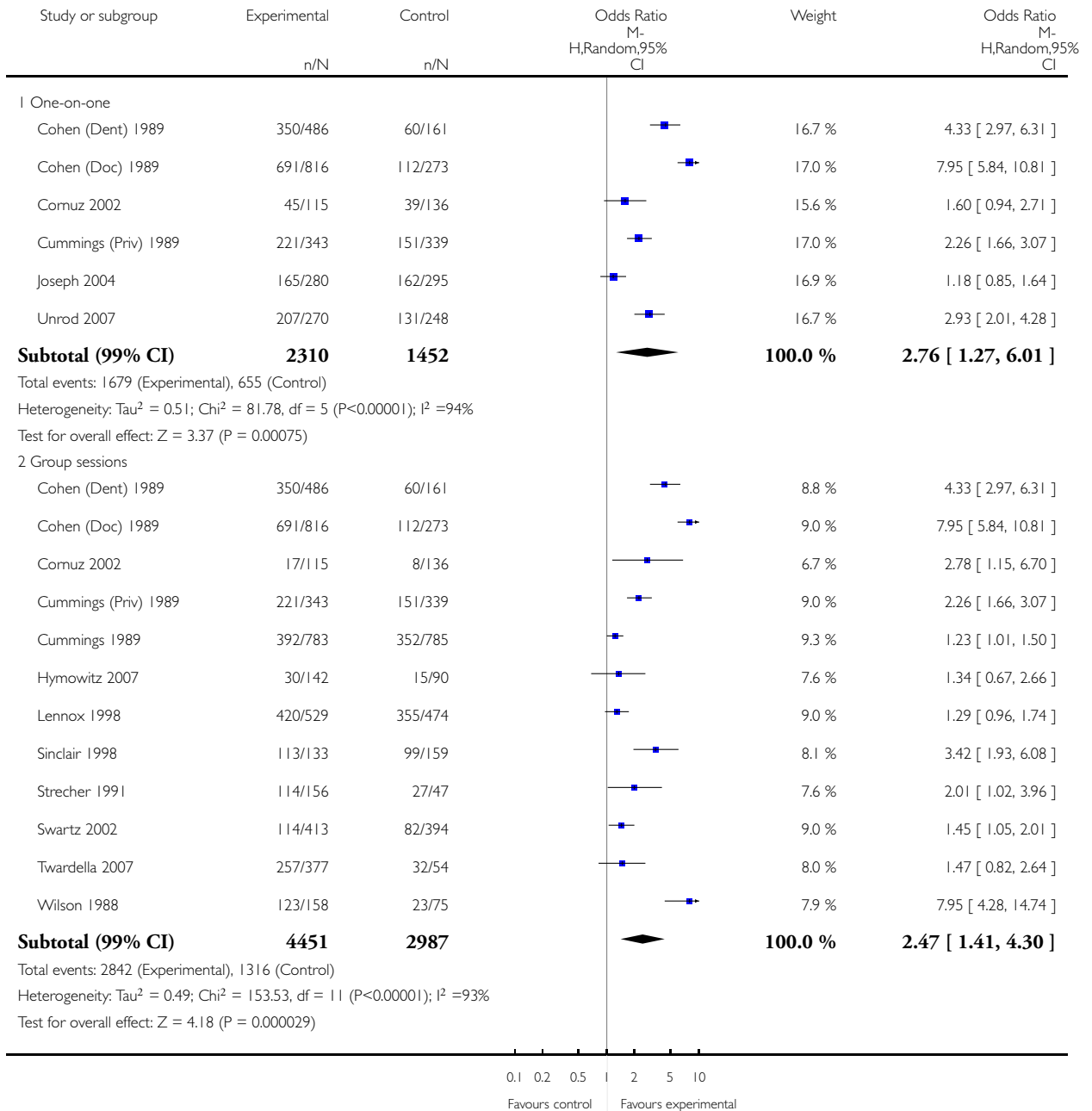


Analysis 5.3. Comparison 5 Sub-group: mode of intervention delivery, Outcome 3 Number of smokers counselled.

Review: Training health professionals in smoking cessation

Comparison: 5 Sub-group: mode of intervention delivery

Outcome: 3 Number of smokers counselled

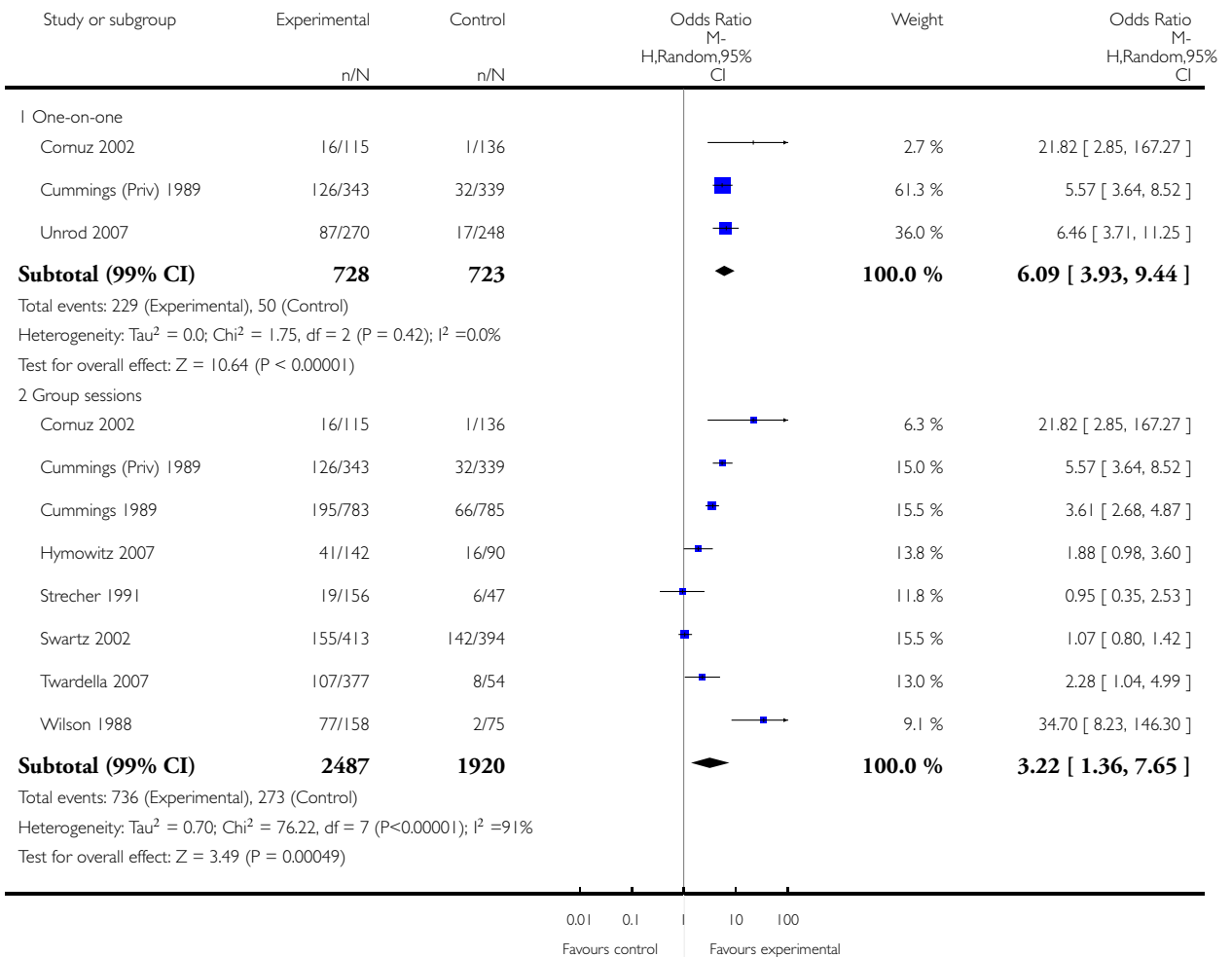


Analysis 5.4. Comparison 5 Sub-group: mode of intervention delivery, Outcome 4 Number of smokers receiving self-help material.

Review: Training health professionals in smoking cessation

Comparison: 5 Sub-group: mode of intervention delivery

Outcome: 4 Number of smokers receiving self-help material

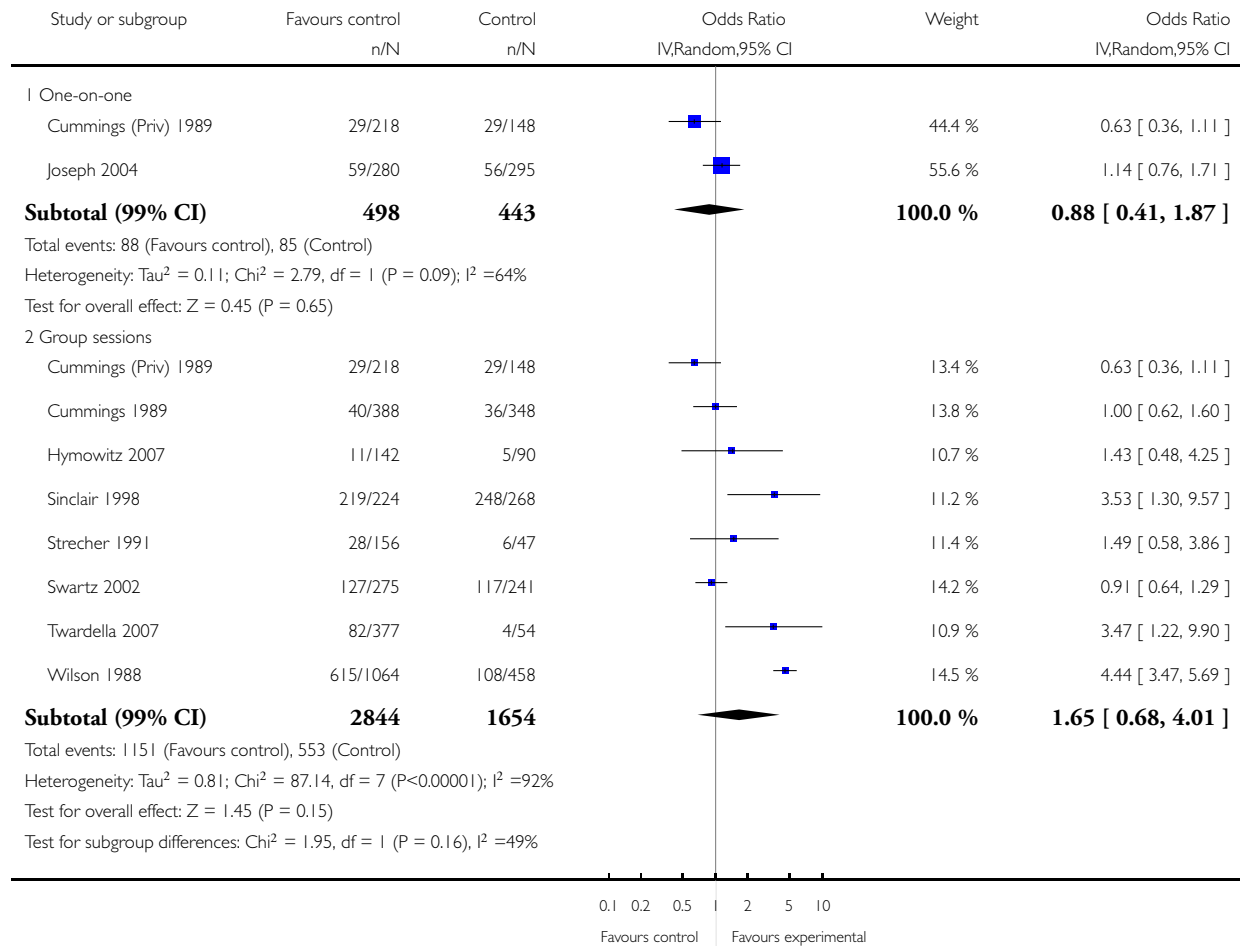


Analysis 5.5. Comparison 5 Sub-group: mode of intervention delivery, Outcome 5 Number of smokers receiving nicotine gum/replacement therapy.

Review: Training health professionals in smoking cessation

Comparison: 5 Sub-group: mode of intervention delivery

Outcome: 5 Number of smokers receiving nicotine gum/replacement therapy

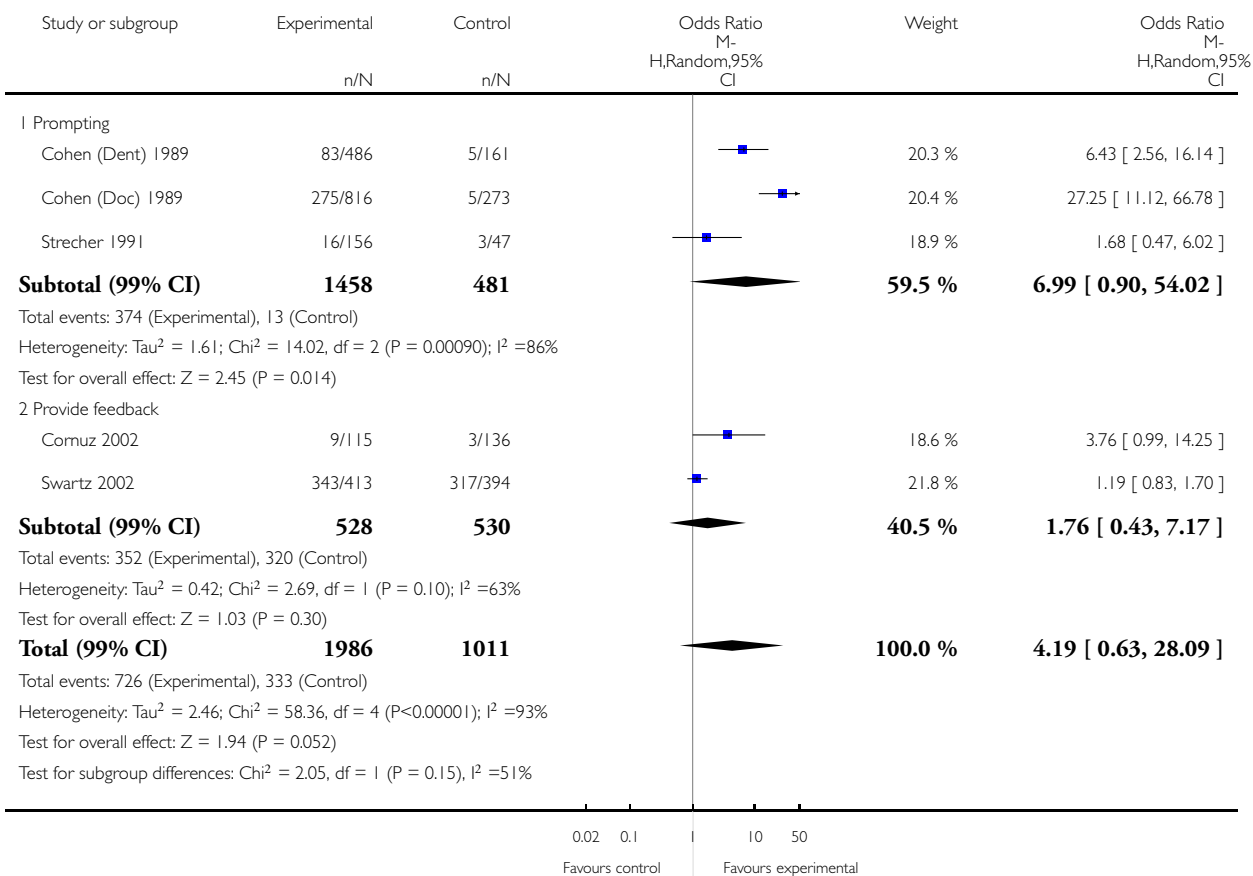


Analysis 6.1. Comparison 6 Sub-group: behavioural change technique used, Outcome 1 Patient asked to set a quit date.

Review: Training health professionals in smoking cessation

Comparison: 6 Sub-group: behavioural change technique used

Outcome: 1 Patient asked to set a quit date

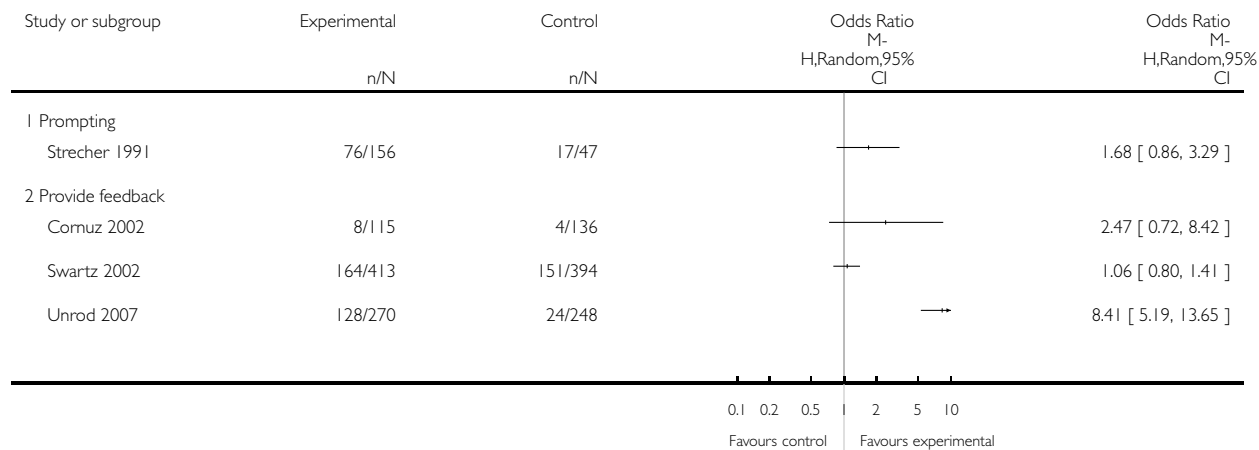


Analysis 6.2. Comparison 6 Sub-group: behavioural change technique used, Outcome 2 Patient asked to make a follow-up appointment.

Review: Training health professionals in smoking cessation

Comparison: 6 Sub-group: behavioural change technique used

Outcome: 2 Patient asked to make a follow-up appointment

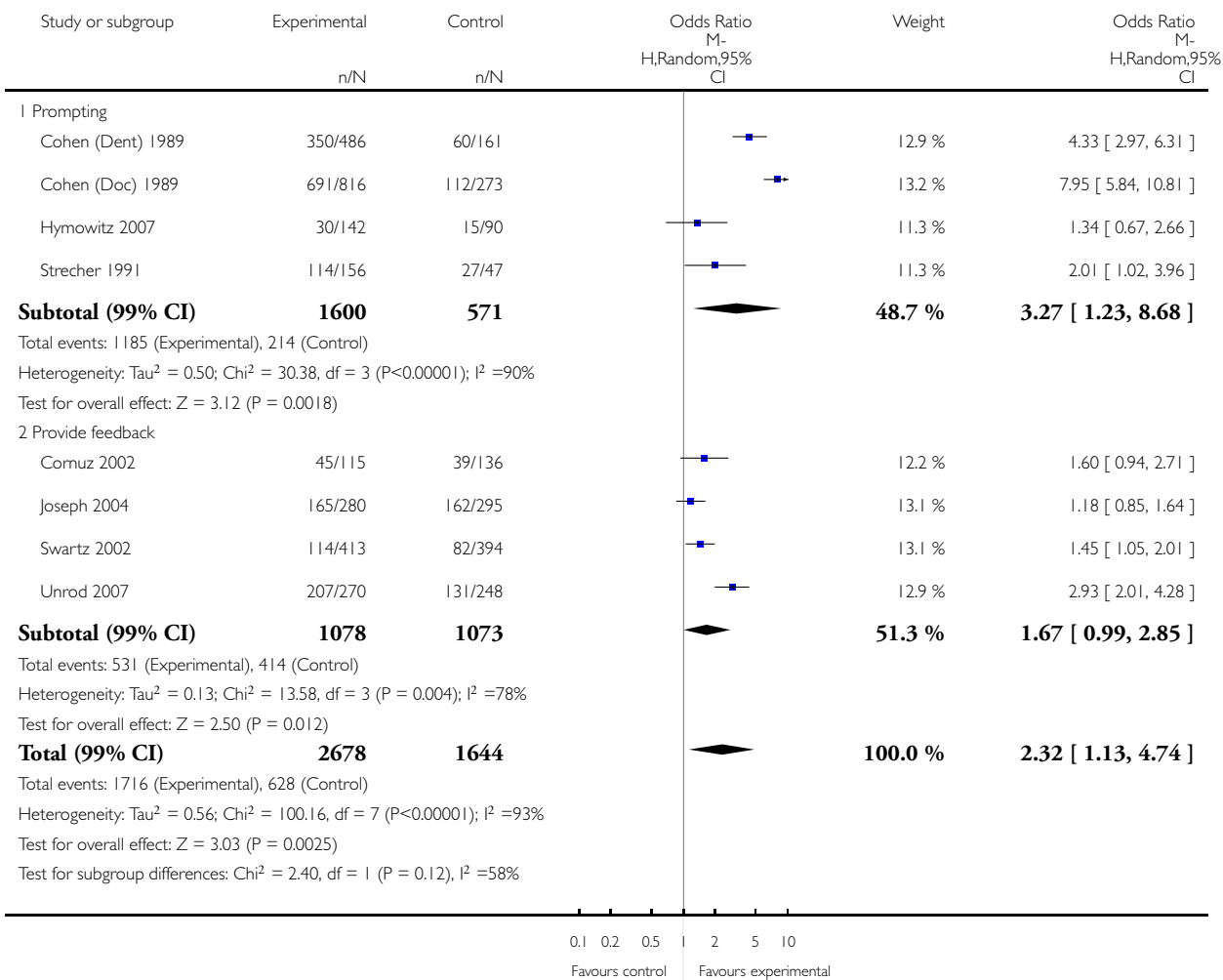


Analysis 6.3. Comparison 6 Sub-group: behavioural change technique used, Outcome 3 Number of smokers counselled.

Review: Training health professionals in smoking cessation

Comparison: 6 Sub-group: behavioural change technique used

Outcome: 3 Number of smokers counselled

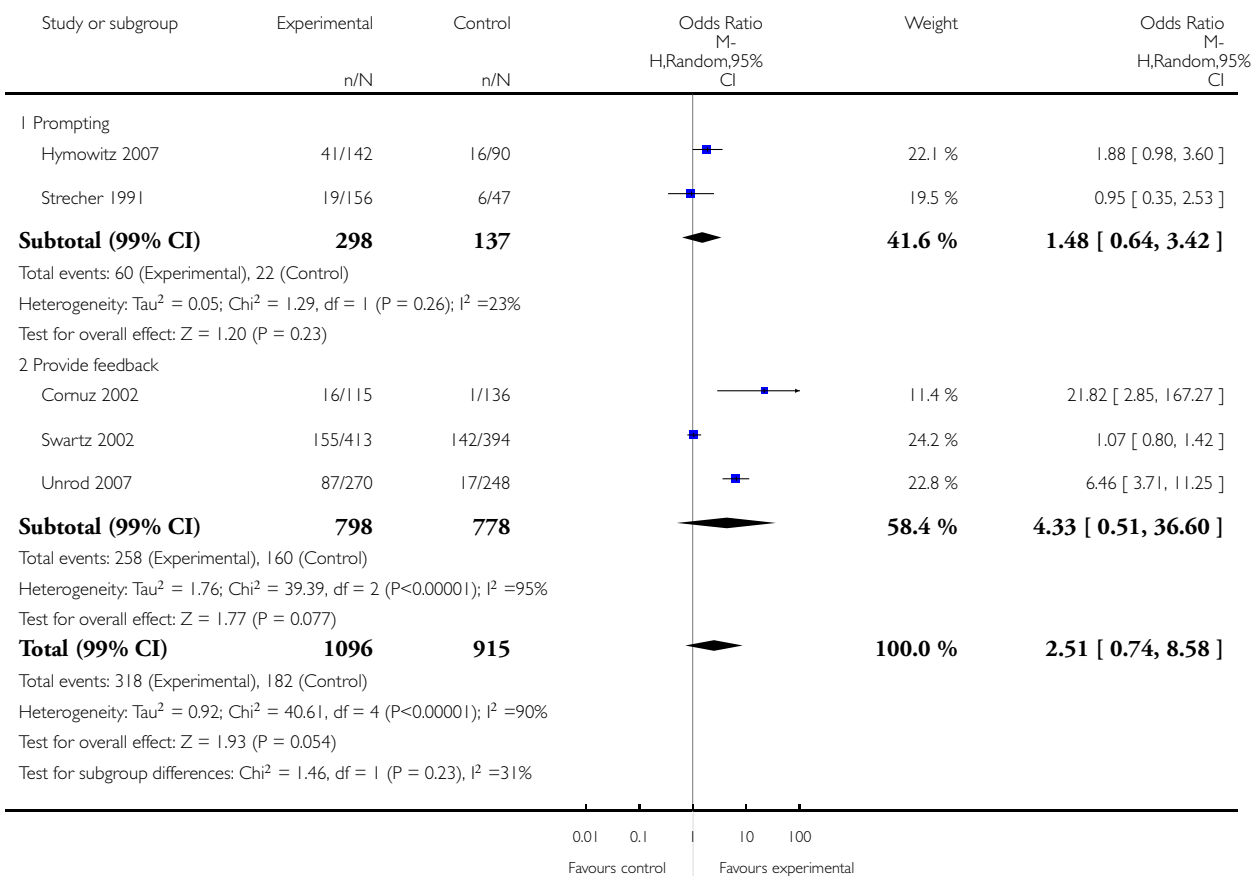


Analysis 6.4. Comparison 6 Sub-group: behavioural change technique used, Outcome 4 Number of smokers receiving self-help material.

Review: Training health professionals in smoking cessation

Comparison: 6 Sub-group: behavioural change technique used

Outcome: 4 Number of smokers receiving self-help material

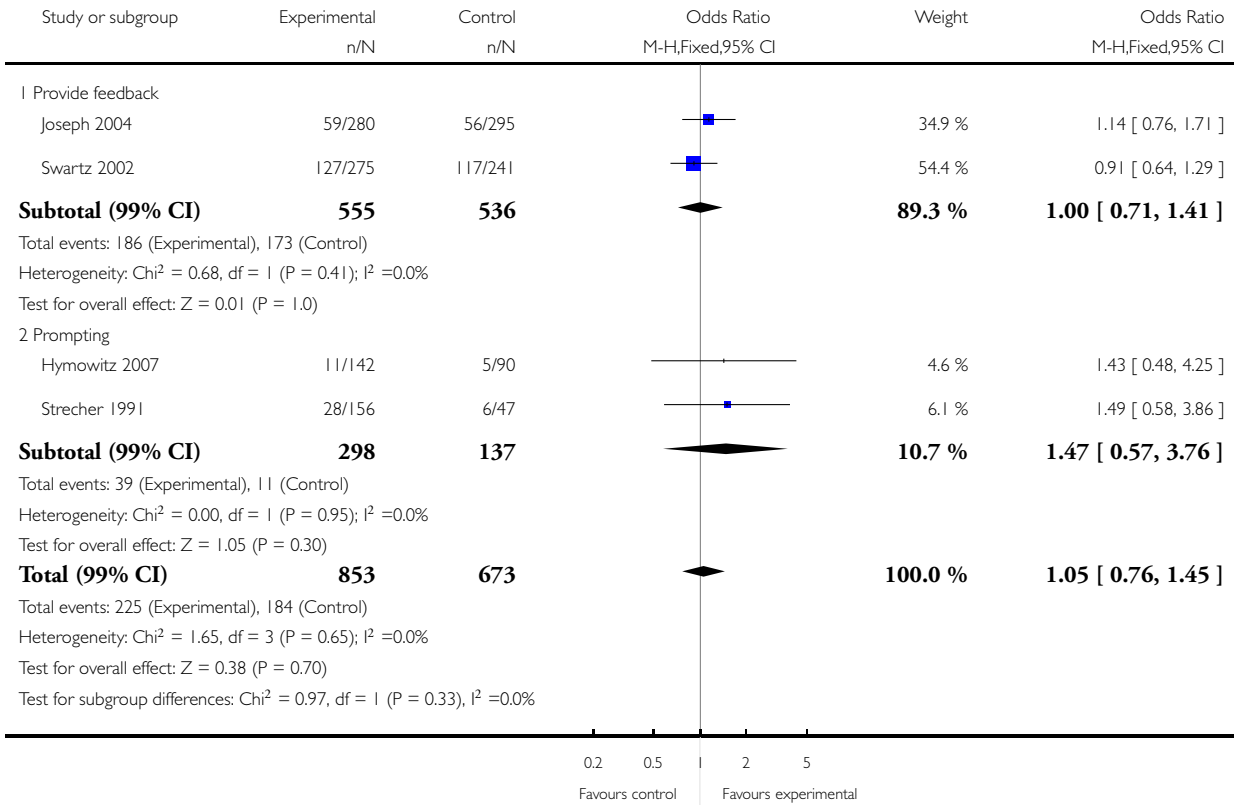


Analysis 6.5. Comparison 6 Sub-group: behavioural change technique used, Outcome 5 Number of smokers receiving nicotine gum/replacement therapy.

Review: Training health professionals in smoking cessation

Comparison: 6 Sub-group: behavioural change technique used

Outcome: 5 Number of smokers receiving nicotine gum/replacement therapy

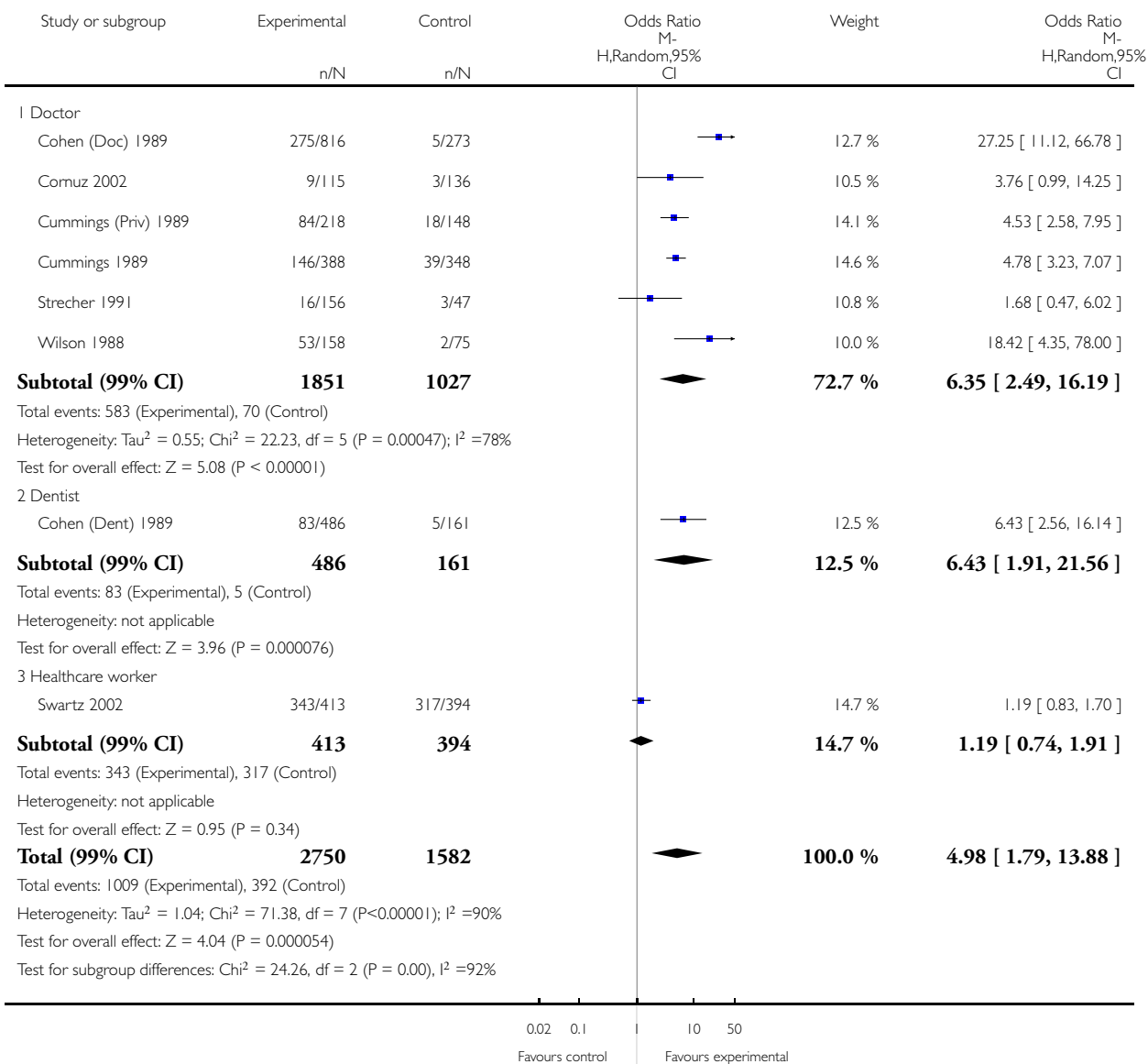


Analysis 7.1. Comparison 7 Sub-group: type of professional being trained, Outcome 1 Patient asked to set a quit date.

Review: Training health professionals in smoking cessation

Comparison: 7 Sub-group: type of professional being trained

Outcome: 1 Patient asked to set a quit date

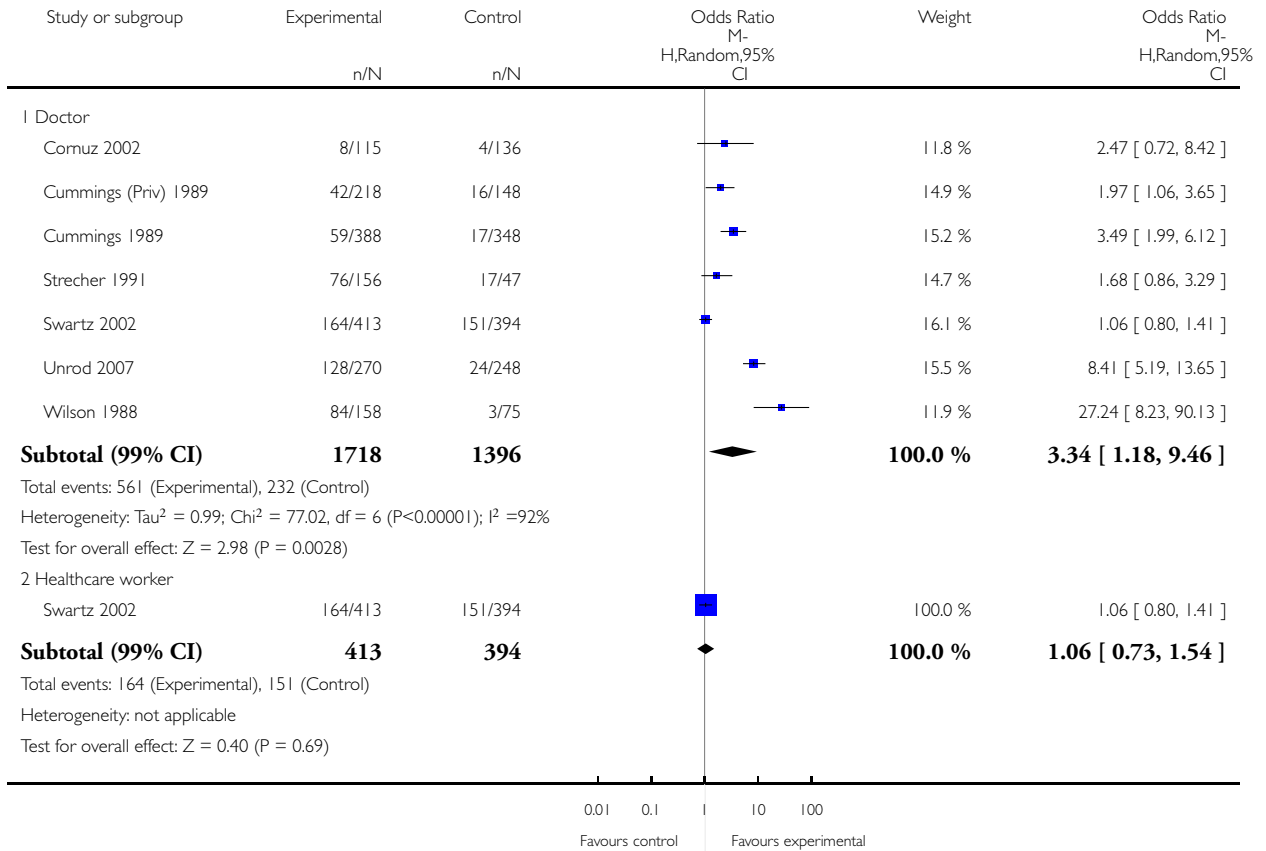


Analysis 7.2. Comparison 7 Sub-group: type of professional being trained, Outcome 2 Patient asked to make a follow-up appointment.

Review: Training health professionals in smoking cessation

Comparison: 7 Sub-group: type of professional being trained

Outcome: 2 Patient asked to make a follow-up appointment

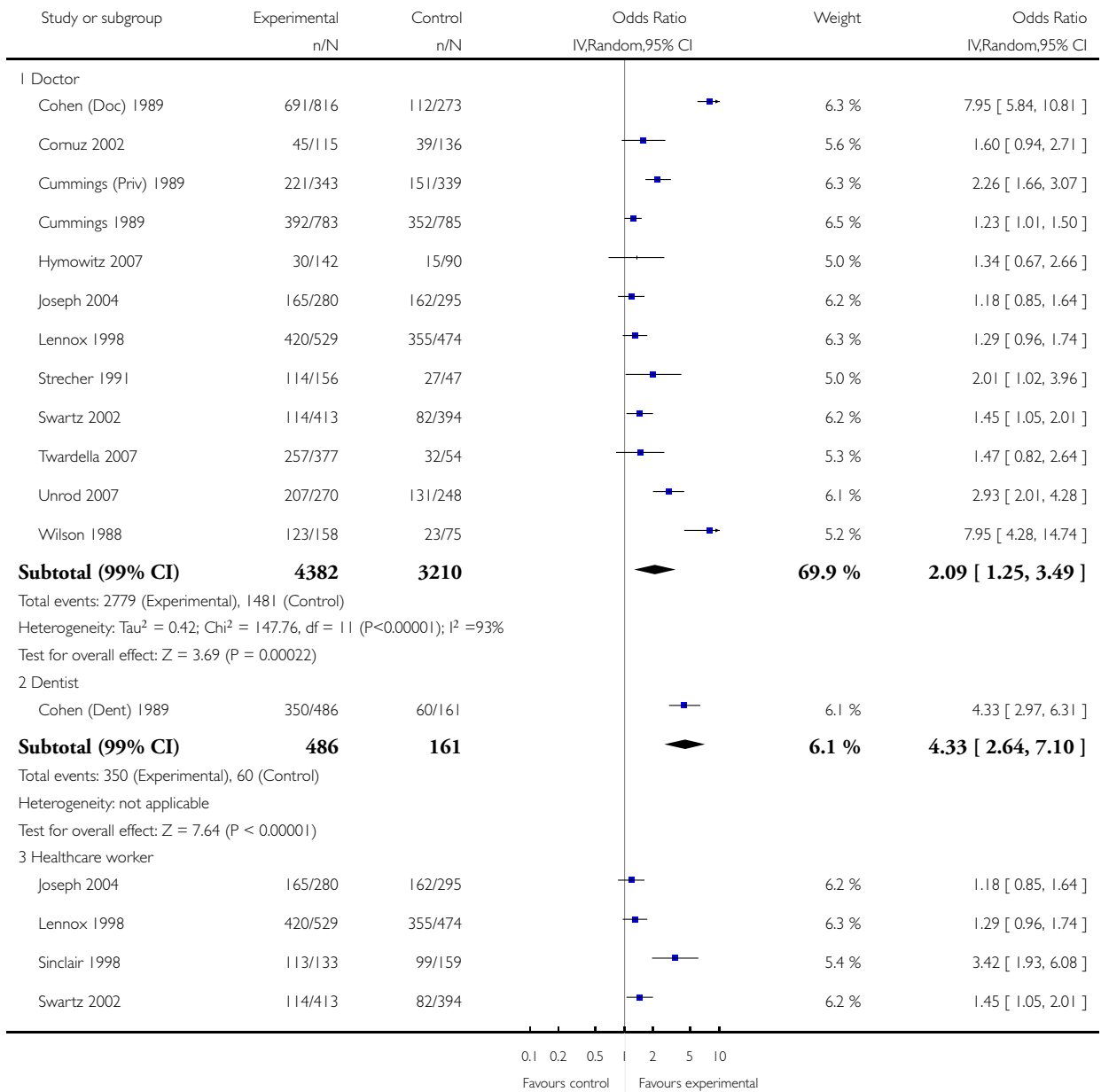


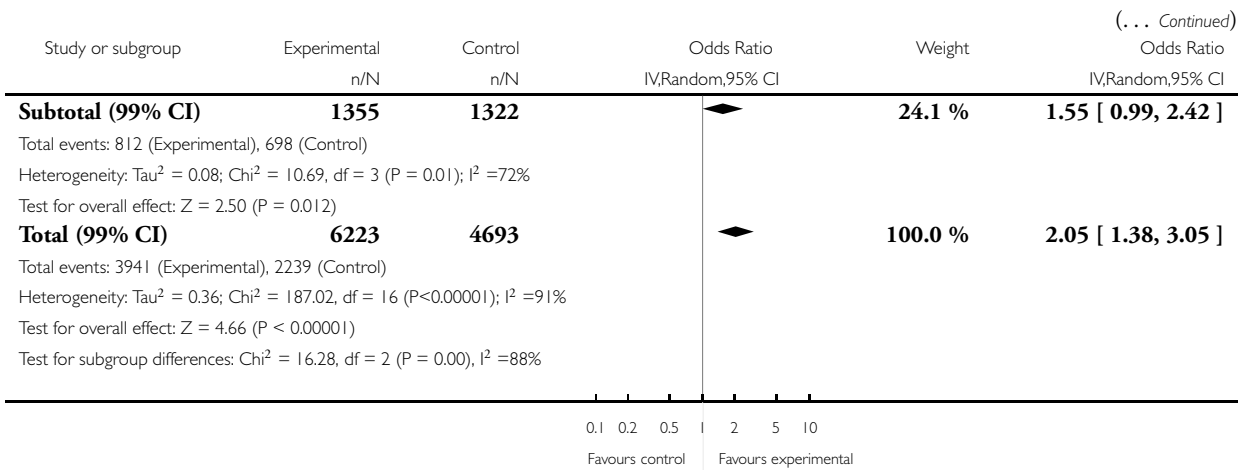
Analysis 7.3. Comparison 7 Sub-group: type of professional being trained, Outcome 3 Number of smokers counselled.

Review: Training health professionals in smoking cessation

Comparison: 7 Sub-group: type of professional being trained

Outcome: 3 Number of smokers counselled



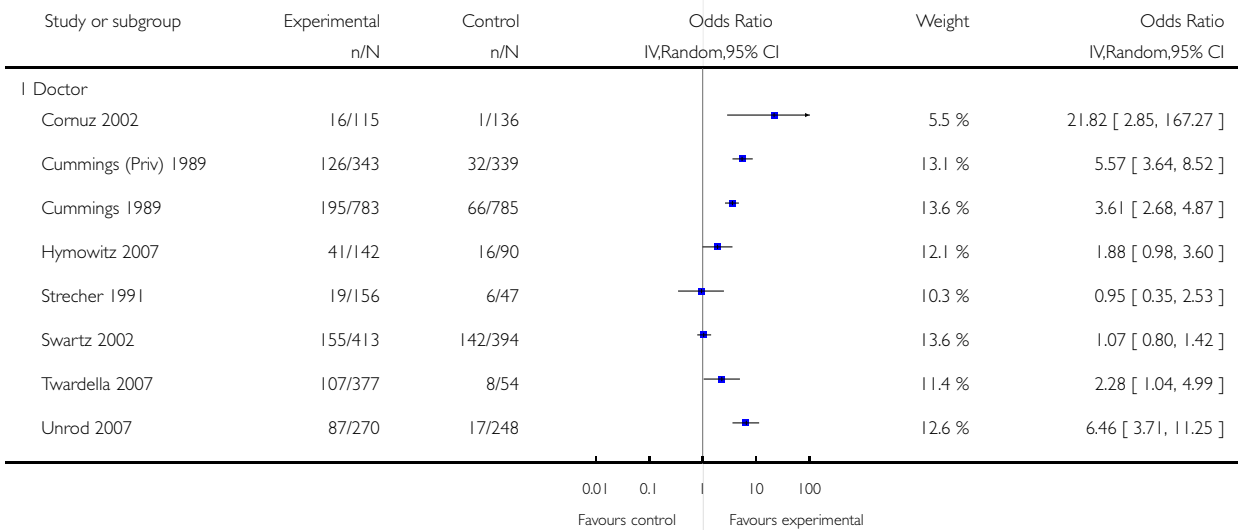


Analysis 7.4. Comparison 7 Sub-group: type of professional being trained, Outcome 4 Number of smokers receiving self-help material.

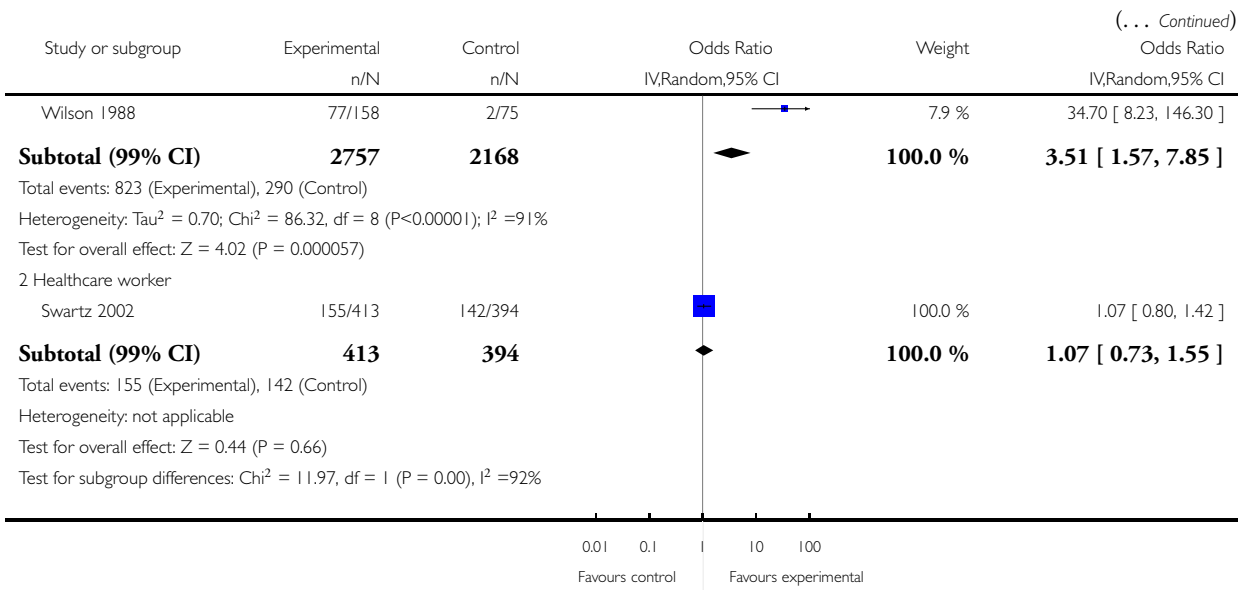
Review: Training health professionals in smoking cessation

Comparison: 7 Sub-group: type of professional being trained

Outcome: 4 Number of smokers receiving self-help material



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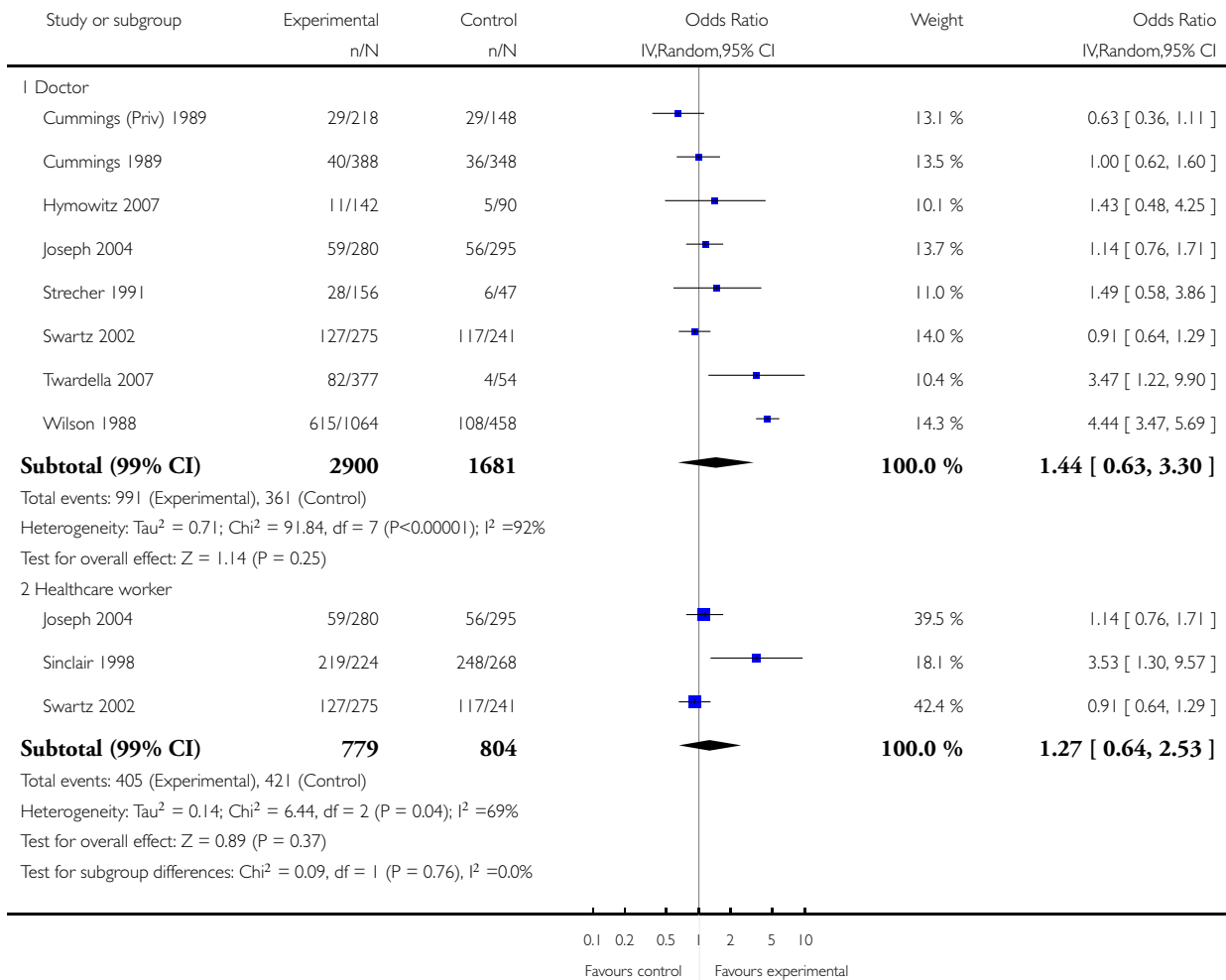


Analysis 7.5. Comparison 7 Sub-group: type of professional being trained, Outcome 5 Number of smokers receiving nicotine gum/replacement therapy.

Review: Training health professionals in smoking cessation

Comparison: 7 Sub-group: type of professional being trained

Outcome: 5 Number of smokers receiving nicotine gum/replacement therapy

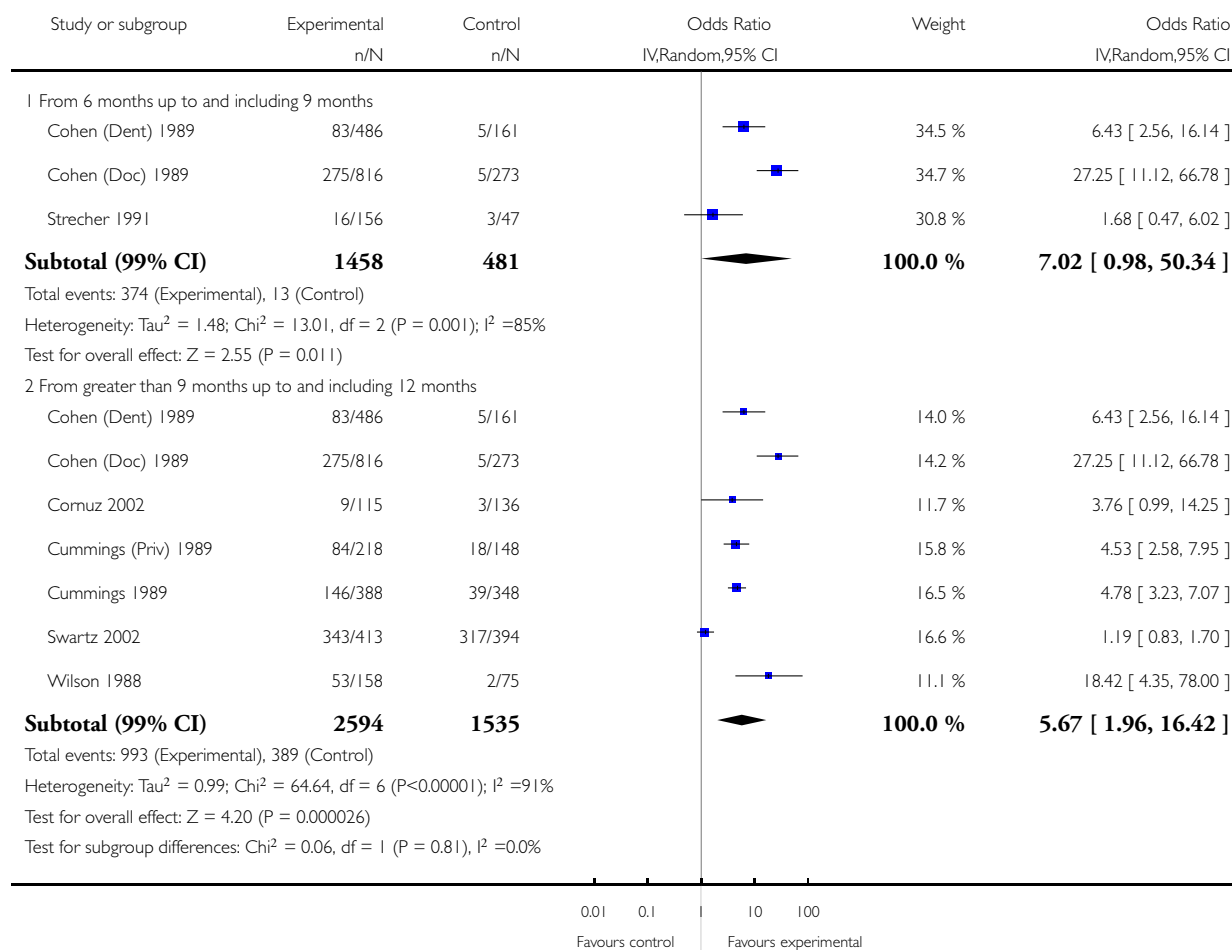


Analysis 8.1. Comparison 8 Sub-group: length of follow-up, Outcome 1 Patient asked to set a quit date.

Review: Training health professionals in smoking cessation

Comparison: 8 Sub-group: length of follow-up

Outcome: 1 Patient asked to set a quit date

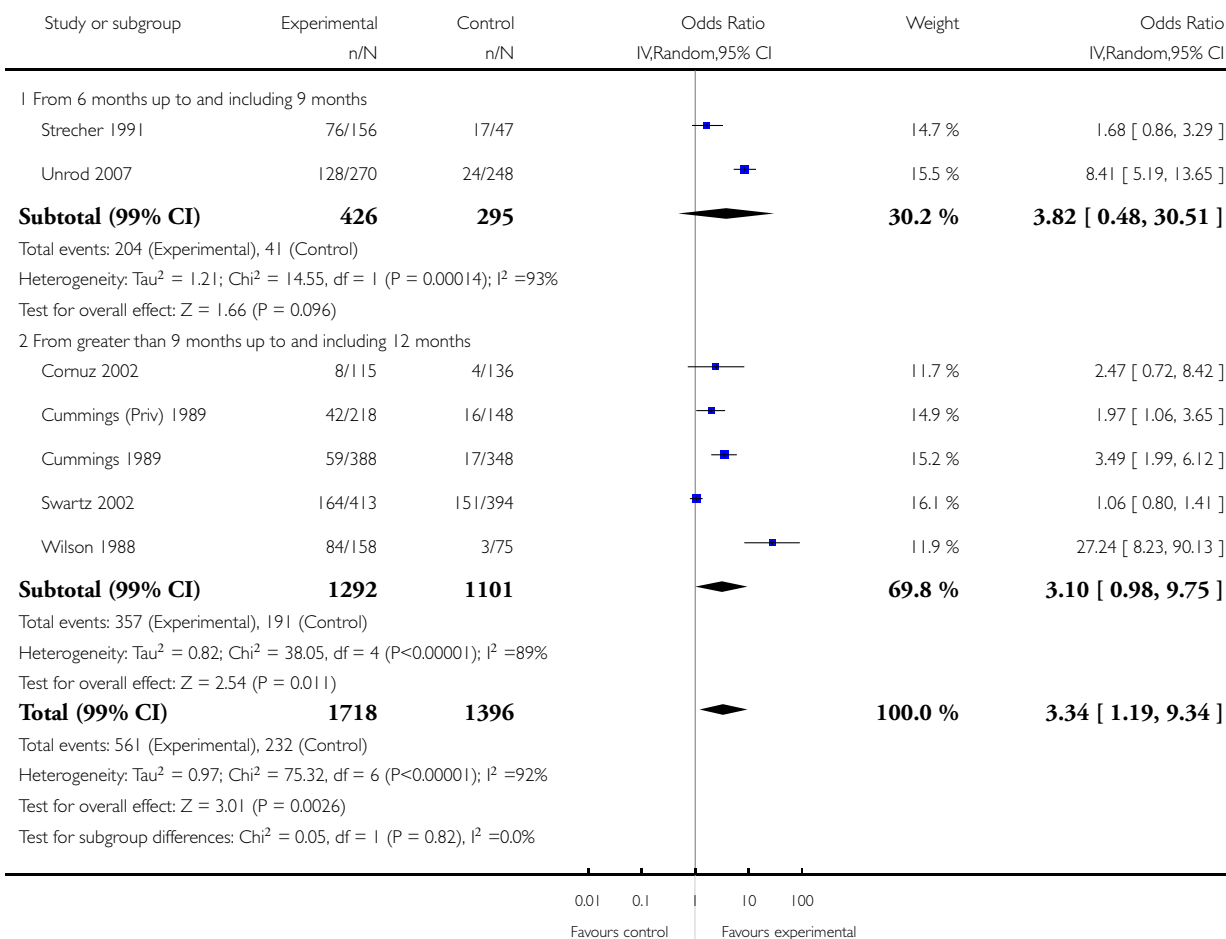


Analysis 8.2. Comparison 8 Sub-group: length of follow-up, Outcome 2 Patient asked to make a follow-up appointment.

Review: Training health professionals in smoking cessation

Comparison: 8 Sub-group: length of follow-up

Outcome: 2 Patient asked to make a follow-up appointment

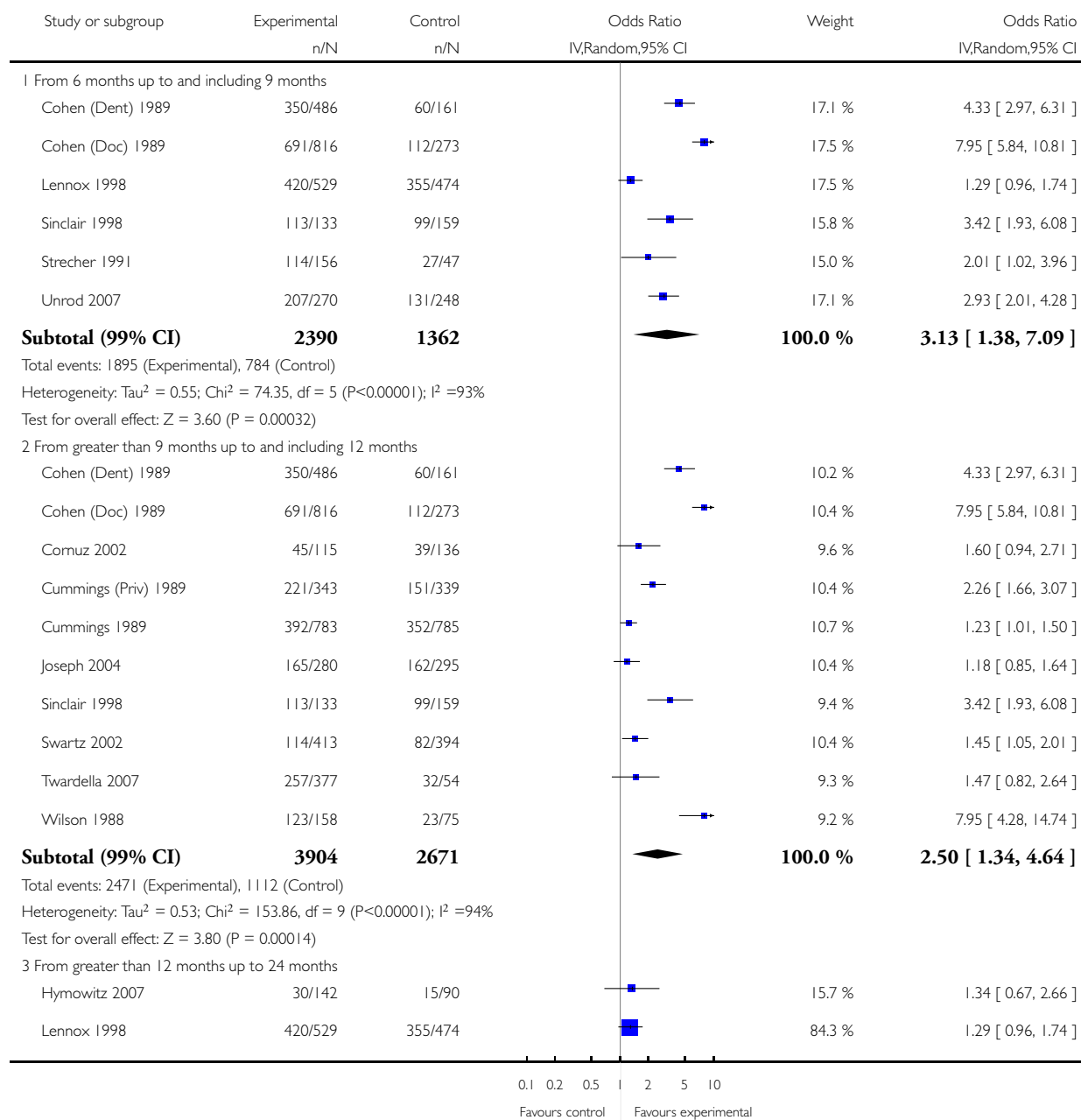


Analysis 8.3. Comparison 8 Sub-group: length of follow-up, Outcome 3 Number of smokers counselled.

Review: Training health professionals in smoking cessation

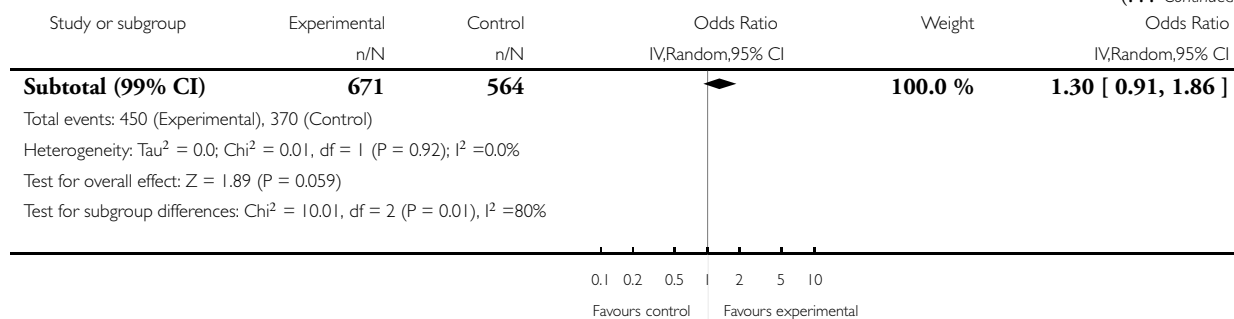
Comparison: 8 Sub-group: length of follow-up

Outcome: 3 Number of smokers counselled



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(... Continued)

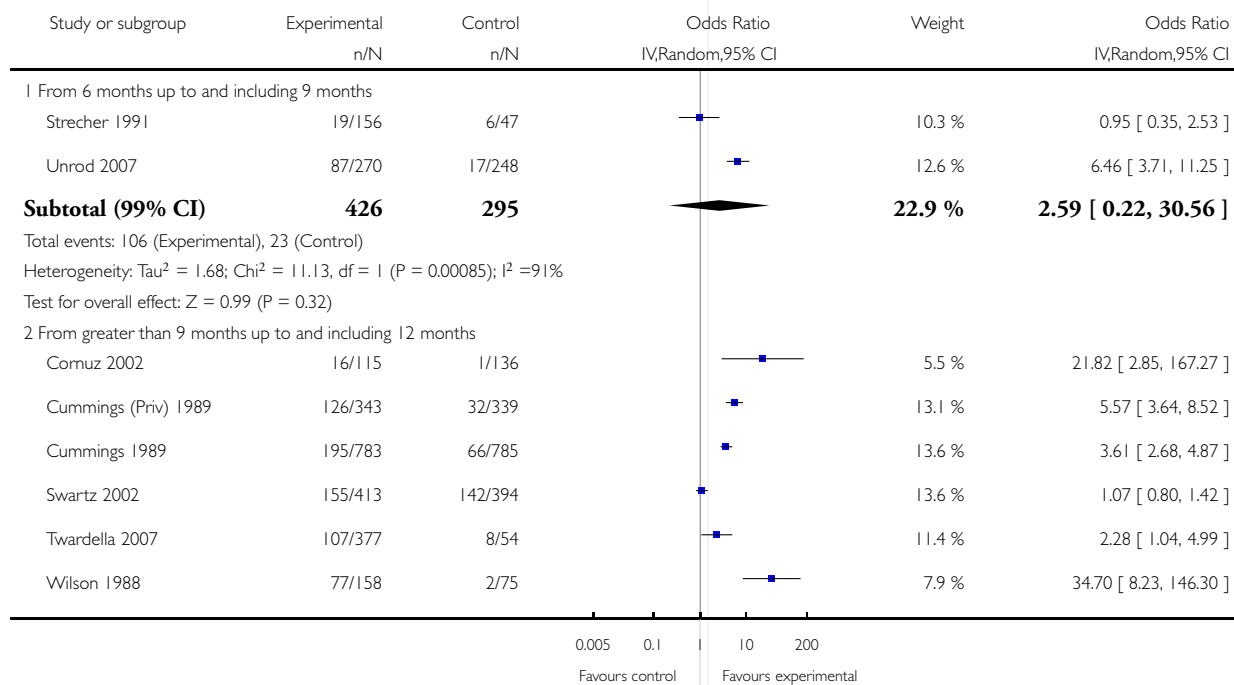


Analysis 8.4. Comparison 8 Sub-group: length of follow-up, Outcome 4 Number of smokers receiving self-help material.

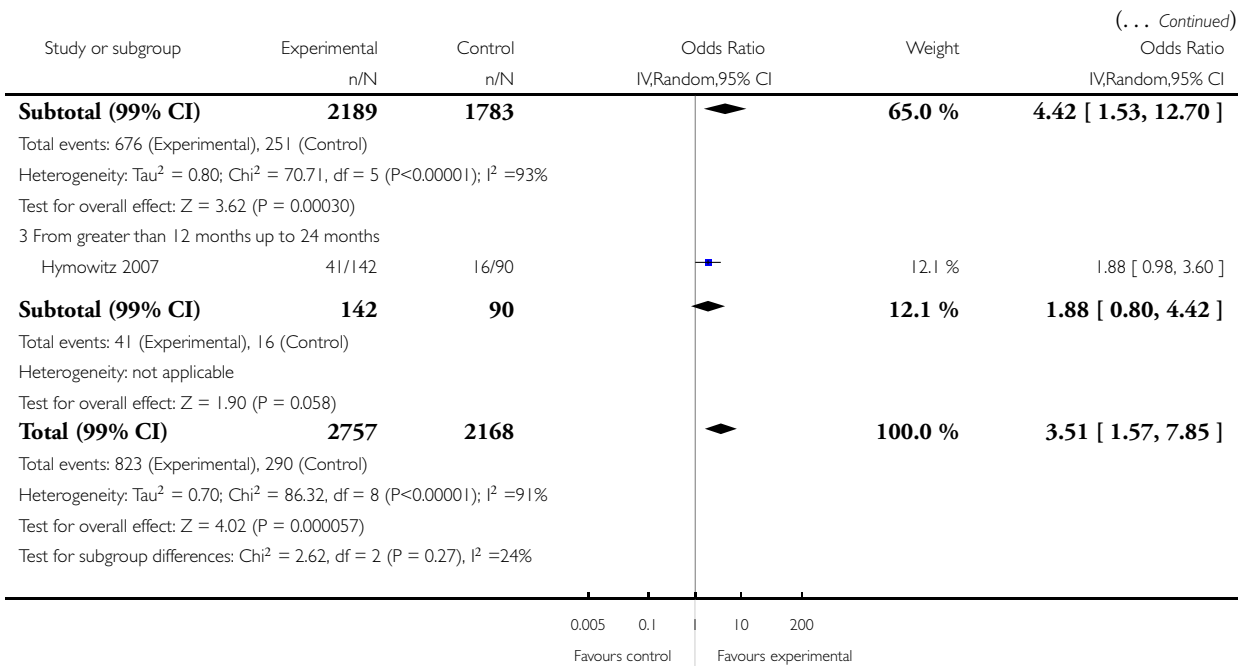
Review: Training health professionals in smoking cessation

Comparison: 8 Sub-group: length of follow-up

Outcome: 4 Number of smokers receiving self-help material



(Continued ...)

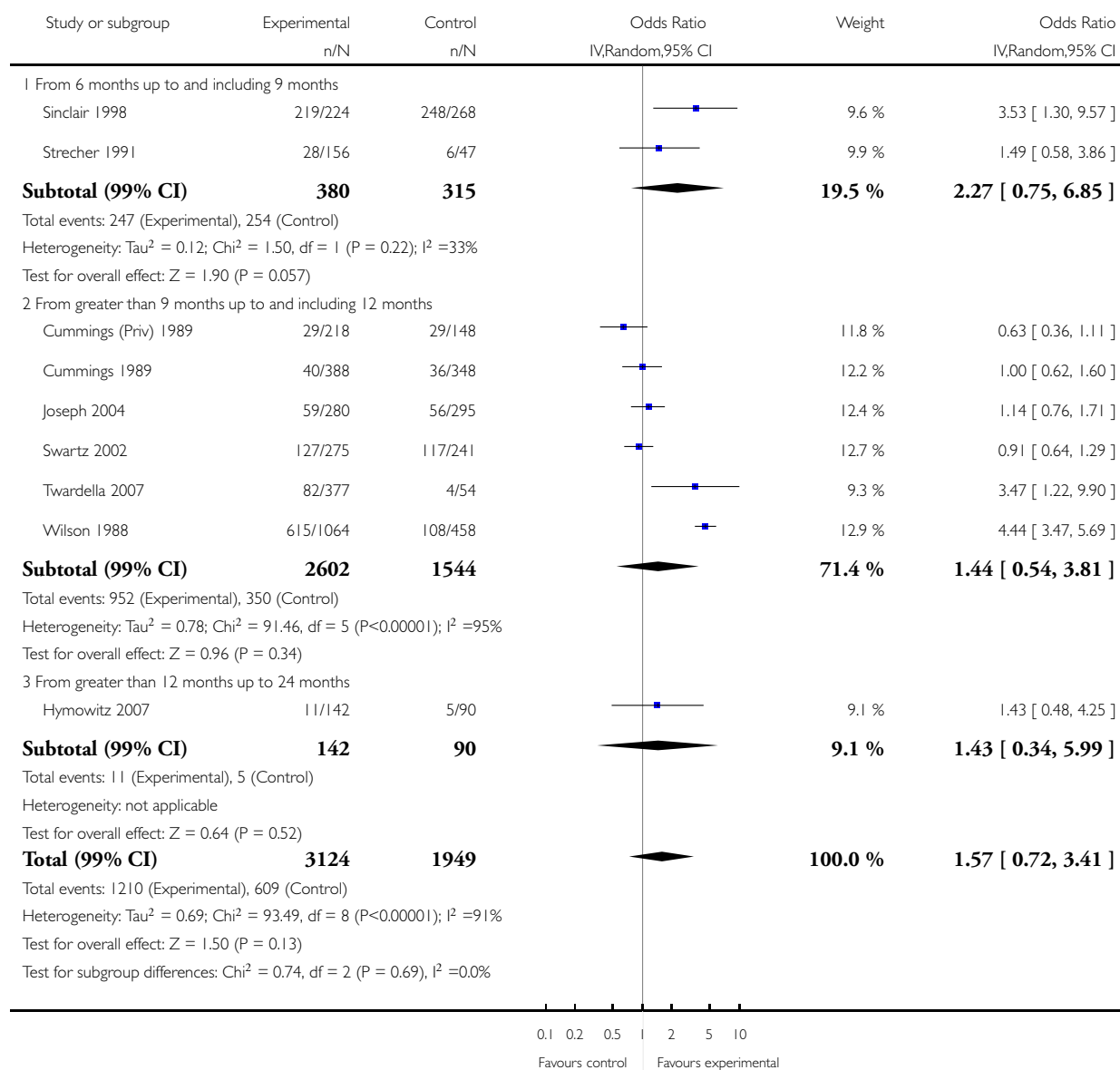


Analysis 8.5. Comparison 8 Sub-group: length of follow-up, Outcome 5 Number of smokers receiving nicotine gum/replacement therapy.

Review: Training health professionals in smoking cessation

Comparison: 8 Sub-group: length of follow-up

Outcome: 5 Number of smokers receiving nicotine gum/replacement therapy

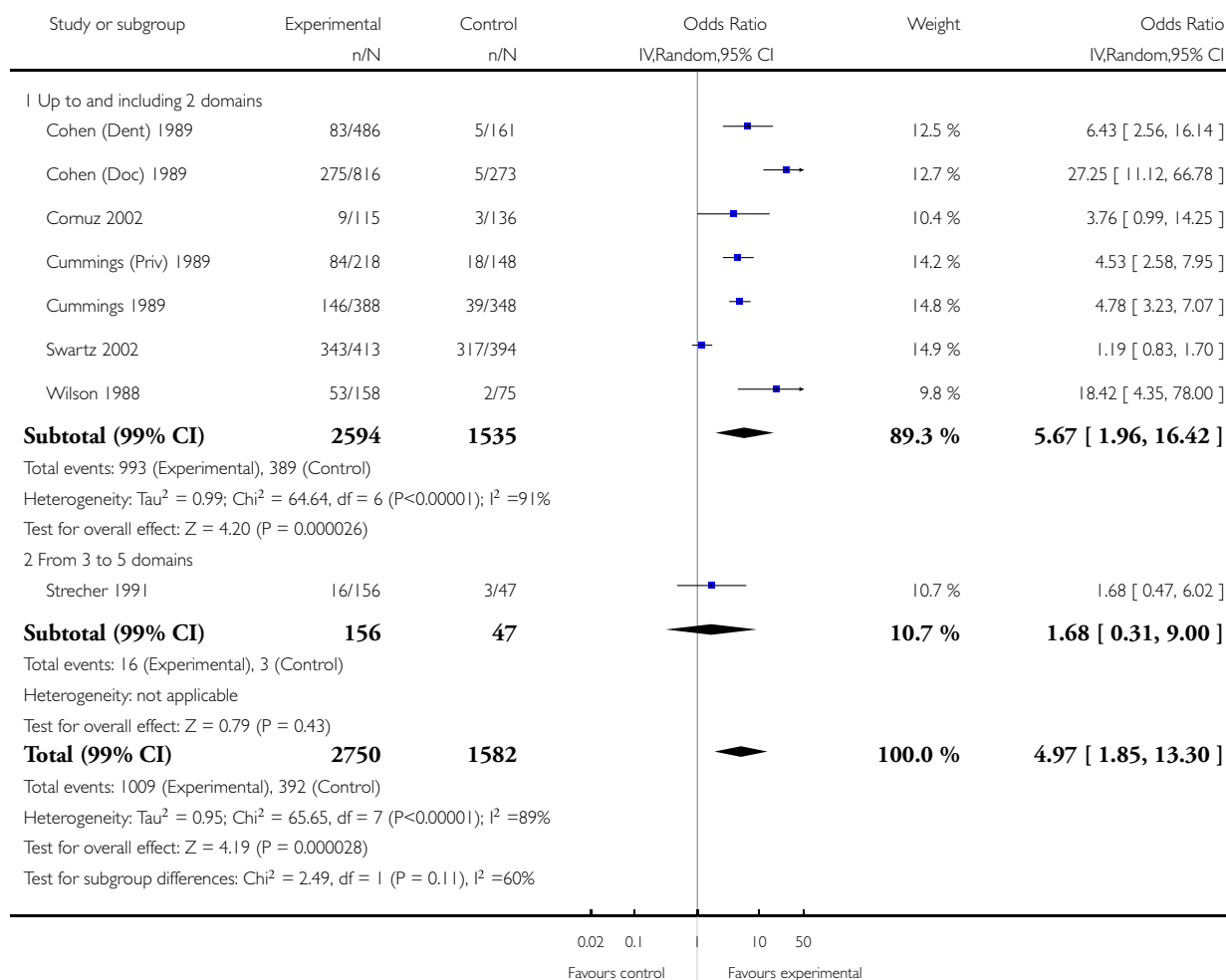


Analysis 9.1. Comparison 9 Sub-group: risk of bias in the studies, Outcome 1 Patient asked to set a quit date.

Review: Training health professionals in smoking cessation

Comparison: 9 Sub-group: risk of bias in the studies

Outcome: 1 Patient asked to set a quit date

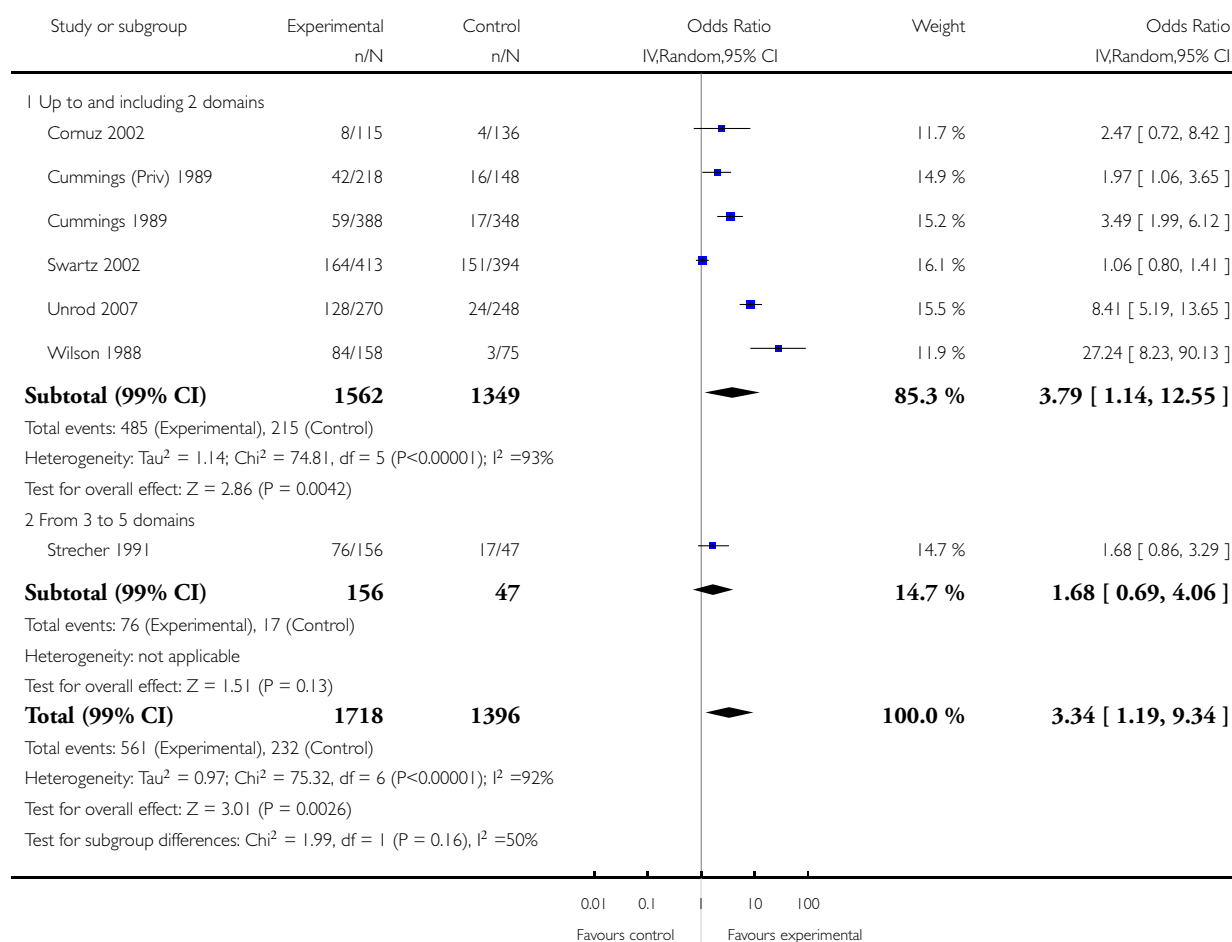


Analysis 9.2. Comparison 9 Sub-group: risk of bias in the studies, Outcome 2 Patient asked to make a follow-up appointment.

Review: Training health professionals in smoking cessation

Comparison: 9 Sub-group: risk of bias in the studies

Outcome: 2 Patient asked to make a follow-up appointment

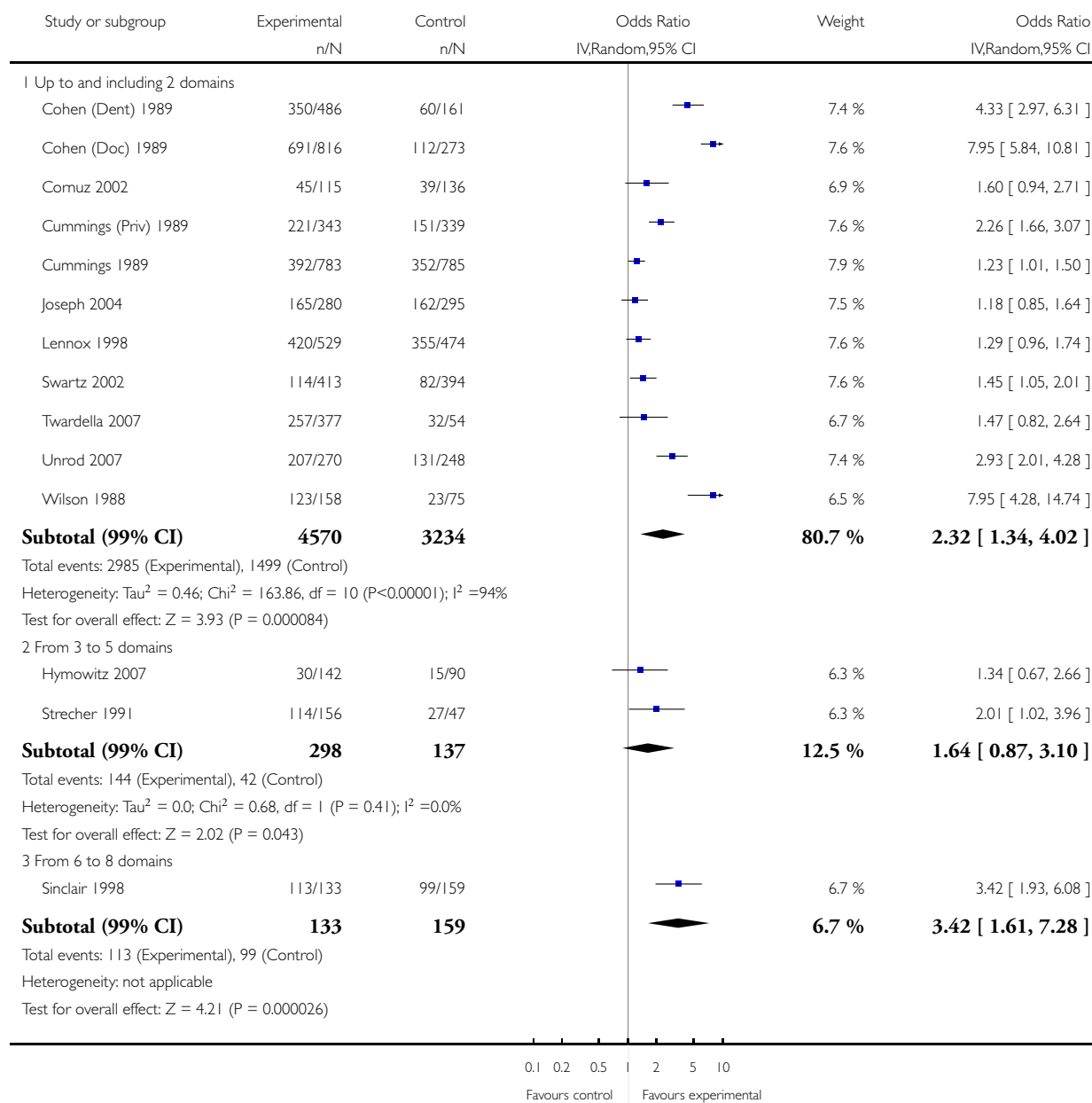


Analysis 9.3. Comparison 9 Sub-group: risk of bias in the studies, Outcome 3 Number of smokers counselled.

Review: Training health professionals in smoking cessation

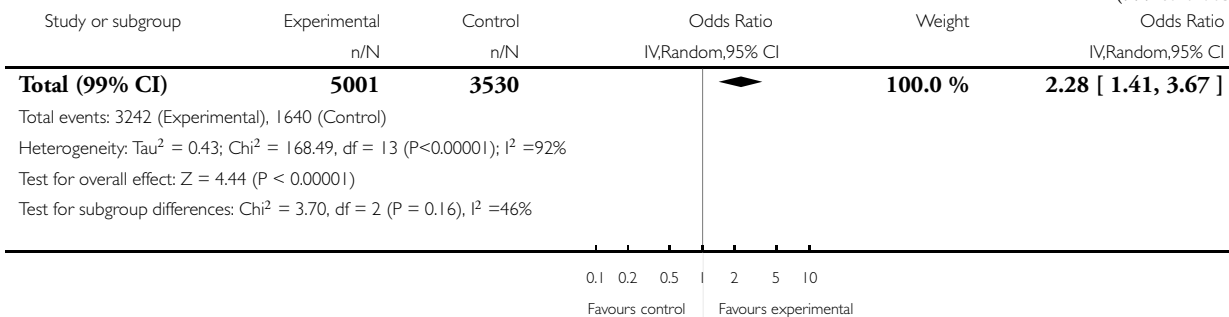
Comparison: 9 Sub-group: risk of bias in the studies

Outcome: 3 Number of smokers counselled



(Continued ...)

(... Continued)

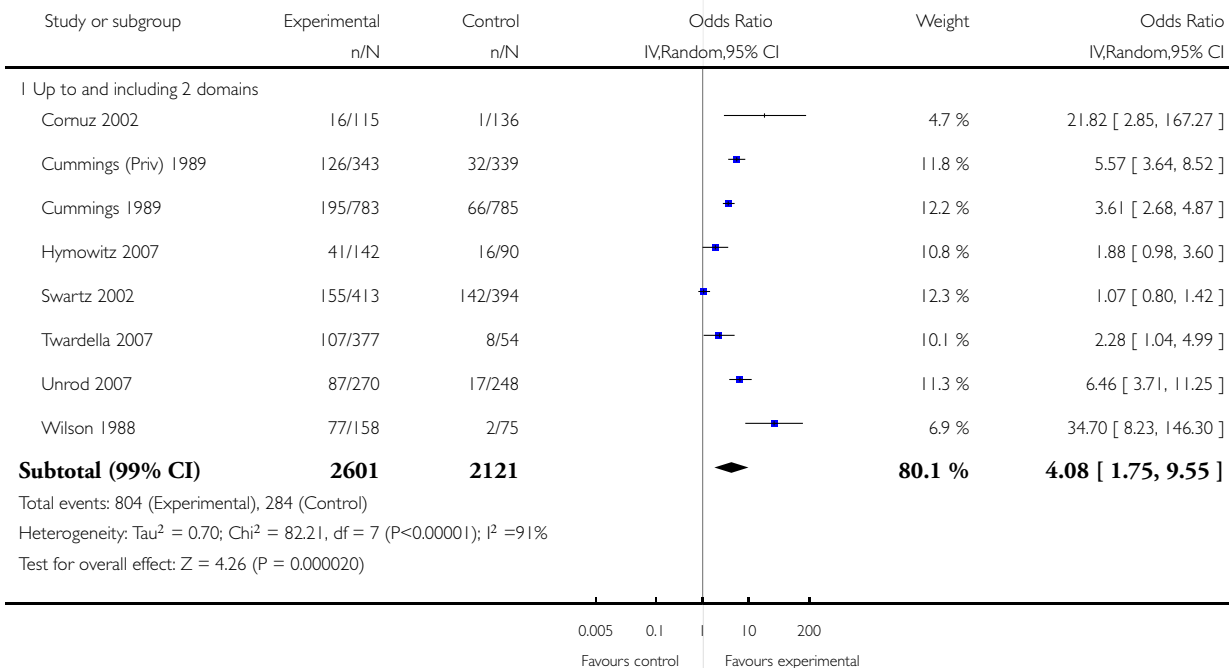


Analysis 9.4. Comparison 9 Sub-group: risk of bias in the studies, Outcome 4 Number of smokers receiving self-help material.

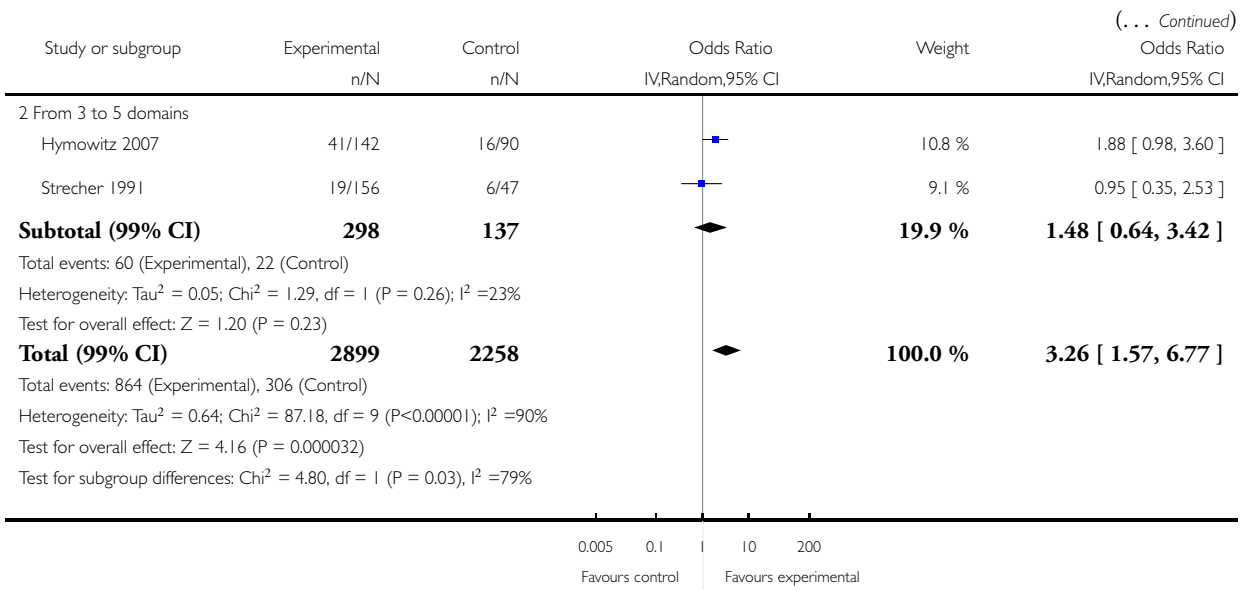
Review: Training health professionals in smoking cessation

Comparison: 9 Sub-group: risk of bias in the studies

Outcome: 4 Number of smokers receiving self-help material



(Continued ...)

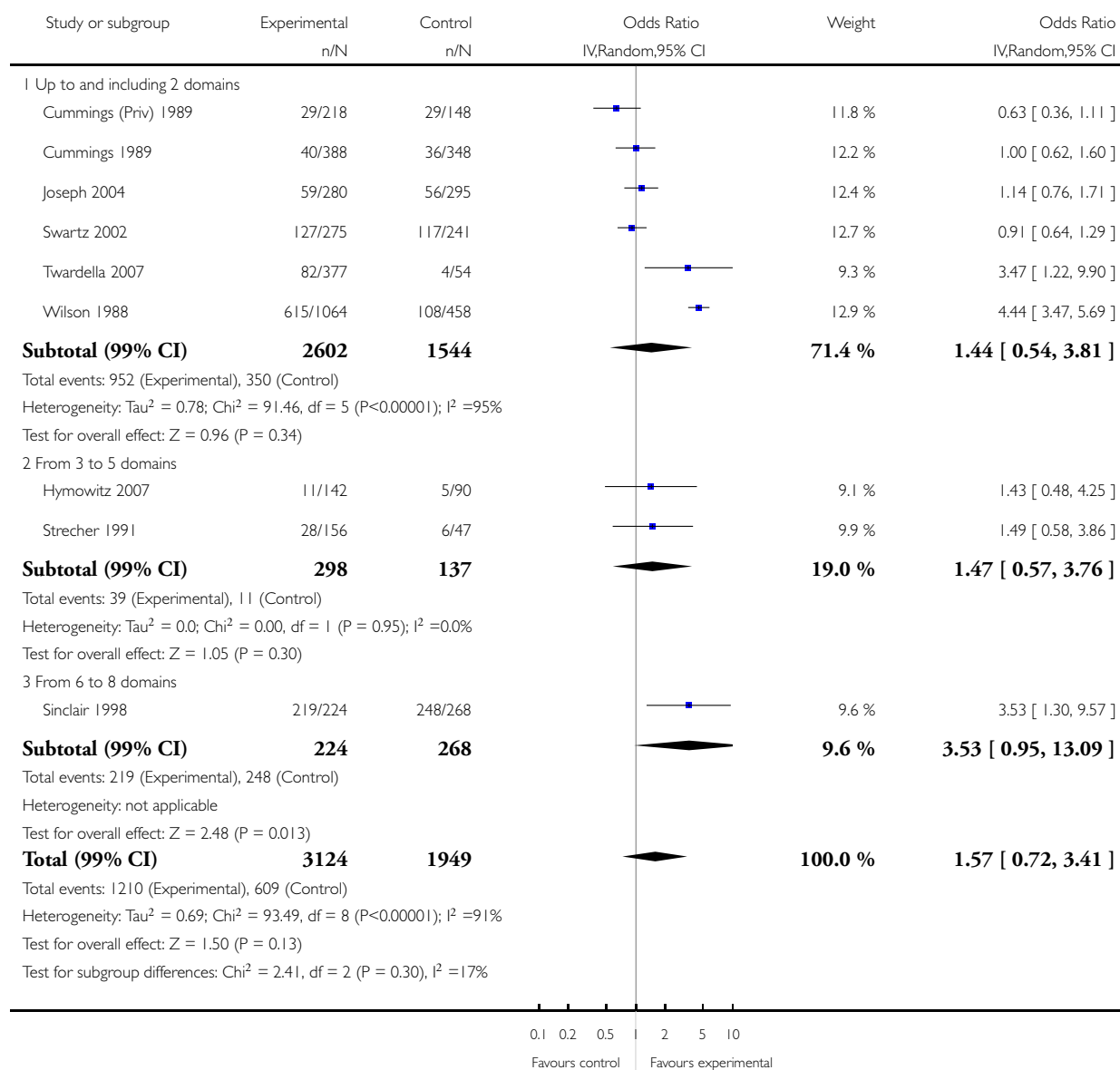


Analysis 9.5. Comparison 9 Sub-group: risk of bias in the studies, Outcome 5 Number of smokers receiving nicotine gum/replacement therapy.

Review: Training health professionals in smoking cessation

Comparison: 9 Sub-group: risk of bias in the studies

Outcome: 5 Number of smokers receiving nicotine gum/replacement therapy



ADDITIONAL TABLES

Table 1. Summary of individual study outcomes

Study ID/sub-headings:	Detailed synthesis of intervention effectiveness:
<p><i>Cohen (Dent) 1989</i> Point prevalence/ continuous abstinence</p>	<p>One year follow-up: At 12 month follow-up there was a significant interaction between subjects receiving the gum compared to control (7.7% and 3.1% for gum and control groups respectively, $p < 0.05$). When the three intervention groups were combined together as per the methods outlined in this review, point prevalence of smoking at 12 month follow-up was 5.1%, compared to the control of 3.1%, which failed to reach statistical significance</p> <p>Six months follow-up: At 6 month follow-up the coefficient for the reminder effect was negative, which authors state is likely to be caused by high cessation in the gum group coupled with the lower percentages in the gum and reminders group (9% for gum only, 3.2% for reminder only, 3% for gum and reminder and 3.1% for control)</p>
<p>Cohen (Dent) 1989 Secondary outcomes</p>	<p>Patient asked to set a quit date: Prompted dentists were more likely to ask patients to set a quit date (6% for gum only, 14% for reminder only, 31% for both reminder and gum and 3% for control)</p> <p>Number of smokers counselled: Prompted conditions increased the likelihood of dentists advising their patients to quit (72% for gum only, 59% for reminder only, 85% for both reminder and gum and 37% for controls)</p>
<p><i>Cohen (Doc) 1989</i> Point prevalence/ continuous abstinence</p>	<p>One year follow-up: The combination of gum and reminders did not increase the percent of patients who quit smoking compared to either condition alone. At 1 year follow-up significant negative interaction between gum and reminders were found ($p < 0.05$). Pair-wise comparisons among the groups showed that the three intervention groups were not significantly different from each other (reminder 15%, gum 8.8%, both 9.6%), however, each of them were significantly different from the control for analyses based on returnees and on all patients (control 2.7%, $p < 0.05$). Twelve month quit percentages for point prevalence were significantly higher for the reminders group (7.9%), compared to those using gum (4.7%), those using a combination of the two (5.2%) and control (1.5%), $p < 0.05$. When the three intervention groups were combined together as per the methods outlined in this review, point prevalence of smoking at 12 months follow-up was 5.9%, compared to the control of 1.5%, which statistically favoured the intervention, $p = 0.002$</p>
<p>Cohen (Doc) 1989 Secondary outcomes</p>	<p>Patient asked to set a quit date: Prompted doctors were more likely to ask patients to set a quit date (10% for gum only, 33% for reminder only, 58% for both reminder and gum and 2% for control)</p> <p>Number of smokers counselled: Both the gum and prompted</p>

Table 1. Summary of individual study outcomes (Continued)

	conditions increased the likelihood of doctors advising patients to quit (84% for gum only, 75% for reminder only, 95% for both reminder and gum and 41% for control)
Cornuz 2002 Point prevalence/ continuous abstinence	One year follow-up: At 12 month follow-up, 7 day point prevalence was significantly higher in the intervention group (15 of 115 patients [13%, 95% CI 7% to 12%]) compared to the control group (7 of 136 patients [5%, 95% CI 1% to 9%]). The eight-percentage point difference between groups translates to a resident needing to counsel 13 patients to gain 1 additional former smoker
Cornuz 2002 Secondary outcomes	<p>Patient asked to set a quit date: The short-term effect of the training program performed by the resident was statistically significant in favour of the intervention with 8% compared to 2% for the intervention and control groups respectively</p> <p>Patient asked to make follow-up appointment: Short-term effect was not significantly different between groups with 7% of the intervention and 3% of the control population asked by their physician to make a follow-up appointment</p> <p>Number of smokers counselled: Not statistically significant with 39% of intervention patients and 29% of control patients counselled not to smoke</p> <p>Number of smokers receiving self-help materials: Short-term effects were statistically significant between groups with 14% of intervention subjects provided with a brochure compared to 1% of control</p>
Cummings (Priv) 1989 Point prevalence/ continuous abstinence	One year follow-up: There was no statistical significance on 7 day point prevalence for validated smoking cessation at one year follow-up, with 6.7% for trained group patients quit compared to 8.2% for control. Biochemically validated continuous abstinence (defined as > 9 months abstinence) results were similar with 3.2% for intervention subjects and 2.5% for control (95% CI for the 0.7% difference= -1.7 to +3.1%)
Cummings (Priv) 1989 Secondary outcomes	<p>Patient asked to set a quit date: Physicians in the experimental group asked more smokers to set quit dates with 100 out of 261 for intervention and 22 out of 177 for control</p> <p>Patient asked to make follow-up appointment: Trained physicians were significantly more likely to arrange a follow-up appointment to discuss smoking with 50 out of 261 for the intervention and 19 out of 177 for control</p> <p>Number of smokers counselled: Trained physicians were significantly more likely to discuss smoking (64%) compared to the control (44%)</p> <p>Number of smokers receiving self-help materials: Physicians in the experimental group gave self-help booklets to more smokers with 151 out of 411 for intervention compared to 38 out of 407 for control</p>

Table 1. Summary of individual study outcomes (Continued)

	<p>Number of smokers receiving nicotine gum/replacement therapy: There was no significant difference in the prescription of nicotine gum; Control group patients with whom smoking was discussed were more likely to be prescribed it (19%) than the trained group (13%)</p>
<p>Cummings 1989 Point prevalence/ continuous abstinence</p>	<p>One year follow-up: There was no significant effect on validated abstinence at one year follow-up, with 8.0% of trained group patients quitting versus 7.1% of control</p>
<p>Cummings 1989 Secondary outcomes</p>	<p>Patient asked to set a quit date: Trained physicians were significantly more likely to ask patients to set a quit date with 37.6% of intervention subjects and 11.1% of control subjects asked Patient asked to make follow-up appointment: Significantly more subjects in the intervention group had a follow-up appointment arranged with 15.2% compared to 5% in the control population Number of smokers counselled: Trained and control physicians were similar in terms of asking patients to discuss smoking (50.1% vs 44.9% respectively) Number of smokers receiving self-help materials: Physicians in the intervention arm were more likely to provide patients with self-help materials with 24.9% compared to control physicians with 8.4% Number of smokers receiving nicotine gum/replacement therapy: There was no significant difference in the prescription of nicotine gum; Approximately 10% of patients with whom smoking was discussed were prescribed gum Number of smokers prescribed a quit date: Trained physicians were significantly more likely to prescribe patients with a quit date (16.1%) compared to control physicians (1.2%)</p>
<p>Gordon 2010 Point prevalence/ continuous abstinence</p>	<p>Six months follow-up: Significantly higher abstinence levels were reported for both continuous abstinence and point prevalence at 7.5 month (six months post-enrolment plus six week grace period) follow-up (continuous abstinence: 74 out of 1394 for intervention and 22 out of 1155 control, $p < 0.01$; Point prevalence: 158 out of 1394 for intervention and 79 out of 1155 for control, $p < 0.05$)</p>
<p>Gordon 2010 Secondary outcomes</p>	<p>No secondary outcomes reported across both groups, however two outcomes reported for intervention group only: Number of smokers receiving self-help materials: Among intervention patients, 66.5% reported receiving the self-help reading materials and 96.7% reported reading them Number of smokers receiving nicotine gum/replacement therapy: Of the intervention subjects 16.9% reported using nicotine replacement therapy</p>

Table 1. Summary of individual study outcomes (Continued)

<p><i>Hymowitz 2007</i> Point prevalence/ continuous abstinence</p>	<p>One year follow-up: There was an increase in the special training condition of reported quitting during the past year of 3.8% (an 8.5% increase over baseline levels), however the change from baseline failed to achieve statistical significance. Among parents associated with standard training, the change was only 0.8%</p>
<p>Hymowitz 2007 Secondary outcomes</p>	<p>Number of smokers counselled: There was a significant increase in the percentage of parents counselled at both intervention and control training sites from baseline, however absolute levels of this activity for residents in each conditions was low (intervention 21.4% (OR 2.08, 95% CI 1.12 to 3.87), control 16.7% (OR 1.84, 95% CI 0.84 to 4.02)). There was no significant difference between groups</p> <p>Number of smokers receiving self-help materials: Provision of cessation materials increased significantly across both groups over the four year period when compared to baseline values (intervention 28.8% (OR 1.95, 95% CI 1.10 to 3.46), control 17.6% (OR 1.76, 95% CI 0.76 to 4.08)). There was no significant difference between groups</p> <p>Number of smokers receiving nicotine gum/replacement therapy: Few parents in either condition reported that residents prescribed nicotine replacement therapy (intervention n= 7.6%, control n= 5.9%)</p>
<p><i>Joseph 2004</i> Point prevalence/ continuous abstinence</p>	<p>One year follow-up: At follow-up the point prevalence of smoking cessation did not significantly improve for the intervention subjects, over that of control (intervention 11.4%, control 13.2% (p= 0.51 for Pearson Chi² test))</p>
<p>Joseph 2004 Secondary outcomes</p>	<p>Number of smokers counselled: During the intervention period, 59% of subjects in the intervention arm received behavioural support to stop smoking in comparison to 55% in the control (p= NS)</p> <p>Number of smokers receiving nicotine gum/replacement therapy: Twenty-one percent of subjects reported receiving medications for smoking cessation in the intervention arm whilst 19% received medication in the control group (p= NS)</p>
<p><i>Kottke 1989</i> Point prevalence/ continuous abstinence</p>	<p>One year follow-up: Almost half of the participants in each group who were smoking at baseline reported quit attempts for at least 24 hours during the previous year, with a mean duration of cessation of 2-months. No differences between the three groups were identified</p>
<p>Kottke 1989 Secondary outcomes</p>	<p>Patient asked to set a quit date: Almost 20% of patients seen in the workshop group reported being asked to set a quit date, compared to 10% in the materials group and 5% in the no-assistance group (p< 0.005)</p> <p>Patient asked to make follow-up appointment: Greater propor-</p>

Table 1. Summary of individual study outcomes (Continued)

	<p>tions of patients in the workshop group were asked to make a follow-up appointment compared to the other two groups but this was not significant</p> <p>Number of smokers counselled: Slightly over half of the patients interviewed reported that they had been 'asked if they smoked' when visiting their physicians during the campaign ($p < 0.025$); This did not differ significantly between intervention groups</p> <p>Number of smokers receiving self-help materials: One third of patients in the workshop group reported receiving self-help material compared to 11% in the no-assistance group ($p < 0.001$)</p>
<p>Lennox 1998 Point prevalence/ continuous abstinence</p>	<p>Fourteen months follow-up: There was no significant difference in sustained abstinence at 14 months between intervention (3.6%) and control (4.7%)</p> <p>Eight months follow-up: No significant difference was observed between intervention and control groups as to whether an attempt was made to give up smoking at any time during the study period</p>
<p>Lennox 1998 Secondary outcomes</p>	<p>Number of smokers counselled: No significant difference in discussion of smoking with doctors, nurses or health visitors, however results in both groups were above 70%; Intervention subjects who smoked were more likely than control subjects who smoked to recall smoking having been mentioned in a consultation during the 14-month follow-up period (significant for GP consultations at the 10 percent level, but not for consultations with practice nurses or health visitors)</p>
<p>Sinclair 1998 Point prevalence/ continuous abstinence</p>	<p>Nine month follow-up: There was no significant difference in nine month continuous abstinence with Intervention group 12%, control 7.4%, and no difference in one month point prevalence</p>
<p>Sinclair 1998 Secondary outcomes</p>	<p>Number of smokers counselled: Patients consulting training pharmacists were significantly more likely to report discussion of smoking (85% vs 62.3%)</p> <p>Number of smokers receiving nicotine gum/replacement therapy: Anti-smoking products were bought by most subjects following enrolment, however, intervention subjects were significantly more likely to make a purchase ($p = 0.0085$); There was a significantly greater use of nicotine patches relative to nicotine gum in the intervention group compared with the control group ($p = 0.029$). Overall, approximately three-quarters of the customers used patches compared with a quarter using gum</p>
<p>Stretcher 1991 Point prevalence/ continuous abstinence</p>	<p>Six months follow-up: There were no significant differences between 6 month validated abstinence rates, which ranged from 1.7% to 5.7%</p>

Table 1. Summary of individual study outcomes (Continued)

<p>Stretcher 1991 Secondary outcomes</p>	<p>Patient asked to set a quit date: Trained physicians were significantly more likely to advise smokers to quit (73% vs 58%) based on physician reported outcomes, however patient reports of this outcome are not significant</p> <p>Patient asked to make follow-up appointment: Overall there were no significant differences in scheduling follow-up appointments; According to patient outcomes however, more tutorial physicians asked to schedule follow-up appointments compared to non-tutorial physicians ($p < 0.05$)</p> <p>Number of smokers counselled: A prompt alone achieved similar counselling levels compared to control (75% vs 70% respectively) and there was no significant interaction between tutorial and prompt; After adjusting for pre-test scores and speciality, physicians receiving the tutorial reported a significantly greater number of patients advised to quit (76%) compared to non-tutorial physicians (69%) ($p < 0.05$)</p> <p>Number of smokers receiving self-help materials: All physicians were equally likely to give self help materials</p> <p>Number of smokers receiving nicotine gum/replacement therapy: There were no differences in the proportion of physicians who prescribed nicotine gum</p> <p>Number of smokers prescribed a quit date: There were no differences in advice to set a quit day, but the trained group was significantly more likely to write a quit day prescription according to physicians; Patients reported that significantly more tutorial physicians prescribed a quit date than non-tutorial physicians, however when groups were combined (tutorial and prompt, prompt only and tutorial only) this was not significant</p>
<p>Swartz 2002 Point prevalence/ continuous abstinence</p>	<p>One year follow-up: Intervention subjects were more likely to quit at follow-up (14.8% quit percentage) compared to control subjects (10.7%). Although this result was not statistically significant ($p = 0.08$), authors of the study report long-term clinically important reductions</p>
<p>Swartz 2002 Secondary outcomes</p>	<p>Patient asked to set a quit date: There was no significant difference between intervention and control groups for patients being advised to quit smoking (OR 1.22, 95% CI 0.81 to 1.83)</p> <p>Patient asked to make follow-up appointment: No significant difference was observed between intervention and control groups for patients asked to make a follow-up appointment (OR 1.08, 95% CI 0.77 to 1.51)</p> <p>Number of smokers counselled: Providers discussed counselling more in the intervention group compared to control (27.7% vs. 20.8%; OR 1.39, 95% CI 0.96 to 2.02)</p> <p>Number of smokers receiving self-help materials: There was no statistically significant difference between groups for the provision of self-help materials (OR 1.04, 95% CI 0.76 to 1.43)</p> <p>Number of smokers receiving nicotine gum/replacement therapy:</p>

Table 1. Summary of individual study outcomes (Continued)

	Subjects in both intervention and control groups had similar offers for the provision of nicotine replacement therapy (intervention 46.2%, control 18.6%, OR 0.89, 95% CI 0.63 to 1.25)
<i>Twardella 2007</i> Point prevalence/ continuous abstinence	One year follow-up: Point prevalence of smoking abstinence was 3%, 3%, 12% and 15% for the control, treatment plus incentive (TI), treatment plus medication (TM) and treatment plus incentive and medication (TI+TM) arms respectively. There were statistically significant differences between the TM, TI+TM and control arms ($p= 0.046$ and $p= 0.02$, respectively). Continuous abstinence (for at least 6-months) was higher in the TM arm (13/140, 9%) and TI+TM arm (17/219, 8%) compared to the control arm (1/74, 1%) and TI arm (2/144, 1%), however this difference was not statistically significant
Twardella 2007 Secondary outcomes	Number of smokers counselled: No significant differences were observed for number of smokers counselled between the four groups (control 59%, TI 73%, TM 67%, TI+TM 65%) Number of smokers receiving self-help materials: A significant difference was observed when comparing TM group to control group ($p=0.03$), however no other between group difference were observed (control 15%, TI 32%, TM 31%, TI+TM 24%) Number of smokers receiving nicotine gum/replacement therapy: There was a significant difference between groups for prescription of nicotine replacement therapy, particularly for those provided with reimbursement for costs of the medication (TM and TI+TM) (control 7%, TI 13%, TM 30%, TI+TM 22%)
<i>Unrod 2007</i> Point prevalence/ continuous abstinence	Six months follow-up: Seven day point prevalence of abstinence results were higher in the intervention group (12%) than the control group (8%), however this difference approached but did not reach significance (OR 1.77, 95% CI 0.94 to 3.34, $p= 0.078$)
Unrod 2007 Secondary outcomes	Patient asked to make follow-up appointment: Intervention physicians were five times more likely to arrange a follow-up appointment (47.5%) compared to control (9.7%) (OR 8.14, 95% CI 3.98 to 16.68, $p< 0.0001$) Number of smokers counselled: Significantly more intervention physicians provided quit smoking assistance to their patients (55.1%) compared to control physicians (20.2%) (OR 4.31, 95% CI 2.59 to 7.16, $p< 0.0001$) Number of smokers receiving self-help materials: Physicians in the intervention group were more than three times as likely to provide self-help materials to patients (32.3%) compared to control physicians (6.9%) (OR 5.14, 95% CI 2.60 to 10.14, $p< 0.0001$)
<i>Wang 1994</i> Point prevalence/ continuous abstinence	Six months follow-up: Statistically significant difference favouring the lesson intervention over the control ($p=0.02$) and significant difference ($p=0.054$) between lessons (G1) and poster (G2),

Table 1. Summary of individual study outcomes (Continued)

	however there was no significant difference between group 2 and control. When group 1 and group 2 were combined in meta-analyses and adjusted for potential clustering effects, no significant differences were observed
Wang 1994 Secondary outcomes	No secondary outcomes were reported
Wilson 1988 Point prevalence/ continuous abstinence	One year follow-up: Differences between the training arm and the other two arms were significant for sustained abstinence at one year and for 2 point prevalence, but not for one year point prevalence. Results were similar when mean cessation percentages were adjusted for baseline values. Twelve month sustained abstinence results were 8.8% for the intervention group, compared to 6.1% and 4.4% in the two comparison arms. However, when the two intervention groups were combined and adjustments for potential clustering effects taken into account, these results were no longer significant for point prevalence or continuous abstinence
Wilson 1988 Secondary outcomes	Patient asked to make follow-up appointment: Training groups more likely to ask for a quit date (54%) and arrange follow-up (12%) than gum only (12%/22%) or usual care (2%/4%) Number of smokers counselled: Training (85%) and gum (70%) groups more likely to mention smoking than usual care (31%) Number of smokers receiving nicotine gum/replacement therapy: Training (63%) and gum (59%) groups more likely to suggest use of gum than usual care (9%)

APPENDICES

Appendix I. MEDLINE search strategy

- 1 RANDOMIZED-CONTROLLED-TRIAL.pt. (223948)
- 2 CONTROLLED-CLINICAL-TRIAL.pt. (38083)
- 3 CLINICAL-TRIAL.pt. (265615)
- 4 Meta analysis.pt. (29188)
- 5 exp Clinical Trial/ (457811)
- 6 Random-Allocation/ (38507)
- 7 randomized-controlled trials/ (69081)
- 8 double-blind-method/ (68631)
- 9 single-blind-method/ (13151)
- 10 placebos/ (12338)
- 11 Research-Design/ (43437)
- 12 ((clin\$ adj\$ trial\$) or placebo\$ or random\$).ti,ab. (530665)
- 13 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj5 (blind\$ or mask\$)).ti,ab. (67270)

14 (volunteer\$ or prospectiv\$).ti.ab. (340629)
 15 exp Follow-Up-Studies/ (269958)
 16 exp Retrospective-Studies/ (314812)
 17 exp Prospective-Studies/ (233927)
 18 exp Evaluation-Studies/ or Program-Evaluation.mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier] (187044)
 19 exp Cross-Sectional-Studies/ (115024)
 20 exp Behavior-therapy/ (25130)
 21 exp Health-Promotion/ (34021)
 22 exp Community-Health-Services/ (246874)
 23 exp Health-Education/ (69098)
 24 exp Health-Behavior/ (59981)
 25 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 (1995011)
 26 smoking cessation.mp. or exp Smoking Cessation/ (17529)
 27 "Tobacco-Use-Cessation"/ (545)
 28 "Tobacco-Use-Disorder"/ (5569)
 29 Tobacco-Smokeless/ (1457)
 30 exp Tobacco-Smoke-Pollution/ (6538)
 31 exp Tobacco-/ (13929)
 32 exp Nicotine-/ (10241)
 33 ((quit\$ or stop\$ or ceas\$ or giv\$) adj5 smoking).ti.ab. (6469)
 34 exp Smoking/pc, th [Prevention & Control, Therapy] (8740)
 35 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 [A category smoking terms] (50315)
 36 1 or 2 or 3 [Likely CT design terms; RCTs, CCTs, Clinical trials] (384162)
 37 (animals not humans).sh. [used with 'not' to exclude animal studies for each subset] (1521160)
 38 (35 and 36) not 37 [Set 1: A smoking terms, likely CT design terms, human only] (3290)
 39 Education, Premedical/ (192)
 40 exp Education, Professional/ (102079)
 41 exp Inservice Training/ (13162)
 42 Physician's Practice Patterns/ (30147)
 43 Dentist's Practice Patterns/ (1382)
 44 exp Delivery of Health Care/ (479118)
 45 exp Comprehensive Health Care/ (120957)
 46 Critical Pathways/ (3744)
 47 Disease Management/ (8035)
 48 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 (622105)
 49 (training or trained).ti.ab. (152010)
 50 48 not 49 [MeSH without training text terms] (575357)
 51 38 and 49 [training text terms with smoking trials] (224)
 52 38 and 50 [sensitive MeSH terms, no mention of training in text] (600)

Records retrieved by this strategy that matched records in the Tobacco Addiction Group Specialised Register were screened for potential relevance. Records not already in the Register were not checked because they would previously have been retrieved during regular searches, and excluded for not being reports of controlled trials or other potentially eligible evaluations of tobacco control interventions.

Appendix 2. Glossary of tobacco-specific terms

Term	Definition
Abstinence	A period of being quit, i.e. stopping the use of cigarettes or other tobacco products, May be defined in various ways; see also: point prevalence abstinence; prolonged abstinence; continuous/sustained abstinence
Biochemical verification	Also called 'biochemical validation' or 'biochemical confirmation': A procedure for checking a tobacco user's report that he or she has not smoked or used tobacco. It can be measured by testing levels of nicotine or cotinine or other chemicals in blood, urine, or saliva, or by measuring levels of carbon monoxide in exhaled breath or in blood
Bupropion	A pharmaceutical drug originally developed as an antidepressant, but now also licensed for smoking cessation; trade names Zyban, Wellbutrin (when prescribed as an antidepressant)
Carbon monoxide (CO)	A colourless, odourless highly poisonous gas found in tobacco smoke and in the lungs of people who have recently smoked, or (in smaller amounts) in people who have been exposed to tobacco smoke. May be used for biochemical verification of abstinence
Cessation	Also called 'quitting' The goal of treatment to help people achieve abstinence from smoking or other tobacco use, also used to describe the process of changing the behaviour
Continuous abstinence	Also called 'sustained abstinence' A measure of cessation often used in clinical trials involving avoidance of all tobacco use since the quit day until the time the assessment is made. The definition occasionally allows for lapses. This is the most rigorous measure of abstinence
'Cold Turkey'	Quitting abruptly, and/or quitting without behavioural or pharmaceutical support
Craving	A very intense urge or desire [to smoke]. See: Shiffman et al 'Recommendations for the assessment of tobacco craving and withdrawal in smoking cessation trials' Nicotine & Tobacco Research 2004: 6(4): 599-614
Dopamine	A neurotransmitter in the brain which regulates mood, attention, pleasure, reward, motivation and movement
Efficacy	Also called 'treatment effect' or 'effect size': The difference in outcome between the experimental and control groups
Harm reduction	Strategies to reduce harm caused by continued tobacco/nicotine use, such as reducing the number of cigarettes smoked, or switching to different brands or products, e.g. potentially reduced exposure products (PREPs), smokeless tobacco

(Continued)

Lapse/slip	Terms sometimes used for a return to tobacco use after a period of abstinence. A lapse or slip might be defined as a puff or two on a cigarette. This may proceed to relapse, or abstinence may be regained. Some definitions of continuous, sustained or prolonged abstinence require complete abstinence, but some allow for a limited number or duration of slips. People who lapse are very likely to relapse, but some treatments may have their effect by helping people recover from a lapse
nAChR	[neural nicotinic acetylcholine receptors]: Areas in the brain which are thought to respond to nicotine, forming the basis of nicotine addiction by stimulating the overflow of dopamine
Nicotine	An alkaloid derived from tobacco, responsible for the psychoactive and addictive effects of smoking
Nicotine Replacement Therapy (NRT)	A smoking cessation treatment in which nicotine from tobacco is replaced for a limited period by pharmaceutical nicotine. This reduces the craving and withdrawal experienced during the initial period of abstinence while users are learning to be tobacco-free. The nicotine dose can be taken through the skin, using patches, by inhaling a spray, or by mouth using gum or lozenges
Outcome	Often used to describe the result being measured in trials that is of relevance to the review. For example smoking cessation is the outcome used in reviews of ways to help smokers quit. The exact outcome in terms of the definition of abstinence and the length of time that has elapsed since the quit attempt was made may vary from trial to trial
Pharmacotherapy	A treatment using pharmaceutical drugs, e.g. NRT, bupropion
Point prevalence abstinence (PPA)	A measure of cessation based on behaviour at a particular point in time, or during a relatively brief specified period, e.g. 24 hours, 7 days. It may include a mixture of recent and long-term quitters. cf. prolonged abstinence, continuous abstinence
Prolonged abstinence	A measure of cessation which typically allows a 'grace period' following the quit date (usually of about two weeks), to allow for slips/lapses during the first few days when the effect of treatment may still be emerging. See: Hughes et al 'Measures of abstinence in clinical trials: issues and recommendations'; <i>Nicotine & Tobacco Research</i> , 2003; 5 (1); 13-25
Relapse	A return to regular smoking after a period of abstinence
Secondhand smoke	Also called passive smoking or environmental tobacco smoke [ETS] A mixture of smoke exhaled by smokers and smoke released from smouldering cigarettes, cigars, pipes, bidis, etc. The smoke mixture contains gases and particulates, including nicotine, carcinogens and toxins
Self-efficacy	The belief that one will be able to change one's behaviour, e.g. to quit smoking
SPC [Summary of Product Characteristics]	Advice from the manufacturers of a drug, agreed with the relevant licensing authority, to enable health professionals to prescribe and use the treatment safely and effectively

(Continued)

Tapering	A gradual decrease in dose at the end of treatment, as an alternative to abruptly stopping treatment
Titration	A technique of dosing at low levels at the beginning of treatment, and gradually increasing to full dose over a few days, to allow the body to get used to the drug. It is designed to limit side effects
Withdrawal	A variety of behavioural, affective, cognitive and physiological symptoms, usually transient, which occur after use of an addictive drug is reduced or stopped. See: Shiffman et al 'Recommendations for the assessment of tobacco craving and withdrawal in smoking cessation trials' Nicotine & Tobacco Research 2004: 6(4): 599-614

WHAT'S NEW

Last assessed as up-to-date: 13 April 2012.

Date	Event	Description
5 December 2013	Amended	Correction to Summary of Findings Table (confidence interval for continuous abstinence)

HISTORY

Protocol first published: Issue 2, 1996

Review first published: Issue 2, 1996

Date	Event	Description
30 March 2012	New search has been performed	Seven new studies added; SOF table, meta-analyses and summary of individual study effectiveness table added
30 March 2012	New citation required and conclusions have changed	Structure of review changed, body of text updated and re-written; Conclusions changed
4 August 2008	Amended	Converted to new review format
31 May 2000	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

Kristin Carson updated the protocol, reviewed the literature, identified studies for inclusion, extracted data, entered and analysed data and updated the text of the manuscript.

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Malcolm Brinn extracted data, entered and analysed data and updated the text of the manuscript.

Adrian Esterman updated the protocol, analysed data and updated the text of the manuscript.

Willem Assendelft assisted in updating the protocol and updating the text of the manuscript.

Brian Smith assisted in updating the protocol and updating the text of the manuscript.

DECLARATIONS OF INTEREST

None known.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

RevMan version 5.1 was upgraded to version 5.1.2 during the review update, as such risk of bias domain categories were altered from 'yes', 'no' and 'unclear' to 'high risk', 'low risk' and 'unclear risk'.

INDEX TERMS

Medical Subject Headings (MeSH)

Health Personnel [*education]; Outcome Assessment (Health Care); Program Evaluation; Randomized Controlled Trials as Topic; Smoking Cessation [*methods]

MeSH check words

Humans

Chapter 16. Discussion

16.1 Significance and contribution to knowledge

The publications and submitted manuscripts presented in this thesis discussed several important studies examining options for tobacco cessation and prevention in Indigenous populations and smoking cessation amongst hospitalised smokers with tobacco related illnesses. Results from this research can be used to underpin current practice, policy and direct future investigations and research to reduce smoking prevalence in Australia.

On a population wide scale we are seeing reductions in tobacco prevalence among Western countries in light of pharmacotherapeutic aids, behavioural counselling and improved knowledge about the health effects of tobacco (153). Yet the significant gap between Indigenous and non-Indigenous smoking persists despite these population-wide reductions (154). When reflecting on the current status of tobacco use globally it is clear that use of general tobacco cessation models have done little to reduce the high smoking prevalence amongst Indigenous populations (59, 116-119). It is also important to consider that cultural and geographic diversity has created considerable variations of tobacco use between sub-populations and regions and as such cessation interventions that appear effective in one population will not necessarily work in another. It also cannot be assumed that tobacco cessation initiatives that are effective in the general population will work in the Indigenous setting, particularly considering the different characteristics of these groups (67). Indeed, it is only in recent years that community involvement within the planning and implementation of tobacco cessation initiatives has resulted in the first significant reduction in tobacco use prevalence for many countries (67, 142). The evidence base upon which health care decisions are made for Indigenous populations has been poor with useful resources lacking and patients suffering as a result.

Each year MEDLINE indexes over 750,000 new articles and Cochrane Central adds approximately 20,000 new randomised trials (155). This translates to 2,055 new articles and 55 new trials per day. Cochrane reviews seek to collate all evidence that fit pre-specified eligibility criteria, in order to address one specific research question, whilst minimising bias through the use of systematic methods (156). The Cochrane Collaboration prepares, promotes and importantly maintains these systematic reviews to inform health decisions, ensuring that the evidence does not become out of date or misleading. It was

clear that Cochrane reviews were needed to establish a regularly updated appraisal of this important area of research that will extend beyond the input of the authors.

Subsequently, two Cochrane reviews have been produced highlighting a paucity of data in the existing literature (Chapters 4 and 5). Considering published evidence from around the world was systematically evaluated to identify studies for inclusion within these reviews, it is remarkable that only four studies were identified for the tobacco cessation review (67). Two studies examined tobacco use prevention for Indigenous youth (110) with only one of these studies originating from Australia (121). This lack of evidence can be attributed to a number of challenges associated with Indigenous research such as: difficulty in recruiting participants, appropriate study design and appropriate consultation with key stakeholders and Indigenous Elders (67, 69).

Dissemination of the results from these two Cochrane reviews has occurred through publication and presentation of the findings at local and national meetings and conferences (see publications and conference presentations above). In addition, strong engagement with the media was undertaken to disseminate the findings, particularly in relation to the lack of empirical evidence from Australia and the possibility that we could be doing more harm than good. Articles have since been written on page 5 of 'The Australian' newspaper, aired across Australia through several local radio broadcasts and presented in online news articles. In January 2015 the findings were also discussed during a live radio interview for The Press Club at The Senate in Parliament House on Australia Day, which was met with an invitation to return and discuss additional results as they develop.

The only methodologically rigorous smoking cessation study identified in the tobacco cessation Cochrane review as coming from Australia, found that no participants completed the full course of nicotine patches (121). A mean of five patches were used and only six subjects reported using more than seven patches (out of 40 subjects with a full course of patches being 70) (121). These 'failed' studies are of particular concern as the provision of resources for programmes with unproven effectiveness in the Indigenous context can have a harmful result, as resources provided for the delivery of ineffective interventions means an opportunity cost for other potentially effective initiatives (66). The qualitative investigations (presented in Chapters 6 and 7) to examine the barriers and facilitators for the uptake of pharmacotherapies within Aboriginal and TSI Australians aimed to address this gap and identify possible solutions. Our qualitative evidence uncovered that all medications, though varenicline tartrate in particular, is currently underutilised within the

Aboriginal and TSI smoking population. There are also culture barriers to the use of products such as nicotine patches, with some communities reporting the side effect of vivid dreams as a bad omen or being 'sung' to. A multi-faceted approach which provides cessation and prevention from various sources simultaneously and engages the community should be considered. This was also the recommendation from the systematic review of evidence prepared for the Australian and New Zealand School of Government in the policy publication (Chapter 8). A focus on youth needs to be made a priority and the use of schools, community groups and influential role models such as sporting personalities should be utilised. However, there are methodological challenges specific to the Indigenous context that has made producing a rigorous evidence base to support clinical practice and policy difficult. These can be overcome with evaluations that uphold the scientific integrity of the research whilst ensuring that communities and Aboriginal people are respected, as discussed in Chapter 9. Providing a solid evidence base built on the systematic appraisal of research to support clinical practice is necessary to assist effective resource allocation and optimise the chances of success.

The three invited systematic reviews (Chapters 10, 11 and 12) summarised current and emerging options for smoking cessation (111) and established that even quit attempts in later life (157) and following diagnosis of tobacco related illnesses such as lung cancer (158), can have a considerable impact on morbidity, mortality, health services and quality of life. Building on this line of inquiry, the STOP study evaluated the efficacy (131) and safety (129) of varenicline tartrate plus Quitline counselling compared to Quitline counselling alone using a multi-centre randomised controlled trial design. This is the first known study to examine the use of varenicline tartrate (Champix) amongst inpatients in the acute setting, following hospital admission due to a tobacco-related illness. Use within this setting had not been considered in the past due to the neuropsychiatric (159) and cardiovascular (160) concerns raised in outpatient studies. However, the inpatient setting offers an opportunistic environment in which to implement primary prevention programs due to the captive audience who are generally more susceptible to smoking cessation as a result of their recent hospitalisation.

Hence it should be no surprise that the medication had a modest effect through to 12 months follow-up within the intervention arm (31% of subjects' maintained continuous smoking abstinence). Even the control arm who only received a 10-minute bedside counselling session (delivered by a researcher who had previously undergone motivational interviewer training) and a phone call made at the patient's bedside to put them in contact

with the Quit SA counselling, produced 21% continuous smoking abstinence at 12-month follow-up. To provide a comparison, only 6% of people who are referred to external smoking cessation services through a doctor actually utilise them (161) and only 2-3% of unassisted quit attempts are successful at 12-months (94). Hence our minimalist smoking cessation intervention, employing motivational interviewing techniques with the 5A model (ask, assess, advise, assist and arrange (162)), had a significant impact on helping patients to quit smoking and improve quality of life.

A range of conventionally accepted interventions, such as lipid lowering medications, antihypertensives, angioplasty, and bypass surgery, have cost estimates greatly exceeding smoking cessation interventions (18). Recent published economic evaluations and modelling from Belgium (163), Japan (164), Spain (165), USA (166), Sweden (167), and The Netherlands (168) show that varenicline in the outpatient setting is cost saving and more cost effective than other approaches including bupropion, nicotine replacement therapy, counselling alone or no active assistance. Yet standard smoking cessation practices with the use of medication such as varenicline tartrate within the hospital setting, where a targeted secondary prevention programme could be implemented, are still not considered for standard practice.

After completion of the STOP trial and dissemination of the findings via conference presentations and publication, uptake of the therapy into standard practice still had not occurred. In an attempt to rectify this situation, several meetings and lobbying to senior members of SA Health resulted in the addition of varenicline tartrate onto hospital formulary and inclusion within smoking cessation guidelines for staff and patients attending the Central Adelaide Local Health Network. In addition, an opportunistic invitation from the Health Minister at the time, John Hill, to attend parliament house cumulated in the results of the STOP trial being presented at Parliament House and provision of an additional 12 month salary for continued smoking related research. In addition, the results were aired on Channel 9 news, discussed during several radio interviews and disseminated via online news websites (see appendices 'Media – dissemination of PhD research findings and media related to PhD').

Discussions about the results with influential doctors, scientists, health care workers, policy makers and consumers to share the findings and determine how best to use the information from the 'grass roots' level is already underway. The results of this research has also been shared with the Indigenous contributors who participated in the research

(healthcare workers, key stakeholders and the broader Indigenous community) at several fora chosen by them.

The qualitative research results also identified that many of the healthcare workers and some doctors are reporting that they do not believe they have the skills or ability to offer smoking cessation/prevention initiatives to patients (Chapter 6), and perhaps more importantly, admit to the attitude of *'even if I did, it's not going to work so why bother'* (169-171). The Cochrane review of training health professionals in smoking cessation techniques supports these findings (169), whilst simultaneously identifying an opportunity for intervention using a minimal impact model. A key finding from the Cochrane review was the ability to obtain effectiveness through interventions employing one-off group interactions of as little as 40 minutes. This suggests that short intervention studies may be all that is needed to effectively change practice, providing the correct content and delivery mechanisms are employed. These findings have attracted media attention with the production of several online news articles.

Built into any good research initiative should be the means to disseminate research findings and translate the evidence into practice. With this in mind, I attempted to translate the evidence from all of my studies via: contributions to policy (such as through publication into the policy journal 'Evidence Base' on behalf of the Australia and New Zealand School of Government); influencing current practice by participation in several committees and working parties (listed above under 'Membership of relevant committees and working parties associated with the PhD'); and through mass dissemination of the findings through publication (16 produced during candidature related to the PhD including two published book chapters), presentations at conferences (total of 56 presentations) and engaging with the media (total of 216 since 2012 including television, radio, newspapers, online articles and magazines; see appendices for comprehensive list of media citations). Dissemination of these findings to the scientific and medical community via multiple channels as well as translation into lay summaries for mass distribution to the general public is necessary to ensure timely uptake of the findings and aid progress in the field.

16.2 Limitations and problems encountered

16.2.1 Systematic reviews, Cochrane meta-analyses and policy publications:

For the systematic literature reviews (111, 157, 158), Cochrane meta-analyses (67, 110, 169) and Australia and New Zealand School of Government Policy Document (172) there

is a possibility that potentially relevant information will not have been included. Although all attempts are made to ensure that the search strategies are as comprehensive as possible with inclusion of grey literature via screening of bibliographies for included studies, review of online clinical trial registries and author contact, there is still a possibility that relevant citations will be missed.

Moreover, for the Cochrane reviews in particular, only studies of sound methodological quality that meet the pre-specified and pre-published (173, 174) (see appendices) eligibility criteria are included within the meta-analyses. This means that the number of included studies will be sacrificed at the expense of review quality. However, studies which were excluded from the Cochrane reviews were later captured in the policy document (172) as the evidence still has useful implications that can be used to underpin clinical practice in the absence of other high quality evidence.

16.2.2 Indigenous qualitative and mixed method research:

Research with Indigenous populations has been notoriously problematic in the past. One New Zealand Maori author writes that:

“the word itself ‘research’, is probably one of the dirtiest words in the Indigenous world’s vocabulary” (123).

There is also a native Alaskan saying that:

“researchers are like mosquitoes; they suck your blood and leave” (144),

This suggests that the research being conducted is perceived to have very little benefit for the Indigenous community. There are reports from within Aboriginal communities of significant distrust of research, researchers, government officials and doctors, which should not come as a surprise particularly when considering how often Aboriginal people are portrayed as ‘broken’ ‘helpless’ and in need of outside ‘expert’ assistance in existing research publications (68). Historically, research among Indigenous peoples has been a source of distress due to inappropriate methods and practices (144), historical abuse of research, non-collaborative in nature, paternalistic, with reference to colonising approaches (123). With consideration of these over-arching issues, it is not surprising that difficulties were encountered with participant recruitment for the qualitative and mixed method studies. In particular, several focus groups were planned with Indigenous smokers, ex-smokers and non-smokers from both Murray Bridge and Adelaide. Yet recruiting the

required number of participants within each focus groups, which was to be separated by males and females, was unable to be achieved by the time of thesis submission. However, the planned work will still be undertaken as additional research personnel support has been secured to complete the work.

The one-on-one interview studies with doctors and other health professionals was able to be completed (Chapter 6), however, several limitations are present. The lack of self-reported Aboriginal and TSI doctors in that group is of concern as this does limit the context of the findings to the attitudes, knowledge and behaviours of non-Indigenous doctors. However, in a standard clinical practice setting the large majority of doctors treating Aboriginal and TSI Australians are non-Indigenous themselves. According to the Australian Indigenous Doctors Association there are currently 204 Indigenous doctors (139) and over 80,000 non-Indigenous doctors (140), meaning that the majority of Indigenous people are treated by non-Indigenous doctors. Thus less than a quarter of one percent of doctors are Indigenous and therefore the results are a reflection of real-world practices. Secondly, seven of the eight doctors included in this analysis are specialists, meaning that the population of patients they consult tends to have more severe underlying illnesses than those seen by general practitioners. As such willingness to quit smoking and approaches taken amongst their cohort of patients is likely to be different to the general population.

A substantial limitation in the design of the survey delivered to health professionals during the Thoracic Society of Australia and New Zealand conference (Chapter 7), relates to the opportunistic sampling method used. As recruitment was not systematic and participants had to 'opt in' to participate, it is likely that those who responded were more likely to feel strongly about their views and the topic area in general. Moreover, the respondents represent slightly less than 20% of the participants who were approached to participate. The lack of demographic data about these non-responders is another limitation, as having that information would have aided the ability to generalise the findings. However, the data obtained and approach used still provides useful information that can direct patient care and future investigations as well as provide a learning experience upon which improved research methodologies can be built respectively.

16.2.3 Smoking Termination Opportunity for inPatient (STOP) trial:

Several limitations are present within the STOP trial. Firstly, the lack of blinding for participants, investigators and outcome assessors is a serious weakness. Open-label studies

are at risk of overestimating patient-reported outcomes in the intervention arm and underestimating events in the control arm. The intervention efficacy is confounded by the possibility of an additional placebo effect due to the presence of an active treatment, which did not occur in the control population. In addition, there is potential for a demoralisation effect in the control arm as participants are aware that they are not receiving the active treatment. Although this is a draw back for maintaining a high standard of methodological rigour for treatment efficacy and safety, it can also be seen to have a beneficial result when considering the study as a real-world reflection of treatment response. The superior efficacy of varenicline over that of a placebo has already been well established in the empirical evidence through several double blinded randomised controlled trials (147, 148, 150), as well as in comparison to other pharmacotherapeutic aids for smoking cessation (54, 175). Therefore, it was not necessity for the STOP trial to employ a blinded approach. Subsequently what the STOP trial offers is a real-world practical demonstration of how varenicline tartrate plus Quitline counselling and Quitline counselling alone would fair in the inpatient setting amongst acute hospitalised patients.

Another possible issue relates to the selection of an intention to treat analysis within the STOP trial, as some control subjects did commence varenicline tartrate through their general practitioner and some varenicline tartrate subjects didn't commence the medication. Thus the potential for fidelity issues caused by contamination raises an impurity bias. However, the intention to treat analysis model is currently considered to be the gold standard in studies employing a randomised controlled design. This method of data reporting also permitted comparisons with other published studies, most of which have also used the intention to treat analysis method.

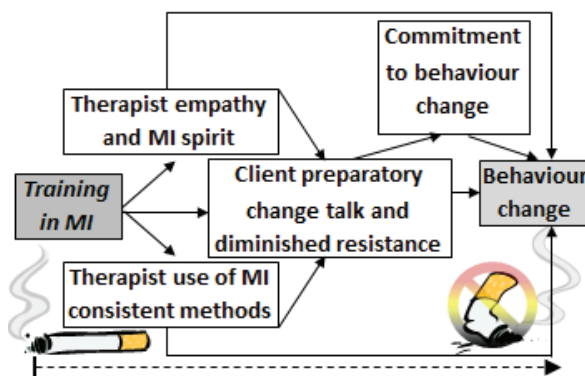
The majority of the population recruited in STOP was reflective of the patient population attending the hospital. As such there are few non-Caucasian subjects included (<4%), seriously limiting the generalisability of these findings outside of this population. However, as recruitment was systematic with each smoker admitted to hospital approached for participation, the uptake of the intervention again would be likely to reflect the typical population response to treatment.

16.3 Future directions

16.3.1 Training health professionals:

Collaborating with health services provides an opportunistic and unique environment in which to deliver smoking cessation programs, as HPs consult countless people each year and are perceived to be influential sources of information for smoking cessation (90). In addition to works presented in this thesis (110, 111, 131, 172) studies have consistently shown that individual counselling from smoking cessation specialists increase the chances of successful abstinence compared to less intensive support (91, 92). This is further supported by the Cochrane meta-analysis presented in Chapter 15 on ‘Training health professionals in smoking cessation’ (169), where we identified that even training of short duration (a one-off session of 2-3 hours) *can* have substantial implications for quit attempts amongst patients of HPs long-term. Moreover, behavioural change techniques used in smoking cessation counselling have recently been associated with greater levels of quitting success (176). Motivational interviewing (MI) skills are fundamental to these successful models and are a tool which some of my collaborators have developed and refined over the past decade (162, 177) and was also successfully implemented the STOP trial amongst recalcitrant hospitalised smokers (131).

Figure 4: Theory of MI showing relationships between process and outcome variables.



MI is designed to improve performance areas such as inquiring about smoking habits, offering advice about quitting, supplying self-help materials and locally developed resources, counselling smokers, setting a quit date and making follow-up appointments. MI is a collaborative, person-centred form of guidance and counselling that can be adopted by HPs to elicit and strengthen a client's motivation to change his/her behaviour (178). It is internationally recognised as one of the more effective, evidence-based intervention methods for supporting people to make and maintain positive changes in the management of their chronic conditions and associated lifestyle behaviours reducing the risk of developing further health co-morbidities (179). MI training differs significantly from other more general interviewing techniques, as it is designed not only to rely on a relational component shared by other interviewing approaches, but also on a unique technical component involving the differential evocation and reinforcement of client change (see *Figure 4*) (178).

Given the gaps identified in existing tobacco cessation and prevention studies (172), coupled with a lack of empirical evidence (180), a cluster randomised controlled trial, through an opportunistic vehicle, could be used to develop a sustainable and culturally-appropriate tobacco strategy for Indigenous health services and communities in Australia. By engaging with communities who want to participate, using their preferred health care workers as a vector, the program would be consistent with the National Aboriginal Community Controlled Health Organisation (NACCHO) 2013-30 healthy futures approach (181). If proven successful, this program can be easily implemented to provide a nationwide cost-effective means of improving Aboriginal and TSI health by facilitating greater access to community resources and quit services, whilst concurrently building community capacity.

In this regard a Translating Research In to Practice (TRIP) Fellowship application was submitted to the National Health and Medical Research Council (NHMRC) during 2014 to undertake just such a program. The title of the application was ‘Training health professionals in smoking cessation and tobacco abuse prevention for Aboriginal Australians’ and not only was it successful, but the application also received co-funding from Cancer Australia (see Appendices). As such, the information presented in this and preceding chapters provided the foundation upon which a randomised delayed-intervention controlled trial will be conducted in Australia.

The study design will include a multi-site cluster randomised delayed intervention (DI) controlled trial for Aboriginal and/or TSI health professionals across 6 South Australian community groups (four urban and two regional with geographical separation large enough to reduce the risk of potential contamination between groups) to either:

1. Training program for health professionals including two half-day skills workshops in a) motivational interviewing techniques for smoking cessation and tobacco prevention, b) a seminar about the latest cessation and tobacco prevention options, and c) guidance to optimise the use of culturally-tailored and community-driven (local) tobacco programs, plus a booster session and feedback at one month, OR
2. Delayed intervention control where communities have data collection at the same time as the intervention populations however the training intervention commences three months later.

The tobacco cessation training seminars for this NHMRC/Cancer Australia TRIP Fellowship will combine information produced from the investigations presented in this

thesis (67, 110, 111, 129, 131, 157, 158, 169, 172, 180), coupled with guidelines and recommendations within ‘Quitskills’ resources developed by Quit SA (a telephone smoking cessation service delivered by the Cancer Council of SA; ‘Quitskills’ provides support packages in brief intervention training for tackling Indigenous smoking) and through adopting local smoking cessation programs that have been culturally tailored for each community. The latter step is important to consider as due to the diversity in cultural characteristics and language across these communities, what may work well in one location will not necessarily be well received in another if the cultural features are not matched. For this reason adopting local initiatives will strengthen the intervention.

Finally, optimising delivery of community driven programs is a priority for this study to strengthen community capacity and build on existing research and initiatives that have already been funded, developed and accepted within each study site. Tobacco use in the Aboriginal and TSI setting is more complicated than simply addiction or habit, as highlighted in the qualitative investigations presented in Chapter 6. There are peer pressures, social and historical implications surrounding tobacco use, with some even viewing nicotine as a form of self-medicating to treat anxiety and depression (37, 182). Smoking cessation is also considered by most to be only one in a myriad of other health, social, lifestyle and environmental issues faced by Indigenous Australians. This training health professionals study has been designed to take these complexities into account, through collaboration with Aboriginal and TSI Elders throughout study development, extensive preliminary and pilot investigations and through incorporating existing community-driven health programs. Our intervention coupled with these broader healthy lifestyle programs (e.g. diabetes, alcoholism, depression, hypertension, heart disease etc.) will enhance quit smoking attempts by addressing the ‘syndrome’ of needs rather than merely isolating tobacco. This study intervention also endeavours to improve facilitation and dissemination of local health initiatives to the broader community of professionals, who may not be aware of the breadth of services and resources available to them (as discussed in Chapters 6 to 9).

Once complete it will be the first methodologically rigorous trial of its kind and if proven successful, it will provide a cost effective, sustainable model upon which standard practice can be structured.

The study hypotheses are that training HPs who work within Aboriginal communities in smoking cessation counselling techniques, when compared with the DI controls, will:

1. Increase the rate and duration (quality) of patient quit attempts as measured by self-reported continuous smoking abstinence and 7-day point prevalence, validated by saliva cotinine
2. Increase the number of HPs who **a)** counsel their patients about smoking **b)** ask their patient about setting a quit date **c)** offer a follow-up appointment **d)** provide self-help material **e)** refer their patients to local health services and **f)** offer smoking cessation medications, as measured by a self-reported pre/post comparison questionnaire, patient survey, qualitative interview data and examination of electronic and hard-copy patient case notes
3. Produce cost effective outcomes long-term (12 months) in hospital avoidance and reduced length of stay subsequent to reductions in morbidity and premature mortality as measured by electronic South Australian DRG data (five years pre-study and 12 months post) supplemented by review of health professional records, SA Department of Health Data and Medicare data sets
4. Produce sustainable skills that will benefit the community long-term (12 months) as measured by pre/post enrolment health professional and patient questionnaires, supplemented by qualitative interview data and review of medical records
5. Increase uptake of evidence translation for existing initiatives of other health and social priorities, as measured by a self-reported pre/post comparison questionnaire, patient survey, qualitative interview data and examination of electronic and hard-copy patient case notes

Each community group will receive a total of two, half day workshops (total eight hours contact time over one month), with each half day workshop incorporating all three components of the intervention (a-c) described above, to ensure greater dissemination of techniques in case of missed sessions. Cluster randomisation will occur by random number generator software with stratification to urban and regional locations. A statistician has calculated the sample size of 240 per study arm (n=480 in total), providing 80% power to detect a difference between the group proportions of 0.08 whilst also taking adjustments for clustering effects, drop-outs and participants lost to follow-up. With an estimated minimum of 20 HPs recruited per community group, each professional would only need to recruit and maintain contact with four patients each over the three month follow-up period, which is decidedly achievable and practical.

This smoking cessation and healthy lifestyle program can be easily implemented nationwide with little expense. Health professionals participating in this research will also gain new skills, knowledge and build confidence in their abilities to offer smoking cessation and prevention advice, motivational interviewing, as well as gain access to a broader range of culturally-tailored and community-driven resources that can be used in everyday practices. In addition, patients of the health professionals will benefit through increased and enhanced opportunities to quit smoking, with improved access to support services, resources and other smoking cessation and prevention aids such as counselling, pharmacotherapy and pamphlets. Furthermore, the majority of resources that will be used in this program have already been developed with extensive community consultation and participation, with the purpose of this proposal to simply facilitate greater dissemination of these resources to community members, with health professionals as the vector.

In 2010 the South Australian Department of Health State-wide Service Strategy Division stressed the need to support the jobs and health of Aboriginal Health Workers. Building capacity through offering a low-intensity but high-impact training in the latest smoking cessation strategies will contribute toward capacity building, by offering long-term and sustainable skills that can be utilised throughout the health professional's career. This training will benefit the health professionals (the majority of which are likely to be of either Aboriginal and/or TSI heritage) by 1) enhanced skills, knowledge and confidence for the delivery of smoking cessation strategies, 2) development of general motivational interviewing techniques that can be applied to other scenarios and 3) additional skills to include in Curriculum Vitae's. For non-Indigenous health professionals, they will learn cultural sensitivity and awareness, which was reported in Chapters 6 to 9 as currently lacking in existing health practices. Finally, if proven successful the results from this research will be used to make a case to the Australian Government for wide-spread National implementation of this program that will require funding for additional health professionals who will need to be trained (up-skilling) in motivational interviewing techniques with knowledge around tobacco use and smoking cessation.

16.3.2 Utilising social media and role models for tobacco prevention amongst youth:

The lack of methodologically rigorous evaluations for existing government funded tobacco prevention initiatives amongst youth revealed in the Cochrane review (Chapter 5) is of great concern, particularly considering that we identified a potential for harm (110). More participants reported smoking following the tobacco prevention program in the

intervention group of one study, in comparison to the control group who received no tobacco prevention program at all. The policy document commissioned by the Australia and New Zealand School of Government identified nine studies as being conducted among youth, five of which showed no evidence of any effect and a sixth that favoured the control group over that of the intervention. By continuing to invest funding and other resources into these ineffective programs an opportunity cost for potentially effective initiatives ensues.

In addition, my previous Cochrane reviews evaluating the effects of mass media interventions for preventing smoking in young people (183) (update also in press) and community interventions for preventing smoking in young people (184), have both identified a lack of social media as a means to engage youth. Both reviews also found significant results in favour of the intervention, suggesting that these types of programs can be effective. This is of particular relevance considering a 2012 report which found that on average children aged 8 to 18 years will spend seven and a half hours every day using media for fun, including watching television and using social networking sites (185). This supports the findings from an earlier 2010 study which identified that the average time spent with screen media among 8 to 18 year olds is more than twice the average amount of time spent in school each year (186). With this in mind, it would be worth considering a randomised controlled trial of a novel web and app-based interactive healthy lifestyle program for youth, with a particular focus on Aboriginal and TSI populations.

With this in mind, an expression of interest funding application has been submitted to the Channel 7 Children's Research Foundation to fund just such a program. Funding from this grant will be used to create and evaluate an interactive web-based intervention aimed at reducing tobacco use and improving knowledge, behaviours and attitudes around other healthy lifestyle initiatives and career development. Already we have secured the support of several high profile partners including Credit Union SA (who will help to facilitate uptake of the program within school curriculum), St John Ambulance (who will provide tutorials for basic first aid skills training), Bravehearts (founder Hetty Johnson (QLD Australian of the Year) will provide content on how to recognise abuse, what to do and who to contact when this happens), ABC television will film the intervention as it is being developed to do a BTN (Behind The News) story and SDF Illuminate (run by TAS Young Australian of the Year will integrate our curriculum to existing school curriculum across Australia for ease of amalgamation later) amongst several others.

Several high-profile role models have also agreed to take part in the intervention by doing video chats with students and agreeing to be filmed talking about the healthy lifestyle issues as well as motivational speeches. These include Adam Goodes (2014 Australian of the Year), Jessica Mauboy (singer who has Indigenous Australian heritage), Patty Mills (NBA basketballer and Indigenous Australian), all eight of the Young Australian of the Year winners from 2015 and several players from the Port Adelaide Football club amongst several others. In addition, three educational games will be developed through Holopoint Interactive Pty Ltd by technical director Richard Taylor. These will be in the style of Fruit Ninja, Candy Crush and the traditional card game 'snap' but instead of slicing the fruit kids will need to slice the cigarettes and avoid the smoke. For the candy crush simulation, kids will crush the junk food and collect the fruits and vegetables. In the snap simulation, Professor Ghil'ad Zuckermann who is the Chair of Linguistics and Endangered Languages for the University of Adelaide will help to create a game using traditional Aboriginal and Torres Strait Islander words (that fit with the healthy lifestyle theme) to match them to the English words. These games will also be available as apps on iphones, androids and ipads. In addition, hard copy resources will be produced to supplement the web-based intervention. These hard copy resources will also use a new and exciting technology called augmented reality, which can be seen here <http://tinyurl.com/OBH-InteractivePrint>. This technology will animate still images using iphones, ipads and androids for no cost to the viewer (app is free to download and content free to view). Showcases of this technology have already sparked a large amount of interest and the application is likely to engage youth in the resources to improve uptake of the intervention.

Until methodologically rigorous evaluations occur alongside Indigenous tobacco prevention interventions amongst youth, we cannot identify ineffective programs so that resources can be redirected into the initiatives most likely to prevent youth from taking up smoking.

Chapter 17. Conclusions

The meta-analyses and qualitative research identified that Indigenous populations are willing to attempt smoking cessation, and some limited evidence was produced to support culturally-tailored smoking cessation interventions for Indigenous peoples. Barriers to smoking cessation programs amongst Aboriginal and TSI populations include: compliance, availability and sharing of medications, fear of adverse events and reservations held by health professionals about the ability of pharmacological interventions to be successful in this setting. Consideration should also be given to tailored interventions to disadvantaged populations as a whole, rather than focusing specifically on the Indigenous. Several facilitators were also identified including, when appropriate, to offer cessation medications to individuals already motivated to quit (such as following an acute tobacco-related illness episode), and to utilise medical clinics and health services, which are good venues for delivery of smoking cessation messages. Multi-faceted approaches are needed with extensive community input, engagement and ownership of any interventions, and prevention is always better than cure, therefore a focus on youth needs to be a priority.

A paucity of methodologically rigorous evidence for tobacco cessation and prevention programs amongst adults and youth limits the ability to draw reliable conclusions. Therefore, evaluations alongside existing programs are needed to build this evidence base, to ensure that the interventions being implemented are effective and not causing more harm, as was the case in one of the studies included in the youth tobacco prevention meta-analysis. Following these evaluations, funding can then be re-directed into the programs most likely to be effective in aiding smoking cessation and reducing tobacco uptake and use.

The randomised controlled trial of varenicline tartrate plus Quitline counselling has provided evidence supporting the efficacy and safety of this smoking cessation strategy in the inpatient acute-illness setting. Counselling-alone, which consisted of a brief phone call to initiate the Quitline call-back program at the patient's bedside, was also shown to be superior to the current *ad hoc* standard practices within the three recruitment hospitals.

To conclude, there is a substantial amount of community-developed interventions already heavily resourced by the COAG and other funding bodies. Qualitative and quantitative research is needed that aims to determine if methods that have been proved to be helpful

for non-Aboriginal Australians will work for Aboriginal people. If they do then the next step is to translate this work onto the front-line of clinical practice and for policy initiatives, where it can produce the most benefit to the everyday lives of smokers. All of these steps must be undertaken if we want to ‘close the gap’ in Indigenous disadvantage.

Existing community-interventions should be combined as a package that includes best-practice pharmacotherapy such as varenicline tartrate and culturally-tailored counselling and resources, which are then evaluated in the Indigenous context. A multi-faceted approach engaging with the community, health professionals, Elders/role models, sporting groups and schools should be undertaken. Training health professionals in skills and knowledge about the latest evidence to enhance smoking cessation and tobacco prevention interventions, is one method identified that may provide a sustainable approach to reducing the gap whilst simultaneously aiding capacity building. It is really important to note that tobacco use should not be addressed in isolation from other related issues including nutrition, alcohol, physical activity, depression, housing, education, violence and employment amongst others as these issues are often related. Only through addressing healthy lifestyle, social and environmental issues for disadvantaged populations as a whole can we address the ultimate goal of closing the health and life-expectancy gap between Indigenous and non-Indigenous Australians.

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Appendices

- Appendix 1 Cochrane Indigenous tobacco cessation protocol (Publication)
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Interventions for smoking cessation in Indigenous populations (Protocol)

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This is a reprint of a Cochrane protocol, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2011, Issue 3

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Interventions for smoking cessation in Indigenous populations (Protocol)
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[Intervention Protocol]

Interventions for smoking cessation in Indigenous populations

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To evaluate the effectiveness of smoking cessation interventions in Indigenous populations and to summarise these approaches for future cessation programmes and research.

BACKGROUND

Indigenous populations bear a disproportionate burden of substance-related morbidity and mortality in comparison to non-Indigenous populations throughout the world. The prevalence of tobacco use amongst the Indigenous populace is often, in fact, double that of the relevant non-Indigenous population, with estimates of 51-59% in Canada (Health Canada 2003; CEITC 2005), 51% in Australia (ABS 2006; CEITC 2005), 51% in New Zealand (Borman 1999; CEITC 2005) and 44% in the United States for Alaskan natives (First Nations Center 2005; Alaska Department of Health 2006). One report from Canada suggests that 62% of first nations and Inuit people are smokers, with the greatest smoking prevalence of 74% within their young adults aged 20 to 24 years (CEITC 2005). Similarly, approximately two million American Indians and Alaskan natives live in the United States and combined they have the highest prevalence of tobacco use, (32%) among ethnic minorities. Another evaluation of Māori, indigenous to New Zealand, suggested that tobacco kills nearly 600 Māori prematurely every year (Reid 1991), with the average life expectancy of 69 years in males compared to 73 years for a non-Māori and 74 years compared to 77 years for Māori and non-Māori women respectively (Laugesen 1998).

Due to cultural and geographic diversity, tobacco use often varies widely between sub-populations and regions. An increased smoking prevalence can be attributed to a comparatively low socio-economic status (SES) in Indigenous communities, and the 'normalisation' of tobacco use. Within the Australian Indigenous, high levels of community acceptance for smoking has been identified as a barrier in cessation initiatives for hospital patients (Harvey 2002) and school students (Lowe 2004), since smoking appears to play a key role in social interaction and relationship building (Briggs 2003). Furthermore, substandard, overcrowded living conditions increases tobacco exposure in young people and non-smokers (ABS 2006; DHA 2006). Tobacco cessation interventions which appear effective in one population will not necessarily work in another. Many Indigenous tribes in America consider tobacco as a sacred gift and use it during religious ceremonies and as traditional medicine. As a result of this high smoking prevalence, the leading cause of death in these communities is cardiovascular disease (MMWR 2007).

Specific definitions for 'Indigenous' vary between regions and populations. These terms remain highly contested and are not always accepted or used (Nettelton 2007). Such examples include 'Australian Aboriginal' or 'Torres Strait Islanders' for the Australian Indigenous, 'First Nations' is sometimes used to describe the Indian, Metis, and Inuit populations indigenous to the United States of America and Canada. 'Native Hawaiians' is used for Hawaii's Indigenous and 'Tangata Whenua' or 'People of the land' for the Maroi of New Zealand (Cunningham 2003). In an attempt to create consistency, though cognisant of the preferential syntax for populations, the term 'Indigenous' has been chosen to encompass participants within this review as it reflects "the experiences shared

by a group of people who have inhabited a country for thousands of years, which often contrast with those of other groups residing in the same country for a few hundred years" (Cunningham 2003). No offence is meant to any group whose preferred descriptor is not used.

Despite the fact that there is a high prevalence of tobacco smoking in Indigenous populations compared to non-Indigenous populations, most research in smoking intervention has occurred in the latter (Lancaster 2005a; Lancaster 2005b; Rigotti 2007; Rice 2008; Stead 2008; Civljak 2009). In view of this gap, systematic consolidation of interventions and sub-components for these in this high-risk populace is warranted, to identify features of any effective programs for Indigenous populations (US Dept Health and Human Services 1998).

OBJECTIVES

To evaluate the effectiveness of smoking cessation interventions in Indigenous populations and to summarise these approaches for future cessation programmes and research.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCT) or quasi-randomised controlled trials (CCT).

Types of participants

Participants will be young people and adults of any age, of either gender, who are indigenous to their country and are current smokers participating in a smoking cessation study. Trial participants are not required to be selected according to their susceptibility to quitting or suitability for particular interventions. Studies aimed at pregnant women will also be included even though this area may be considered highly specialised, as some of the issues may be common to Indigenous people generally.

No attempts will be made to re-define Indigenous status for the purpose of including a study in this review. If meaningful data is found which refers to an Indigenous subpopulation in a larger study, it will be considered for inclusion in this review.

Types of interventions

We will include interventions in five categories:

1. Pharmacotherapies (including nicotine replacement therapies, bupropion and varenicline tartrate)
2. Cognitive and behavioural therapies (including CBT, counselling, support groups, self-help, seminars, motivational lectures)
3. Alternative therapies (including acupuncture, hypnotherapy, aversion therapy)
4. Public policy (including legislative interventions, media campaigns, community interventions)
5. Combination therapy (including a combination of at least two therapies from the above four categories)

We will not exclude trials with high levels of attrition, however this will be documented within the risk of bias tables and discussed. Controls must be usual practice, no intervention, placebo, co-interventions or reduced intervention. Control participants receiving reduced interventions may be offered brief advice on quitting, but support must be of a lower intensity than that given to the intervention participants.

Types of outcome measures

Primary outcomes

The primary outcome will be smoking cessation as defined by continuous abstinence and/or the relevant 'point prevalence' as described by the authors for the longest follow-up point reported in the study (minimum of six months). The strictest definition of sustained abstinence will be used (e.g. if results are presented as 'no smoking' or 'smoking \leq 5 cigarettes' throughout the study period, the data for the 'no smoking' population will be used). Where possible these will be biochemically validated. Trials reporting less than six-month follow up will be excluded.

Secondary outcomes

Secondary outcomes that will be extracted if reported will include:

1. Adverse effects of interventions (through relevant reporting scales or narrative synthesis)
2. Mortality
3. Costs of interventions
4. Change in quality of life (e.g. St George Respiratory Questionnaire, SF-36 (Short Form-36), PsyQol (Psychological Quality of Life) or any other generic quality of life tool)
5. Change in pulmonary function (e.g. FEV¹, FVC etc)
6. Change in attitudes (e.g. readiness to quit)
7. Change in knowledge (e.g. health effects of tobacco)
8. Change in exercise tolerance (e.g. six-minute walking distance (6MWD))

Search methods for identification of studies

Electronic searches

We will identify potential studies from the Tobacco Addiction Group's specialised register. This is generated by regular searches of The Cochrane Library, EMBASE, MEDLINE, PsycINFO and Science Citation Index for trials of smoking cessation and prevention interventions. No language restrictions will be applied. The following free text search terms will be used to identify records relevant to the topic:

'aborig*' OR 'Indig*' OR 'inuit' OR 'maori' OR 'native american' OR 'american indian' OR 'tribe*' OR 'tribal'

Online clinical trial registers will be searched for ongoing and recently completed studies including Controlled Clinical Trials (www.controlled-trials.com), the National Research Register (www.nrr.nhs.uk), government registries (clinicaltrials.gov), and WHO registries (www.who.int/trialsearch/).

For these searches the topic related terms will be combined with the term 'smoking cessation'.

Searching other resources

We will review reference lists of all included studies and of reviews to identify potentially relevant citations. In addition, we will make enquiries regarding other published or unpublished studies known to the authors of the included studies.

Data collection and analysis

Selection of studies

From the title, abstract, or descriptors, KC will independently review the literature searches to identify potentially relevant trials. All studies that clearly do not meet the inclusion criteria in terms of study design, population or interventions, will be excluded. KC will extract the data, which will be checked by another reviewer MB. Both KC and MB will independently extract data for risk of bias for all included studies.

Data extraction and management

KC will extract data from the trials using a standardised data extraction form prior to entry into The Cochrane Collaboration software program Review Manager 5.0. KC will also correspond with authors to obtain any missing or raw data as required. Risk of bias for each included study will be extracted by two independent authors (KC and MB).

The following information will be extracted:

Methods: country/setting of trial; design; objectives; study site; methods of analysis,

Participants: age; gender; ethnicity; socio-economic status; n-values for eligibility, recruitment and completion; recruitment means, Interventions: descriptions of interventions and controls; duration; intervention delivery; type/dose/duration of pharmacotherapy or behavioural support and control group components.

Outcomes: method of outcome collection; pre-specified outcome data; validation; follow-up period; other follow ups and definitions of abstinence; outcome data as defined under 'Types of outcome measures' in this protocol.

Risk of bias: methods of sequence generation; allocation concealment; blinding; incomplete outcome data; selective outcome reporting and other potential threats to validity.

Assessment of risk of bias in included studies

Risk of bias (ROB) will be evaluated by two independent reviewers, KC and MB, in line with recommendations made in the Cochrane Handbook of Systematic Review of Interventions (Higgins 2009). Evaluation will be on the basis of allocation sequence, allocation concealment, blinding for participants and outcome assessors, incomplete outcome data, selective outcome reporting and other potential threats to validity. ROB for each domain will be assessed as 'Yes' (low risk of bias), 'No' (high risk of bias), or 'Unclear' (uncertain risk of bias), as per the guidelines from table 8.5.c of the Cochrane Handbook (Higgins 2009). Conflicts in the assessments will be resolved either by consensus or by referring to a third party of either BS or AV.

Measures of treatment effect

If possible, a risk ratio (RR) will be provided for the primary outcome of each trial. These will be defined as (number of subjects that stopped smoking in the intervention group/ total number randomised to the intervention group) / (number of subjects that stopped smoking in the control group/ total number randomised to the control group). The RR will be greater than 1 if more subjects ceased smoking in the intervention group in comparison to the control group. An estimated pooled weight average for RRs will be calculated using the Mantel-Hetzel fixed-effect model, with 95% confidence intervals. We aim to conduct an intention-to-treat analysis. For secondary outcomes the differences in change scores will be analysed.

Unit of analysis issues

For cluster controlled trials, the analysis will be performed at the level of individual whilst accounting for the clustering in the data. Studies that did not include adjustments for clustering, the size of the trial will be reduced to the effective sample size (Rao 1992) using the original sample size from each study, divided by a design effect of 1.2 which is consistent with other smoking cessation intervention trials (Gail 1992) and as per recommendations in the Cochrane Handbook, section 16.3.4 (Higgins 2009). Trials may

use a variety of statistical methods to investigate or compensate for clustering; we will record whether studies used these and whether the significance of any effect was altered. In the case of multi-arm trials we will include each pair-wise comparison separately, but with shared intervention groups divided out approximately evenly among the comparators. However, if the intervention groups are deemed similar enough to be pooled, the groups will be combined using appropriate formulas in the Cochrane Handbook (table 7.7.a for continuous data and chapter 16.5.4 for dichotomous data) (Higgins 2009).

Dealing with missing data

Missing information regarding participants will be evaluated on an available case analysis basis as described in chapter 16.2.2 of the Cochrane Handbook (Higgins 2009). Missing standard deviations will be addressed by imputing data from the studies within the same meta-analysis or from a different meta-analysis as long as these use the same measurement scale, have the same degree of measurement error and the same time periods, (between baseline and final value measurement), as per chapter 16.1.3.2 of the Cochrane Handbook (Higgins 2009). Where statistics essential for analysis are missing (e.g. group means and standard deviations for both groups are not reported) and cannot be calculated from other data, we will attempt to contact the authors to obtain data. Loss of participants that occur prior to performance of baseline measurements will be assumed to have no effect on the eventual outcome data of the study. Any losses after the baseline measurement are taken will be assessed and discussed. Subjects lost to follow up will be assumed to be smoking and will be included in the denominators for calculating the relative risk, as per standard Tobacco Addiction Group methods.

Assessment of reporting biases

Providing there are more than ten included studies, potential reporting biases will be assessed using a funnel plot. Asymmetry in the plot could be attributed to publication bias, but may well be due to true heterogeneity, poor methodological design or artefact. In case of asymmetry, we may include contour lines corresponding to perceived milestones of statistical significance ($p=0.01$, 0.05 , 0.1 etc.) to funnel plots, which may help to differentiate between asymmetry due to publication bias from that due to other factors (Higgins 2009). In instances of fewer than ten studies, the reporting biases will be extrapolated within the 'other bias' section in the risk of bias tables.

Subgroup analysis and investigation of heterogeneity

We will attempt to categorise trials according to the subgroups listed in Types of interventions above. Consideration will be given to pooling trials within these subgroups, but we will not attempt to pool trials of different pharmacotherapies, or trials of different intensities of behavioural interventions, or different types of

population based interventions. There may be further heterogeneity contributed by factors such as baseline smoking status, participant and community characteristics (e.g. age, physical state, cultural and educational differences), time of measurement of results and varying measurement tools used to assess outcomes. The chi square and I^2 statistic (Higgins 2009) will be used to quantify inconsistency across studies. In groups of trials where meta-analysis is judged potentially appropriate, extracted data will be pooled using the fixed-effect model. In the presence of significant heterogeneity (as defined by: $I^2 > 60\%$, visual inspection of study data and consideration of study design and methodology), the use of a random-effects model will be considered. However, this will be performed with caution taking into account the possible influence of smaller studies which could over or under estimate the true treatment effect. If meta-analysis is not judged appropriate we will use a narrative synthesis, treating the studies individually with consideration of their confidence intervals or reporting the results restricted to the larger, more rigorous studies as suggested in section 10.4.4.1 of the Cochrane Handbook (Higgins 2009). These data will all be analysed using Review Manager 5.0. Ideally we will aim to conduct subgroup analyses for each population (e.g. Australian Aborigines, Alaskan native etc.). Also within each population, smoking prevalence may vary widely between dispersed community groups, further adding to potential heterogeneity of results. As each Indigenous population is unique and each has specific characteristics (such as remoteness) that could in-

fluence the effectiveness of smoking cessation interventions, subgroup analysis would give the most relevant results for a particular population. However, it is not anticipated that sufficient studies will exist for all (or even any) populations to be analysed as subgroups.

Subgroup analysis of remote versus urban dwelling and isolated versus integrated populations will also be considered if possible.

Providing sufficient studies exist we will also perform a subgroup analysis for cessation initiatives in young people (aged <25 years) and pregnant women.

In studies of long duration, results may be presented for several periods of follow up including short-term (≤ 26 weeks), medium-term (27 to 52 weeks) and long-term (≥ 53 weeks). Data permitting, extended follow up will also be collated for studies presenting data over two years.

Sensitivity analysis

Sensitivity analysis will be conducted on studies with a high risk of bias for sequence generation and/or allocation concealment and studies with participants with significant co-morbidities.

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* Indicates the major publication for the study

HISTORY

Protocol first published: Issue 3, 2011

CONTRIBUTIONS OF AUTHORS

Protocol conceived and prepared by Kristin V Carson, reviewed by Brian J Smith and Adrian J Esterman.

DECLARATIONS OF INTEREST

No conflicts of interest to report.

SOURCES OF SUPPORT

Internal sources

- No sources of support provided, Australia.

External sources

- No sources of support supplied

Interventions for tobacco use prevention in Indigenous youth (Protocol)

Carson KV, Labiszewski NA, Brinn MP, Peters M, Chang AB, Veale A, Esterman AJ, Smith BJ



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Interventions for tobacco use prevention in Indigenous youth (Protocol)
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[Intervention Protocol]

Interventions for tobacco use prevention in Indigenous youth

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To evaluate the effectiveness of intervention programs to prevent tobacco use initiation or progression to regular smoking amongst young Indigenous populations and to summarise these approaches for future prevention programmes and research.

BACKGROUND

Throughout the world, Indigenous populations bear a disproportionate burden of substance-related morbidity and mortality when compared to non-Indigenous populations. Prevalence for tobacco use amongst the Indigenous populace is often double that of the relevant non-Indigenous population, with estimates of 51-59% in Canada (Health Canada 2003; CEITC 2005), 47-53% in Australia (CEITC 2005; ABS 2009), 45.4% in New Zealand (Ministry of Health 2009) and 44% in the United States for Alaskan natives (First Nations Center 2005; Alaska Department of Health 2006). Addiction to nicotine usually begins during early adolescence, with only 10% of new smokers initiating the habit after the age of 18 years (US Dept Health and Human Services 1998). For Indigenous youth there is an added social context, which one Australian report suggests has resulted in almost half of Indigenous youth aged 14 years and older reporting smoking on a daily basis, compared to approximately 20% in non-Indigenous Australians (AIWH 2002). In a similar perspective, a Canadian survey of Indigenous youth reports smoking initiation peaking at 13 years of age (First Nations Center 2005). An evaluation of British Columbian youth estimates the prevalence of smoking in their Indigenous population to be 41% for youth aged 12 to 18 years and 61% for youth aged 19 to 24 years, whilst non-Indigenous youth have prevalence estimates of 18% and 31% respectively (Reading 1999). A more recent evaluation, the First Nations regional longitudinal health survey in 2002/03, found 37.8% of youth reporting current smoking, which is double that of the relevant non-Indigenous population (Reading 2009). As such, a disproportionate burden of disease has been attributed to the 'normalisation' of tobacco use and the key role that it appears to play in social interactions and relationship building amongst Indigenous youth. The primary social influences resulting in youth initiation of smoking are relevant for all youth, Indigenous and non-Indigenous alike, and include peer group pressure, positive attitudes toward smoking and the observation of adult smoking. For Indigenous youth this is amplified by the increase in adult smoking prevalence and the normalisation of tobacco use as part of the usual Indigenous landscape (Lindorff 2002; Scollo 2008; Leavy 2010). Furthermore, reports suggest that substandard and overcrowding living conditions increase tobacco exposure in young people in indigenous Australian communities (Johnston 1997; Eades 1999; Ivers 2001; Penman 2006; Johnston 2008). A recent Australian survey of tobacco exposure in Aboriginal and Torres Strait Islander households reports that 21% of children aged 0 to 14 years were exposed to indoor tobacco smoke in 2008, which is a decrease from reports of 29% in 2004 to 2005 (ABS 2011). For these reasons systematic consolidation of current prevention strategies in Indigenous youth are required to identify features of effective programs, which can be translated into policy to guide future prevention initiatives.

Specific definitions for 'Indigenous' vary between regions and populations. These terms remain highly contested and are not always accepted or used (Nettelton 2007). Such examples include 'Aus-

tralian Aboriginal' or 'Torres Strait Islanders' for the Australian Indigenous, 'First Nations' are sometimes used to describe the Indian populations indigenous to Canada. 'Native Hawaiians' are used for Hawaii's Indigenous and 'Tangata Whenua' or 'People of the land' for the Maroi of New Zealand (Cunningham 2003). In an attempt to create consistency, though cognisant of the preferential syntax for populations, the term 'Indigenous' has been chosen to encompass participants within this review as it reflects "the experiences shared by a group of people who have inhabited a country for thousands of years, which often contrast with those of other groups of people who reside in the same country for a few hundred years" (Cunningham 2003). No offence is meant to any group for whom their preferred descriptor is not used.

OBJECTIVES

To evaluate the effectiveness of intervention programs to prevent tobacco use initiation or progression to regular smoking amongst young Indigenous populations and to summarise these approaches for future prevention programmes and research.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCT) or quasi-randomised controlled trials (CCT).

Types of participants

Young people aged 25 years or less, of either gender, who are members of indigenous populations, using 'indigenous' in the sense described above, and are participating in a study to prevent tobacco use initiation. Interventions may target groups of individuals (e.g. school classes), some of whom have already used tobacco. We will distinguish between studies that report outcomes only for participants with no experience of tobacco use at baseline and those which include participants who have already smoked at baseline. Trial participants are not required to be selected according to their susceptibility or suitability for particular interventions. No attempts will be made to re-define Indigenous status for the purpose of including a study in this review. If meaningful data is found which refers to an Indigenous subpopulation in a larger study, it will be considered for inclusion in this review.

Types of interventions

We will include interventions to prevent tobacco use initiation or progression from experimentation to regular tobacco use. Interventions will be grouped by type and setting based on the following categories:

- 1) School only (including class lessons etc.), e.g. school-based curriculum delivered by classroom teachers.
- 2) Mass media (including television, radio, billboards, posters etc.), e.g. community- or nation-wide media campaign directed at adolescents through highlighting the health effects of tobacco use.
- 3) Multi-component (i.e. more than one) community based intervention targeting large areas (including school, specialised community groups, health care professionals, mass media etc.), e.g. combined tobacco use prevention campaigns involving peer role models, school curriculums, anti-smoking messages at local sporting or community events, combined into one intervention.
- 4) Family-based programs, e.g. anti-smoking messages involving parent and child communication and activities including games, workbooks, discussions or written information.
- 5) Public policy (including legislative interventions, retailer restrictions etc.), e.g. policy for smoking ban in public places or where children are present, which is enforced by the community.

We will not exclude trials with high levels of attrition, however this will be documented within the Risk of Bias tables and discussed. Controls can be usual practice, no intervention, co-interventions or reduced intervention. Control participants receiving reduced interventions may be offered brief tobacco use prevention advice, but support must be of a lower intensity than that given to the intervention participants.

Types of outcome measures

Primary outcomes

The primary outcome will be tobacco use status as defined by self-reported tobacco use behaviour or objectively through biochemical validation (e.g. saliva thiocyanate levels, alveolar carbon monoxide), at the longest follow-up point reported in the study (minimum of six months).

We will record the definition of smoking or tobacco use used by each study. This may be reported as any smoking/tobacco use since interventions, or as use within a particular period.

We will consider the sustainability of change (whether the effect at longest follow up is larger or smaller than at earlier follow ups) in tobacco use behaviour after the intervention (less than versus longer than one year).

Studies reporting tobacco use prevention data which exclude baseline tobacco users will be reported separately from those including baseline smokers within the reported cohort. If outcomes are reported separately for different categories of baseline users we will extract data for all outcomes. Trials reporting less than six-month follow up will be excluded.

Secondary outcomes

Secondary outcomes that will be extracted if reported will include:

- 1) whether the intervention has had an effect on intentions to use tobacco, attitudes to tobacco use, knowledge about tobacco use, decision making, refusal skills, self-efficacy and tobacco use perception/norms;
- 2) levels of implementation for process measures (e.g. measuring the amount of exposure to the intervention that the participants actually received, including details of implementation) as given in each included study, for example: cigarette purchases by minors, membership of anti-smoking clubs for young people, media reach and level of exposure to each component of an intervention;
- 3) costs of interventions.

Search methods for identification of studies

Electronic searches

We will identify potential studies from the Tobacco Addiction specialised Register. This is generated by regular searches of The Cochrane Library, EMBASE, MEDLINE, PsycINFO and Science Citation Index for trials of tobacco use prevention interventions. No language restrictions will be applied. The following free text search terms will be used to identify records relevant to the topic: 'aborig*' OR 'Indig*' OR 'inuit' OR 'maori' OR 'native american' OR 'american indian' OR 'tribe*' OR 'tribal', AND 'young people' OR 'teen*' OR 'adolesce*' OR 'juveniles' OR 'child*' OR 'boy*' OR 'girl*',

Since the Specialised Register is limited to studies of smoking and other tobacco used behaviour no smoking related terms will be used.

In addition we will search MEDLINE using the search strategy used for the specialised register which combines terms for smoking and terms for identify controlled trials, combined with MeSH terms for indigenous populations, and age related limits.

Online clinical trial registers will be searched for ongoing and recently completed studies including, Controlled Clinical Trials (www.controlled-trials.com), the National Research Register (www.nrr.nhs.uk), government registries (clinicaltrials.gov), and WHO registries (www.who.int/trialsearch/).

Searching other resources

We will review reference lists of all included studies and of reviews to identify potentially relevant citations. In addition, we will make enquiries regarding other published or unpublished studies known to the authors of the included studies.

Data collection and analysis

Selection of studies

From the title, abstract, or descriptors, KC will independently review the literature searches to identify potentially relevant trials. All studies that clearly do not meet the inclusion criteria in terms of study design, population or interventions, will be excluded. KC will extract the data, which will be checked by a second reviewer (either NL or MB). Both KC and either NL or MB will independently extract data for risk of bias for all included studies.

Data extraction and management

KC will extract data for the trials using a standardised data extraction form prior to entry into The Cochrane Collaboration software program, Review Manager 5.1.0. KC will also correspond with authors to obtain any missing or raw data as required. Risk of bias for each included study will be extracted by two independent authors (KC and either NL or MB).

The following information will be extracted:

Methods: country/setting of trial; design; objectives; study site; methods of participant recruitment; methods of analysis

Participants: age; gender; ethnicity; socio-economic status; n-values for eligibility, recruitment and completion

Interventions: descriptions of interventions and controls; duration; intervention delivery; type/duration of behavioural support and control group components

Outcomes: method of outcome collection; pre-specified outcome data; validation; follow-up period; other follow ups and definitions of abstinence; outcome data as defined under 'Types of outcome measures' in this protocol.

Risk of bias: methods of sequence generation; allocation concealment; blinding; incomplete outcome data; selective outcome reporting; imbalance of outcome measures at baseline, comparability of intervention and control group characteristics at baseline, protection against contamination, selective recruitment of participants and other potential threats to validity.

Assessment of risk of bias in included studies

Risk of bias (ROB) will be evaluated by two independent reviewers, KC and either NL or MB, in line with recommendations made in the Cochrane Handbook of Systematic Review of Interventions (Higgins 2009) and additional criteria developed by the Cochrane EPOC Group (EPOC 2009). This will be on the basis of allocation sequence, allocation concealment, blinding for participants and outcome assessors, incomplete outcome data, selective outcome reporting and other potential threats to validity. The three additional domains recommended by the Cochrane EPOC group assess design-specific threats to validity including: imbalance of outcome measures at baseline; comparability of intervention and control group characteristics at baseline; and protection against contamination (EPOC 2009). Finally, for cluster study designs, we assessed the risk of bias associated with an additional domain; selective recruitment of participants. ROB for each domain will

be assessed as 'Low risk of bias', 'High risk of bias', or 'Unclear risk of bias', as per the guidelines from table 8.5.c of the Cochrane Handbook (Higgins 2009). Conflicts in the assessments will be resolved either by consensus or by referring to a third party of either BS or AV.

Measures of treatment effect

If possible, a risk ratio (RR) will be provided for the primary outcome of each trial. The RR will be defined as (number of subjects using tobacco in the intervention group/ total number randomised to the intervention group) / (number of subjects using tobacco in the control group/ total number randomised to the control group). The RR will be less than 1 if the intervention is effective, and more subjects remain non-smokers in the intervention group than in the control group. An estimated pooled weight average for RRs will be calculated using the Mantel-Hetzel fixed-effect model, with 95% confidence intervals, providing a low level of heterogeneity (see [Subgroup analysis and investigation of heterogeneity](#)). Where data are presented as a combination of continuous and dichotomous data for the same outcome, we will combine them using the generic inverse variance (GIV) approach as per section 9.4.6 of the Cochrane Handbook (Higgins 2009). We expect secondary outcomes to be presented in different formats, as such we will present data as either dichotomous, continuous or combine the two if data are presented in different ways for the same outcome, using GIV. We aim to conduct an intention-to-treat analysis, including participants enrolled at baseline whether or not they receive the intended intervention.

Unit of analysis issues

For cluster controlled trials, the analysis will be performed at the level of individual whilst accounting for the clustering in the data. For studies that did not include adjustments for clustering the size of the trial will be reduced to the effective sample size (Rao 1992) using the original sample size from each study, divided by a design effect of 1.2 which is consistent with other tobacco use intervention trials (Gail 1992) and as per recommendations in the Cochrane Handbook, section 16.3.4 (Higgins 2009). Trials may use a variety of statistical methods to investigate or compensate for clustering; we will record whether studies used these and whether the significance of any effect was altered. In the case of multi-arm trials we will include each pair-wise comparison separately, but with shared intervention groups divided out approximately evenly among the comparators. However, if the intervention groups are deemed similar enough to be pooled, the groups will be combined using appropriate formulas in the Cochrane Handbook (table 7.7.a for continuous data and chapter 16.5.4 for dichotomous data) (Higgins 2009).

Dealing with missing data

Missing information regarding participants will be evaluated on an available case analysis basis as described in chapter 16.2.2 of the Cochrane Handbook (Higgins 2009). Where statistics essential for analysis are missing (e.g. group means and standard deviations for both groups are not reported) and can not be calculated from other data, we will attempt to contact the authors to obtain data. Loss of participants that occur prior to performance of baseline measurements will be assumed to have no effect on the eventual outcome data of the study. Any losses after the baseline measurement are taken will be assessed and discussed. We will consider both differential losses between intervention and control conditions, and differential losses within conditions according to baseline characteristics,

Assessment of reporting biases

Providing the inclusion of greater than ten included studies, potential reporting biases will be assessed using a funnel plot. Asymmetry in the plot could be attributed to publication bias, but may well be due to true heterogeneity, poor methodological design or artefact. In case of asymmetry, we may include contour lines corresponding to perceived milestones of statistical significance ($p=0.01, 0.05, 0.1$ etc.) in funnel plots, which may help to differentiate between asymmetry due to publication bias from that due to other factors (Higgins 2009). In instances of fewer than ten studies, the reporting biases will be extrapolated within the 'other bias' section in the risk of bias tables.

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the studies individually with consideration of their confidence intervals or reporting the results restricted to the larger, more rigorous studies as suggested in section 10.4.4.1 of the Cochrane Handbook (Higgins 2009). These data will all be analysed using Review Manager 5.1.0.

Ideally we will aim to conduct subgroup analyses for each population (e.g. Australian Aborigines, Alaskan native etc.). Also within each population, tobacco use prevalence may vary widely between dispersed community groups, further adding to potential heterogeneity of results. As each Indigenous population is unique and each has specific characteristics (such as remoteness) that could influence the effectiveness of tobacco use cessation interventions, subgroup analysis would give the most relevant results for a particular population. However it is not anticipated that sufficient studies will exist for all (or even any) populations to be analysed as subgroups.

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Sensitivity analysis

Sensitivity analysis will be conducted on studies with a high risk of bias for sequence generation and allocation concealment.

Indigenous engagement in the review process

A recent short report by McDonald 2010, outlines the results of a taskforce conducted between the public health group within the Cochrane Collaboration and Indigenous health researches, to discuss the issues and challenges of systematic reviews in Indigenous health. It highlights the levels of complexities involved in the synthesis of evidence in such populations, for whom the social determinants of health are key factors underlying health inequalities. An important outcome of this project was to emphasize the need for engagement through Indigenous people, organisations and communities to ensure that the health research meets the needs of those that use them, including the Indigenous communities themselves. For this reason, the review will be examined by two independent Indigenous representatives for consideration of applicability and content. At least one of these reviewers will be an Indigenous researcher or health care worker.

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* *Indicates the major publication for the study*

HISTORY

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CONTRIBUTIONS OF AUTHORS

Protocol conceived and prepared by Kristin V Carson, reviewed by Antony Veale, Adrian J Esterman and Brian J Smith

DECLARATIONS OF INTEREST

No conflicts of interest to report.

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Internal sources

- None, Not specified.

External sources

- No sources of support supplied

Appendix 3 Audit trail and contact log for qualitative research

Interviews and surveys

Date	Time	Duration (end time)	Task/Method	Participant name	Location of event	Conducted by
05/03/2013	14:30	1hr (15:30)	PIS+C, Key stakeholder interview and survey	Malcolm Brinn	BHI, Ground Floor Atrium	KC
06/03/2013	08:30	1hr (09:30)	PIS+C; Respiratory Dr Interview and Dr survey	Dr Antony Veale	TQEH, 4A, Antony's office	KC
07/03/2013	08:30	30min (09:00)	Pilot tested survey with doctors at TQEH for TSANZ survey	15 doctors, registrars, interns and trainees in Respiratory Medicine	TQEH, 5B meeting room	KC
18/03/2013	15:00	2hrs (17:00)	PIS+C; Key stakeholder interview and survey	Dr Helen Bradley	Uni SA, Helen's office	KC
23/03/2013 to 25/03/2013	10:30	1hr (11:30)	Delivered TSANZ questionnaires for SIGs	Multiple participants including doctors, researchers and allied health professionals	2013 Annual Scientific for the TSANZ conference, Darwin	KC
23/03/2013	12:00	45mins (12:50)	PIS+C; Respiratory Dr Interview and Dr survey	Prof Anne Chang from Menzies Darwin and Royal Children's Hx – Brisbane	2013 Annual Scientific for the TSANZ conference, Darwin	KC
24/03/2013	10:30	1hr (11:30)	PIS+C; Respiratory Dr Interview and Dr survey	Prof Matthew Peters from Concord Hospital Sydney	2013 Annual Scientific for the TSANZ conference, Darwin	KC
24/03/2013	12:30	1hr (13:30)	PIS+C; Respiratory Dr	Prof Graeme Maguire from Baker IDI –	2013 Annual Scientific for the	KC

Date	Time	Duration (end time)	Task/Method	Participant name	Location of event	Conducted by
			Interview and Dr survey	NT	TSANZ conference, Darwin	
26/03/2013	16:30	1hr (17:30)	PIS+C; Respiratory Dr Interview and Dr survey	Dr Chris Schull from MSOAP outreach – QLD	2013 Annual Scientific for the TSANZ conference, Darwin	KC
27/03/2013	08:30	30min (09:00)	PIS+C; Key stakeholder interview and survey	Dr Smita Shah from The University of Sydney	2013 Annual Scientific for the TSANZ conference, Darwin	KC
01/10/2013	10:00	2hr (12:00)	PIS+C, Other Dr (GP) interview and survey	Dr John Bouilly, General Practitioner	Basil Hetzel Institute, Adelaide	KC
28/10/2013	09:30	1.5hr (11:00)	PIS+C; Key stakeholder interview and survey	Klynton Wanganeen, Aboriginal Elder involved in politics and policy	Basil Hetzel Institute, Adelaide	KC
30/10/2013	15:00	1hr (16:00)	PIS+C; Key stakeholder interview and survey	Robert Dann, Aboriginal Elder and cultural officer	Aboriginal Health Council of South Australia	KC
05/11/2013	11:00	1hr (12:00)	PIS+C, Other Dr (Psychology) interview and survey	Prof Malcolm Battersby from Flinders Medical Centre, SA	Flinders Medical Centre, Malcolm Battersby's office	KC
12/11/2013	13:00	1hr (14:00)	PIS+C, Other Dr (Cardiology) interview and survey	Dr Philip Tideman from Flinders Medical Centre Private, Adelaide	Flinders Medical Centre, Philip Tideman's office	KC
04/02/2014	10:30	1hr (11:30)	PIS+C; Key stakeholder interview and survey	Paul Vandenberg, Aboriginal youth engagement officer, PAFC	Port Adelaide Football Club	KC
05/05/2014	10:30	1hr (11:30)	PIS+C; Key stakeholder interview and survey	Dr Sharon Lawn from Flinders Medical Centre, SA	Flinders Medical Centre, Sharon's office	KC

Presentations/media

Date	Time	Duration (end time)	Details	Audience	Location of event	Outcome
07/07/2011	16:00	1hr (17:00)	Presentation for Basil Hetzel Institute Post-graduate seminar series	Prof Jenny Kennedy and other BHI researchers	BHI Seminar Room	Presented core components – outline of candidature and preliminary results from Cochrane review on smoking cessation
25/08/2011	09:30	7.5hr (17:00)	Faculty of Health Sciences Post-graduate research conference	Multiple researchers walking by and assessors	National Wine Centre, Adelaide	Poster presentation at conference for Indigenous smoking cessation research
14/10/2011	09:00	8hr (17:00)	Basil Hetzel Institute research day, gave oral presentation and attended other presentations	BHI researchers	BHI Seminar Room	Oral presentation – was able to practice delivery of orals for national conference presentation
30/11/2011	18:30	3.5hr (22:00)	Presentation for SA/NT Branch Young Investigator Award	Members of the SA/NT branch TSANZ	Ayres House, Adelaide	Presented oral, gained practice for presentation at national conference
02/04/2012	10:00	2.5hr (12:30)	Presented oral at the national ASM for TSANZ about training health professionals in smoking cessation Cochrane review	Audience of the TSANZ annual scientific meeting	Canberra Convention Centre	Presented oral for the Evidence Based Medicine special interest group
03/04/2012	15:00	3hr (18:00)	Presented oral at the national ASM for TSANZ about Indigenous	Audience of the TSANZ annual	Canberra Convention Centre	Presented oral, award winning presentation for the Tobacco Control prize

Date	Time	Duration (end time)	Details	Audience	Location of event	Outcome
			tobacco cessation Cochrane review	scientific meeting		
29/06/2012	14:00	1hr (15:00)	Invited presentation to the Aboriginal Health Council of South Australia about tobacco, tobacco cessation and our research currently underway	Members of the Tackling smoking team and the health leaders (invited by Ruth Miller)	Aboriginal Health Council of South Australia, King William Road	Interactive 30 minute oral about current smoking cessation pharmacotherapy, options and existing evidence around smoking cessation and tobacco prevention, discussed our existing research for advice and input from Elders in attendance (approximately 15 people)
18/07/2012	12:30	1hr (13:30)	Grand round presentation at the Lyell McEwin Hospital about the results from Indigenous research and the STOP smoking trial	Audience members of grand round (doctors, trainees, interns, nursing staff etc.)	Lyell McEwin Hospital	Presented the results to date for the Indigenous research (tobacco cessation and prevention Cochrane reviews) and the STOP smoking trial research – dissemination of results
29/09/2012	18:00	4hr (22:00)	Presentation for SA/NT Branch Young Investigator Award	Members of the SA/NT branch TSANZ	Ayres House, Adelaide	Presented oral, gained practice for presentation at national conference
04/02/2013	10:30am	30min (11:00am)	Presented research outline for notification of research, advice and recruitment options	Aboriginal Elders and community leaders	Murray Bridge – Elders Advisory Committee Meeting	Recruited two participants, one male smoker and one female non-smoker
06/02/2013	09:00	1hr (10:00)	Major review presentation and	Supervisors,	Basil Hetzel Institute	Presented research update and what is left to

Date	Time	Duration (end time)	Details	Audience	Location of event	Outcome
			panel meeting	external assessors, other researchers and panel	Seminar Rooms 1 and 2	do for the Major Review University of Adelaide presentation with panel feedback
14/03/2013	10:00am	1hr (11:00am)	Presented research outline for advice and recruitment options	Aboriginal Elders	Nunukuwarrin Yunti Health Centre	Presented to Aboriginal and TSI health care workers about existing evidence for tobacco, research plan, what should be done in research and to ask their advice and input on the current PhD work
19/03/2013	11:00	10 minutes	Interview for media release with Trevor Gill to occur during TSANZ conference	Nation-wide media release	Over the phone	Media released titled 'Review finds dangerous shortcomings in anti-smoking programs aimed at Indigenous youth' – resulted in article in 'The Australian' on Monday March 25 th 2013 page 5
24/03/2013	15:30	15 min	Oral presentation at National TSANZ conference 'tobacco prevention'	TSANZ Tobacco SIG in Darwin	Darwin Convention Centre	Presented on 'Interventions for tobacco prevention in Indigenous youth: A Cochrane review and a narrative synthesis'
24/03/2013	17:30	20 minute	ABC Radio interview in sound booth regarding media release for tobacco prevention review	ABC radio listeners	Over the phone whilst in Darwin	Resulted in interview being broadcast via ABC radio Darwin, in addition to multiple radio bulletins over ABC radio news across Australia

Date	Time	Duration (end time)	Details	Audience	Location of event	Outcome
25/03/2013	15:30	1.5 hours (17:00)	Chairing session for Aboriginal health working party at TSANZ, now formally known as 'The TSANZ Indigenous Respiratory Health Working Party'	Members of the TSANZ Indigenous Respiratory Health Working Party	Darwin Convention Centre	Established a working party across Australia and New Zealand under the scope of TSANZ to help collate evidence for Indigenous Respiratory Health, identify gaps in evidence and apply for funding to create clinical initiatives/research projects to address these gaps
15/04/2013	10:30	30min (11:00)	ABC 891 in studio radio interview with Ian Henschke about smoking, smoking cessation and Aboriginal research	ABC 891 radio listeners	In studio, North East Road ABC building	Discussed numerous smoking studies, options for smoking cessation and Aboriginal research
18/04/2013	10:00	1hr (11:00)	Channel 7 news interview around smoking cessation options and recent research	Channel 7 news viewers	Basil Hetzel Institute, TQEH	Spoke about results of the smoking/nicotine studies, results of this and what it means
16/05/2013	10:00	30min (10:30)	Radio interview at Coast FM in studio with David Hearn	Coast FM radio listeners	In studio at Coast FM building	Discussed various smoking cessation, prevention and Aboriginal research studies
25/06/2013	16:30	45m (17:15)	Invited presentation at Flinders Medical Centre Academic session for the Southern Respiratory Service Academic Meeting	Staff in Respiratory Medicine at Flinders Medical Centre	Flinders Medical Centre, Level 6, Rm 6B, 207	Opportunity to present Indigenous tobacco cessation and prevention research as part of PhD

Date	Time	Duration (end time)	Details	Audience	Location of event	Outcome
28/06/2013	14:00	1hr (15:00)	Invited presentation at Repatriation General Hospital during the Academic Meeting	Respiratory and Sleep Medicine Staff	Repatriation General Hospital	Opportunity to present Indigenous tobacco cessation and prevention research as part of PhD
02/07/2013	14:00	2.5hr (16:30)	'3 Minute Thesis' first round of faculty heats: Presentation about tobacco prevention for Indigenous youth	Other discipline of Medicine students and panel from the University of Adelaide	Hone Lecture theatre, University of Adelaide, Medical School	Practice for next round being knockouts
05/07/2013	13:00	30m (13:30)	'3 Minute Thesis' practice and critique with Uni representative	Other 3MT researchers and Cally Guerin from the University	Smarte Room, Level 8 Pulteney Street, Adelaide	Amended presentation for knockout round
24/07/2013	14:00	2.5hr (16:30)	'3 Minute Thesis' second round of faculty heats: Presentation about tobacco prevention for Indigenous youth	Other discipline of Medicine students and panel from The University of Adelaide	Hone Lecture theatre, The University of Adelaide, Medical School	Opportunity to present 3MT and hone skills
24/09/2013	14:00	3hr (17:00)	Presented at the SAHMRI Aboriginal Health Research Network Meeting	SAHMRI Aboriginal Health Network	WEA Angus Street, Adelaide	Presented summary of research at the meeting (5 min +5 min questions); obtained new contacts: Cancer Council of SA –

Date	Time	Duration (end time)	Details	Audience	Location of event	Outcome
						currently evaluating; heard about other research happening in SA
25/09/2013	10:00	2.5hr (12:30)	Presented in Semi-Finals for South Australian Young Investigator Award (5 min pres + 2 min question time)	Open invitation to Hospitals and Universities in SA	WCH, Queen Victoria Lecture Theatre	Opportunity to speak and hone skills – did not make final round; will apply again next year
18/10/2013	08:00	9hr (18:00)	TQEH Research Day oral presentation	Other students, doctors and trainees attending research day	Basil Hetzel Institute, TQEH	Presented research on tobacco cessation for Indigenous populations: A Cochrane review and narrative synthesis
29/10/2013	09:00	30min (09:30)	TQEH post-graduate seminar presentation	Other post-graduate students and supervisors	Basil Hetzel Institute, TQEH	Presented research for PhD, what has been done and what is left to do
04/11/2013	11:00	30 min (11:30)	Aboriginal Workforce meeting presentation	Aboriginal Elders and community members	Aboriginal Health Council of South Australia	Presented current research findings and plan for next phase of work, asked for feedback following the presentation and suggestions for next phase
07/11/2013	08:30	1hr (09:30)	Presented at weekly respiratory morning meeting	Consultants, nurses and other allied health professionals	TQEH, 5B main building	Presented an overview of PhD work completed to date and what is left to do for the weekly meeting

Date	Time	Duration (end time)	Details	Audience	Location of event	Outcome
				and students		
28/11/2013	17:30	4.5hr (22:00)	Presented for the SA/NT TSANZ Young Investigator Award	Members of the SA/NT branch TSANZ	Ayres House, Adelaide	Presented tobacco prevention research for Indigenous populations globally
28/11/2013	11:00	30 min (11:30)	Presented at the tackling smoking meeting for health professionals	Attendees of the Aboriginal health professionals workshop	McCracken Country Club, Victor Harbor, Adelaide	Presented results of tobacco cessation and prevention research for Aboriginal populations in addition to current evidence overview of what treatment options are available for smoking cessation
08/04/2014	15:30	15 min	Oral presentation at National TSANZ conference	TSANZ Evidence Based Medicine SIG in Adelaide	Adelaide Convention Centre	Presented results of Respiratory health service delivery and utilisation by Aboriginal and Torres Strait Islander Australians: A qualitative analysis of the barriers and enablers to optimal medical management
09/04/2014	09:00	15 min	Oral presentation at National TSANZ conference	TSANZ Tobacco SIG in Darwin	Adelaide Convention Centre	Presented results of Barriers and enablers to the use of smoking cessation pharmacotherapy in Aboriginal and Torres Strait Islander populations: A qualitative analysis
17/04/2014	08:30	1hr (09:30)	Oral presentation for Respiratory	Respiratory doctors,	TQEH, 5B Main	Presented update of progress on my PhD and

Date	Time	Duration (end time)	Details	Audience	Location of event	Outcome
			Thursday morning meeting	trainees and Allied Health Professionals	Building	spoke about statistical methodology in Respiratory Research
13/05/2014	16:00	30min (16:30)	Oral presentation for Research Highlights seminar, School of Medicine, University of Adelaide	Students and staff from the School of Medicine, UoA	The University of Adelaide, Elanor Harrold Building	Presented the findings from my PhD and an overview of the Respiratory unit's research
18/05/2014	08:15	2.5hr (10:45)	Poster presentation and discussion session around tobacco use cessation in Indigenous populations: A meta-analysis	Other medical staff, academics and students attending the conference	San Diego, USA, Convention Centre	Presented findings from my research as a poster and contributed to the group discussion
03/06/2014	18:30	20min (18:50)	Invited oral presentation for the Australian Society of Medical Research and Healthy Development Adelaide to speak about the importance of networking	Students attending the ASMR conference and HDA members (approx.. 100)	The University of South Australia	Presented about the importance of networking during my PhD and what that has helped me to achieve; also had the opportunity to participate in networking activities after the presentation
01/08/2014	10:30	1hr (11:30)	Invited oral presentation about the importance of networking, for Engineering students at The University of Adelaide	Post-graduate students (approx. 50 Master's and PhD)	The University of Adelaide, Tower building North Terrace	Presented about the importance of networking, how to effectively network and what it has helped me to achieve; After 40 minute presentation about networking I created a 20 minute networking activity for all students to participate in

Date	Time	Duration (end time)	Details	Audience	Location of event	Outcome
06/08/2014	10:30	15min (10:45)	Invited presentation at Kildare College Awards ceremony to whole school about my experience in high school, how I become a scientist and what I do now	Students from year 8 to 12 (approx. 500)	Kildare College, Holden Hill	Delivered presentation to school assembly which was well received
08/08/2015	11:30	5min (11:35)	Speaker for Science Alive Careers Day about what I do as a scientist	Students from primary school through to high school (approx. 1000)	Adelaide show grounds	Successful presentation to students; Opportunity to speak about the PhD research and how it is possible to make a positive impact
08/08/2015	08:30	8hr (16:30)	Booth presenter and organiser for Science Alive	Students from primary school through to high school (approx. 5000 over the course of the event)	Adelaide show grounds	Presenter and co-organiser for the BHI booth for Science Alive where I helped perform spirometry on attendees and spoke about research at BHI
09/08/2015	08:30	8hr (16:30)	Booth presenter and organiser for Science Alive	Students from primary school through to high school (approx.	Adelaide show grounds	Presenter and co-organiser for the BHI booth for Science Alive where I helped perform spirometry on attendees and spoke about research at BHI

Date	Time	Duration (end time)	Details	Audience	Location of event	Outcome
				5000 over the course of the event)		
10/08/2015	08:30	8hr (16:30)	Booth presenter and organiser for Science Alive	Students from primary school through to high school (approx. 5000 over the course of the event)	Adelaide show grounds	Presenter and co-organiser for the BHI booth for Science Alive where I helped perform spirometry on attendees and spoke about research at BHI
14/08/2014	08:30	1hr (09:30)	Presented at weekly respiratory morning meeting	Consultants, nurses and other allied health professionals and students	TQEH, 5B main building	Presented research update and an overview of PhD work completed to date and what is left to do
25/08/2014	13:00	20min (13:20)	UoA Annual Review of Progress for BHI panel	Panel of academics from the BHI	BHI, 1 st floor meeting room	Provided update of progress for the PhD and summarise work remaining for completion with expected timelines
16/09/2014	10:30	1.5hr (12:00)	Presentation for Young Achiever Awards (YAA) launch for 2015 event	Invited audience from corporate, media and industry	RiAus building, Adelaide, also streamed live over the internet	Gave speech to attendees and the media about what it was like to win the YAA and what has happened in the six months since winning
25/09/2014	09:00	8hr (17:00)	Presentation for The University of	Post-graduate	Wine Centre SA	Presented PhD for abstract titled 'Barriers

Date	Time	Duration (end time)	Details	Audience	Location of event	Outcome
			Adelaide post-graduate conference	students		and enablers for the use of smoking cessation pharmacotherapy in Aboriginal and Torres Strait Islander populations: A qualitative analysis'
26/09/2014	18:30	3.5hr (22:00)	Presentation for SA/NT branch Thoracic Society of Australia and New Zealand annual scientific meeting	Dr Ching Li Chai	Ayres House	Presented oral with Brian Smith (15 minutes) about new research and COPD (including Aboriginal health and COPD)
07/10/2014	09:00	1hr (10:00)	Presentation for The University of Adelaide post-graduate meeting	Dr Prue Cowled	Basil Hetzel Institute for Translational Health Research (BHI)	Annual presentation at the BHI, 30 minutes, progress report, data collected, results and where to from here
17/10/2014	08:30	7.5hr (16:00)	Presentation for Basil Hetzel Institute Research Conference	Dr Prue Cowled	Basil Hetzel Institute for Translational Health Research (BHI)	Presented research abstract titled: 'Barriers and enablers for the use of smoking cessation pharmacotherapy in Aboriginal and Torres Strait Islander populations: A qualitative analysis'
30/10/2014	10:30	1hr (11:30)	Invited presentation for the Lung Foundation of Australia for the Annual Patient Education Day	People with COPD, carers and other health professionals	Adelaide Oval	Spoke from a patient and consumer perspective about how to understand scientific and medical research as a consumer for COPD in particular

Date	Time	Duration (end time)	Details	Audience	Location of event	Outcome
27/11/2014	18:30	3.5hr (22:00)	Presentation at the TSANZ Young Investigator Award	Other scientists and medical professionals in the field of Respiratory	Ayres House	Presented research abstract titled: 'Aboriginal and TSI tobacco use and cessation treatment: from the smoker, ex-smoker and non-smokers' perspectives'
09/12/2014	18:40	2hr (20:40)	Invited speaker for Morphett Vale Primary School Year 7 graduation	Year 7 students and their families (approx. 250 people)	Morphett Vale Primary School	Presented about how I became a scientist and the type of work I do now, particularly related to my PhD
26/01/2015	07:30	30min (08:00)	Australia Day radio interview for ABC at Parliament House for the Press Club in the Senate	Approx. 25,000 people listening to ABC (primarily politicians and people involved in politics)	Morning radio interview at Parliament House in the Senate for The Press Club (ABC)	Spoke about the funding cuts to the COAG and the result on Aboriginal and TSI health and research; Invited back to speak on radio again during the year
09/02/2015	18:30	1hr (19:30)	Presented invited oral for the Adelaide City Roteract Club	Roteract members (approx. 25 people)	General Havelock Hotel, Hutt Street	Spoke about how I became a scientist, winning the SA Young Australian of the Year, the research that I do and the microscopes in schools initiative
16/02/2015	13:30	15min (13:45)	Radio interview for 5AA in studio (organised by SA Health, showcasing health professionals)	Listeners of 5AA radio	5AA studios, 75 Hindmarsh Square	Spoke about working in SA Health, how I became a scientist, winning SA Young Australian of the Year and my PhD work

Date	Time	Duration (end time)	Details	Audience	Location of event	Outcome
17/02/2015	09:30	10min (09:45)	Radio interview for ABC in studio	Listeners of ABC radio	ABC studios, North East Road	Spoke about how I became a scientist, winning SA Young Australian of the Year and my PhD work
18/02/2015	11:00	3hr (14:00)	'Celebrating Great South Australians' interviewed on stage by Ian Henschke (ABC radio personality) with my three fellow Australian of the Year winners for SA for an hour	Invited guests for Brand SA and the Australia Day Council	Adelaide Convention Centre	Networking opportunity, made many new connections including Asthma Foundation of SA, Gilad Zuckerman, Serafino Wines, Channel 41 Adelaide, OpenBook Howden and others
04/03/2015	09:00	2hr (11:00)	Presentation of research to Frank and Kathy Seeley from Seeley International for possible funding	Frank and Kathy Seeley	TQEH, 4A Education Room	Spoke with Frank and Kathy about what research is being done within the department and the possibility of funding; They agreed to donate money for an annual scholarship of \$18,000 with review after the first 12 months
05/03/2015	07:00	1hr (08:00)	Invited presentation to the Adelaide City Rotary Club	Members of the Adelaide City Rotary Club	Naval Military and Air Force Club, 111 Hutt Street	Presented about my journey to becoming a medical research scientist; networking opportunity
29/03/2015	15:30	2.5hr (17:00)	Presented oral at the national ASM for TSANZ about Community pharmacy personnel interventions	Audience of the TSANZ annual scientific meeting	Gold Coast Convention Centre	Presented oral for the Evidence Based Medicine special interest group

Date	Time	Duration (end time)	Details	Audience	Location of event	Outcome
			for smoking cessation: A Cochrane systematic review and meta-analysis			
29/03/2015	15:30	2.5hr (17:00)	Presented oral at the national ASM for TSANZ about culturally-tailored smoking cessation interventions for Indigenous populations	Audience of the TSANZ annual scientific meeting	Gold Coast Convention Centre	Presented oral for the Evidence Based Medicine special interest group; award winning presentation for 'Best Oral'
01/04/2015	08:00	2.5hr (10:30)	Presented oral at the national ASM for TSANZ about nicotine receptor up-regulation	Audience of the TSANZ annual scientific meeting	Gold Coast Convention Centre	Presented oral, award winning presentation for the Tobacco Control prize for 'Best Oral'
01/04/2015	13:00	3hr (16:00)	Cochrane review completion workshop presentation and co-convenor	Authors of Cochrane reviews (approx. 10)	Gold Coast Convention Centre	Presented about tips and tricks to timely completion of a Cochrane review and answered questions for individual review authors
13/04/2015	18:00	3hr (21:00)	Invited keynote speaker for the City of Marion Youth Recognition Awards	Awardees and their families (approx. 150 people)	Marion Cultural Centre	Presented about how I became a scientist and the work I do now; networked with the Mayor of the City of Marion

Meetings/networking

Date	Time	Duration (end time)	Meeting/networking	Location of event	Outcome
22/02/2011	10:00	30min (10:30)	Meeting with Jenny Kennedy (post-graduate co-ordinator) for candidature	Jenny Kennedy's office, BHI	Discussed requirements of candidature
03/05/2011	14:30	1hr (15:30)	Meeting with Prof Adrian Esterman (co-supervisor) to discuss research	University of South Australia, North Terrace, Adelaide	Meeting to discuss proposed outline and timeline for candidature completion
22/06/2011	09:00	1hr (10:00)	Meeting with David Johnston and Jill Fisher re: Respiratory Services in Port Lincoln and the possibility of Aboriginal Health Research	4A Main Building Brian's office	Meeting to discuss outreach clinic visits by Respiratory doctors into Remote Aboriginal communities and the possibility of doing Aboriginal health research
23/06/2011	12:00	1hr (13:00)	Meeting with Hon. John Hill (Health Minister) to discuss Aboriginal Health Research	Parliament House	Meeting with Health Minister (organised by KC who was asked to visit Parliament House by the minister following a question asked at a budget discussion – TQEH) to discuss Aboriginal Health Research and tobacco use and where the state should be going from here
13/07/2011	15:00	1hr (16:00)	Meeting with Ral Antic and Brian Smith about Indigenous working party formation	Royal Adelaide Hospital, Ral Antic's office	Discussed Indigenous PhD work and working party with Ral Anitic and Brian Smith and what was about to be undertaken
30/08/2011	12:00	1hr (13:00)	Meeting with Deb Walker; Executive	Ingle Farm Recreation	Discussed PhD work and cultural appropriateness of

Date	Time	Duration (end time)	Meeting/networking	Location of event	Outcome
			director of Aboriginal and Torres Strait Islander Health (SA Health)	Centre	moderator guide questions
31/08/2011	10:00	1.5hr (11:30)	Indigenous respiratory health working party meeting	BHI, ground floor seminar room 1	In attendance: James Martin (WCH pulmonary), Deborah Walker (Executive director of Aboriginal and Torres Strait Islander Health), David Scrimgour, David Johnson, Belinda Moyes, NL, KVC and BS, to discuss direction of Aboriginal and TSI health in Adelaide
14/09/2011	10:00	1hr (11:00)	Meeting with Dr Jonathon Polasek regarding Indigenous tobacco prevention research	4A Main Building, Jonathon's office	Discussed collaboration in Indigenous research and asked questions regarding moderator guide
22/09/2011	13:30	1hr (14:30)	Meeting with Grant Day, Aboriginal researcher working with tobacco and healthy lifestyle interventions for Aboriginal and TSI health	Lizzie's café, Woodville Road	Discussed resources and existing work done in Aboriginal and TSI health and moderator guide for new project we are doing. Conversation assisted in formulating questions to include in moderator guides
27/09/2011	11:00	1hr (12:00)	Meeting with Harrold Stewart, Aboriginal Elder and researcher, Tackling Smoking Co-ordinator (at the time) for the Aboriginal Health Council of South Australia	Aboriginal Health Council of South Australia, King William Road	Discussed the Aboriginal health and tobacco research planning to be done, asked advice, direction and collaboration. Gained input for moderator guides and assistance on informing the direction of research. Also met with Mary Williamson
19/10/2011	11:30	30min	Meeting with Lauren Whitney from	Lauren Whitney	Discussed the media release and article for dissemination

Date	Time	Duration (end time)	Meeting/networking	Location of event	Outcome
		(12:00)	Media Communications about the Port Power photo and story to be included in a media-release		about the donation provided to CPU Indigenous health research from the Port Adelaide Football Club Outer Army
06/12/2011	15:30	1hr (16:30)	Meeting with Darren Adamson and Paul Vandenberg at the Port Adelaide Football Club for research collaboration	Port Adelaide Football Club	Met to discuss research collaboration and tailored questions for moderator guide about healthy lifestyle programs delivered by the Port Adelaide Football Club and youth interventions
15/12/2011	16:00	1hr (17:00)	NHMRC meeting for Aboriginal Health Grant with Harrold Stewart (Aboriginal Elder), Adrian Esterman, Stephanie Fryar-Williams, Brian Smith, Nadina Labiszewski, Malcolm Brinn, John Beltrame etc.	BHI Seminar Room	Discussed the possibility of submitting a NHMRC grant of funding for an Aboriginal health research project. Opportunity to discuss different ideas and intervention areas
16/12/2011	13:00	30min (13:30)	Teleconference with Matthew Peters to discuss NHMRC Aboriginal Health Grant	Teleconference	Discussed the possibility of submitting a NHMRC grant of funding for an Aboriginal health research project. Opportunity to discuss different ideas and intervention areas
02/05/2012	14:00	1.5hr (15:30)	Meeting with Darryl Cameron (Aboriginal Elder) who is a project officer at the Aboriginal Health Council of South Australia	Aboriginal Health Council of South Australia, King William Road	Spoke about current research, gained input into moderator guides and asked about cultural appropriateness of research activities, asked for future directions

Date	Time	Duration (end time)	Meeting/networking	Location of event	Outcome
31/05/2012	09:00	1hr (10:00)	Teleconference with Vanessa Johnson, an experienced Indigenous tobacco researcher from the Northern Territory	Teleconference	Discussed existing work, the possibility of collaboration and asked advice about direction, moderator guide questions and design of research studies
31/05/2012	15:30	1hr (16:30)	Meeting with Femke Busiman-Piljman about possible research collaboration for a project on Aboriginal health and youth	The University of South Australia	Discussed the possibility of collaborating on a research project and writing a grant proposal for the Grand Funding Scheme (Pfizer) to do with Indigenous tobacco cessation
01/06/2012	13:30	10min (13:40)	Discussed Aboriginal research with Steven Sumner (Aboriginal Elder)	Phone discussion	Discussed structure of focus groups and moderator guide questions, asked advice about research design and focus
19/06/2012	10:00	1hr (11:00)	Meeting with Alwin Chong (Aboriginal Elder) at the Aboriginal Health Council of South Australia	Aboriginal Health Council of South Australia	Meeting to discuss direction of Aboriginal research, Alwin suggested quite a few changes to the moderator guides with re-wording of existing questions and the addition of questions relating to healthy lifestyle outside of tobacco, as they interact with each other
27/06/2012	13:00	1hr (14:00)	Meeting with Natalie Williams, the Aboriginal liaison officer at TQEH	Lizzies Caf�, TQEH	Discussed moderator guides, existing research and suggestions for recruitment of participants to be part of the research
12/07/2012	13:00	1hr (14:00)	Meeting with Paul Vandenberg and Darren Adamson from the Port Adelaide Football Club	Port Adelaide Football Club	Discussed current research and the progress made to date, further tailored the moderator guide based on questions from Paul and Darren
14/08/2012	10:00	30min	Meeting with Robert Dann (Aboriginal	Aboriginal Health	Discussed the final requirements for the ethics submission and

Date	Time	Duration (end time)	Meeting/networking	Location of event	Outcome
		(10:30)	Elder) about the ethics application for qualitative research	Council of South Australia	asked for his input about cultural appropriateness; adjusted moderator guides with additional questions about health related racism, highlighted issues of gender inequalities
21/08/2012	14:30	1hr (15:30)	Meeting to discuss possibility of conducting qualitative research in Murray Bridge with Sandy Wilson (Aboriginal Elder and health worker)	Murray Bridge	Spoke about current research, asked for advice about qualitative research design and plan; Sandy suggested recruitment strategy and that we make a presentation at an upcoming event
27/08/2012	10:30	1hr (11:30)	Meeting with Della Rowley from the Drug and Alcohol Services South Australia about current tobacco research	DASSA headquarters, Greenhill Road	Discussed existing research underway with tobacco and Aboriginal health; spoke about overlaps and how best to disseminate the results of existing evidence into clinical practice and policy with the team of tobacco workers (approximately 7 people)
13/09/2012	15:30	1hr (16:30)	Meeting with Mary Buckskin (Aboriginal Elder and chair of the Aboriginal Health Council of South Australia), Robert Dann and Rosie King	Aboriginal Health Council of South Australia	Discussed existing research, asked advice about ethics application and cultural appropriateness of research and participant information sheets, consent forms and research as a whole; all went well, Mary was happy with the research and believed that it would be useful but, important to focus on dissemination of results and community involvement
19/09/2012	09:30	1.5hr (11:00)	Meeting with Klynton Wanganeen (former Aboriginal commissioner) to	Lizzie's Café, TQEH	Discussed qualitative research, reviewed both surveys and moderator guides, Klynton suggested making

Date	Time	Duration (end time)	Meeting/networking	Location of event	Outcome
			discuss research		acknowledgement of participants optional and an option on the consent form, wanted more emphasis on evidence translation and suggested changes to surveys structurally (reduce the number of pages); also highlighted that very little positive news is released in the media about Aboriginal related studies and this should be a focus
24/09/2012	10:00	e-mail	E-mailed Marewa Glover (Maori researcher from New Zealand) about her tobacco related research focussing specifically on Maori health	E-mail correspondence	Conversation via e-mail about tobacco prevention and cessation research done with Maori populations and how findings from this translate into Australian populations
03/12/2012	09:30	1.5hr (11:00)	Meeting/award presentation with the Port Adelaide Football club Outer Army at TQEH	Basil Hetzel Institute, TQEH	Received cheque for research raised from members of the Port Adelaide Football Club Outer Army for work in Aboriginal and TSI research
22/01/2013	15:00	1hr (16:00)	Meeting with Helen Bradley to discuss details of qualitative research	Uni SA Helen's office	Discussed details for Aboriginal focus groups and plan for data collection and analysis
04/02/2013	10:30	1hr (11:30)	Aboriginal Elders meeting in Murray Bridge	Murray Bridge Cultural Centre	Delivered 10 minute presentation to approximately 15 Elders about the proposed research to gain feedback, participation and suggested changes
11/02/2013	11:00	1.5hr (12:30)	Meeting with Ruth Miller – Tackling smoking co-ordinator Aboriginal Health	Aboriginal Health Council of South	Discussed possibility of involvement in research (accepted) and recruitment assistance – Ruth invited KC to present at

Date	Time	Duration (end time)	Meeting/networking	Location of event	Outcome
			Council	Australia (AHCSA)	Nunkuwarrin Yunti Health Service
12/02/2013	15:30	2hrs (17:30)	Meeting with Helen Bradley - qualitative Aboriginal health researcher	Uni SA Helen's office	Discussed details for Aboriginal focus groups and interviews and what is required/advice
25/02/2013	15:00	1.5hr (16:30)	Meeting with Sue Bertosa (suggested by Malcolm Battersby) for Aboriginal research	Basil Hetzel Institute, TQEH	Met with Sue to discuss ongoing research in tobacco already underway with Malcolm Battersby and her group with opportunities for collaboration and to ensure that there is no overlap between the work for this PhD and the work already being done
30/05/2013	09:30	2.5hr (12:00)	SA Aboriginal Health Research Network Meeting with other Aboriginal professionals and researchers	Tandanya Community Centre; 253 Grenfell Street	Attended networking meeting; Approached Sharon Meagher and requested opportunity for meeting
05/06/2013	15:30	1hr (16:30)	Meeting with Prof Alex Brown, head of the Aboriginal research unit for SAHMRI	Level 9, 121 King William Street, Alex's Office	Discussed my current research, asked for feedback and suggestions. Alex provided names of people to contact and commented that the overall design was good. Suggested I consider the potential link between depression and tobacco use
10/06/2013	17:00	3hr (20:00)	The Task Force Story – University of South Australia	Kerry Packer Gallery, Uni SA	Invited by Sharon Meagher to attend 'The Task Force Story' about Aboriginal initiation into the workforce and the University system. Included presentations and an art exhibition

Date	Time	Duration (end time)	Meeting/networking	Location of event	Outcome
25/06/2013	13:00	1hr (14:00)	Meeting with Sharon Meagher to discuss PhD and my research, Aboriginal health researcher and Elder	University of South Australia; Yonggondi Building, office Y2-37	Asked for feedback on study design, suggestions and possibility of interviewing as a key stakeholder. Sharon also offered to assist with moderating the focus groups
10/07/2013	17:00	3hr (20:00)	Met with Dr Helen Bradley at 'The Task Force Story' event (see below)	University of South Australia	Helen is still happy to help moderate the focus groups; asked for a brief update and ready to commence with the next phase of the research; Discussed study design, progress and timeline for qualitative work
23/07/2013	09:00	3hr (12:00)	SA Aboriginal Health Research Network Meeting	Tauondi Aboriginal Community College, 1 Lipson St Port Adelaide	Attended network meeting; presentations from panel members; made contact with A/Prof Jenny Baker
19/09/2013	15:30	1.5hr (17:00)	Met with Dennis Colson, Newly appointed Healthy Lifestyles and Smoking Wiya Program Co-ordinator in the APY Lands for Nganampa Health, Aboriginal Elder	BHI, KVC office	Following contact from AV, Dennis wanted to meet to discuss his new position and how we can help each other; he is keen to be involved in my research and wants me to help with his evaluation of the smoking cessation programs and wants to be involved in the TSANZ Indigenous Respiratory Lung Health Working party
01/10/2013	10:00	3hr (13:00)	Meeting with Dr John Bouilly; GP with interest in Aboriginal and Respiratory Health in Particular	KC Office	Discussed current work from both parties; John wants to collaborate on possible trials including an evaluation of vitamin C to treat a 'syndrome of disease' (cold/flu like symptoms, diarrhoea and otitis media all interlinked); Also

Date	Time	Duration (end time)	Meeting/networking	Location of event	Outcome
					happy to be interviewed as a GP for PhD research
01/10/2013	14:30	1hr (15:30)	Meeting with Lauren Maksimovic; Tobacco Control Evaluator; Cancer Council SA	Greenhill Rd; Cancer Council SA	Discussed current work to detect any overlap; Received suggestions around focus groups including having a person that can look after children who often attend the female focus groups; She will forward any review/audit documents around tobacco evaluations once they are made available; currently tobacco audits performed by the cancer council are not being publically released
02/10/2013	09:30	1hr (10:30)	Meeting with A/Prof Jenny Baker; Associate Professor of Aboriginal Health	Terrace Towers; University of Adelaide; North Tce	Asked Jenny to review current research proposal and make any suggestions; Offered some contacts and suggest that I look at the big picture to include issues around housing, violence, abuse, education etc. as it is all part of the same problem
02/10/2013	12:00	2hr (14:00)	Meeting with Aboriginal Elder Jeffrey Newchurch	KC Office	Discussed research from both parties and possibility of collaboration; very keen to be involved in PhD research, happy to identify male smokers and ex/non-smokers for focus groups and help to facilitate these focus groups; also happy to be involved in the research in any way possible; will be involved as co-author on publications and collaborator for this research; happy to discuss future research possibilities as well;

Date	Time	Duration (end time)	Meeting/networking	Location of event	Outcome
					currently doing work with repatriation initiatives
10/10/2013	10:00	2hr (12:00)	Meeting with Dr John Bouilly about Aboriginal research	KC Office	Met with John to discuss possibility of collaboration and research overlap, what needs to be done next in Aboriginal research and design of my current PhD proposal
14/10/2013	14:00	1hr (15:00)	Meeting with Jeffrey Newchurch about current research	KC Office	Went through research to ensure cultural appropriateness of content including abstracts, manuscripts and next phase of studies
01/11/2013	09:00	3hr (12:00)	Meeting with Dennis Colson from the APY lands about Aboriginal research	KC Office	Discussed the possibility of collaboration, what work we are doing and how this fits in with current practices in the APY lands; Dennis is the tackling smoking co-ordinator for the APY lands
04/11/2013	11:00	1hr (12:00)	Meeting with Ruth Miller (Aboriginal Elder)	Aboriginal Health Council of South Australia	Discussed and presented current research with members of the Aboriginal workforce meeting group and asked for advice in dissemination and possibility of collaboration
11/11/2013	11:30	1hr (12:30)	Meeting with Aboriginal Elder Jeffrey Newchurch	KC Office	Discussed research for focus groups and repatriation; Jeffrey will send through his notes for me to write a submission over the weekend for funding regarding the repatriation work; we went through the TSANZ abstracts for the one-on-one interview work; Jeffrey will help to do focus groups in Adelaide and Murray Bridge with men and he is happy to be

Date	Time	Duration (end time)	Meeting/networking	Location of event	Outcome
					interviewed as an Aboriginal Elder and Key community stakeholder
11/11/2013	15:00	2hrs (17:00)	Meeting with Dr Odette Gibson, Elaine Kite and other researchers from SAHMRI	121 King William Road, SAHMRI headquarters	Discussed contacts at SAHMRI and possibilities for collaboration; Introduced one-on-one to members of the SAHMRI team working under Prof Alex Brown, built collaboration with Dr Odette Gibson for future meta-analyses; Odette mentioned the possibility of my involvement in the translation reference group for Aboriginal research; Introduced to SAHMRI data analysers, one of which worked in tobacco policy for over 8 years and now focusing on Aboriginal health; I asked if he would be willing to be interviewed and he agreed (John Gray); also suggested I talk with Caroline Miller who is now responsible for Tobacco evaluations for SAHMRI (taken over from the Cancer Council SA)
22/01/2014	10:00	1hr (11:00)	Meeting with Jeffrey Newchurch	KC Office	Discussed current research to ensure cultural appropriateness
29/01/2014	15:30	30 min (16:00)	Teleconference with Sharon Lawn for NHMRC Aboriginal research application	KC Office/ teleconference	Discussed proposed research for NHMRC application of training health professionals in smoking cessation
30/01/2014	14:30	1hr (15:30)	Meeting with Ruth Miller	Aboriginal Health Council of South	Discussed smoking cessation NHMRC application and the next phase of Aboriginal research for cultural appropriateness

Date	Time	Duration (end time)	Meeting/networking	Location of event	Outcome
				Australia	and need of work
06/02/2014	10:30	1hr (11:30)	Meeting with Jeffrey Newchurch	KC Office	Discussed current research to ensure cultural appropriateness
06/02/2014	14:00	1hr (15:00)	Meeting with Ruth Miller	Aboriginal Health Council of South Australia	Discussed smoking cessation NHMRC in more detail in relation to requirements of dissemination and collaboration
13/02/2014	09:30	1hr (10:30)	Meeting with Paul Vandenberg, Aboriginal Elder from the Port Adelaide Football Club	Port Adelaide Football Club	Discussed research content, results of current work and next phase of suggested work for input
13/02/2014	12:30	1hr (13:30)	Meeting with Jeffrey Newchurch and Dennis Colson	Aboriginal Health Council of South Australia	Discussed cultural appropriateness of current research
18/02/2014	12:00	1hr (13:00)	Meeting with Corey Taylor	KC Office	Discussed Indigenous research content regarding current manuscripts and analysis for Aboriginal and TSI research with possibility of collaboration
27/02/2014	11:00	1hr (12:00)	Meeting with Jeffrey Newchurch	KC Office	Discussed current research to ensure cultural appropriateness
04/03/2014	17:30	1hr (18:30)	Meeting with Ruth Miller	Ruth's home	Discussed NHMRC grant, current research and practical aspects of recruitment and follow-up for proposal
24/03/2014	12:30	1hr (13:30)	Meeting with Jeffrey Newchurch	KC Office	Discussed current research to ensure cultural appropriateness
24/04/2014	11:30	1hr (12:30)	Meeting with Jeffrey Newchurch	KC Office	Discussed current research to ensure cultural appropriateness
01/05/2014	09:30	2hrs (11:30)	Meeting with Gillian Gould, tobacco	KC Office	Discussed overlapping research, how best to collaborate in

Date	Time	Duration (end time)	Meeting/networking	Location of event	Outcome
			research from NSW specialising in Aboriginal and TSI health		future studies, direction of health promotion for anti-tobacco messages in Aboriginal and TSI health, discussed multiple co-authored publications to be done together and grant applications
16/05/2014	08:30	10hr (18:30)	Met with other researchers, medical professionals and students attending the American Thoracic Society conference	San Diego, USA, Convention Centre	Attended various conference presentations and group discussions during poster sessions about research in respiratory medicine and tobacco from around the world
17/05/2014	08:30	10hr (18:30)	Met with other researchers, medical professionals and students attending the American Thoracic Society conference	San Diego, USA, Convention Centre	Attended various conference presentations and group discussions during poster sessions about research in respiratory medicine and tobacco from around the world
18/05/2014	08:30	10hr (18:30)	Met with other researchers, medical professionals and students attending the American Thoracic Society conference	San Diego, USA, Convention Centre	Presented and attended various conference presentations and group discussions during poster sessions about research in respiratory medicine and tobacco from around the world
19/05/2014	08:30	10hr (18:30)	Met with other researchers, medical professionals and students attending the American Thoracic Society conference	San Diego, USA, Convention Centre	Presented and attended various conference presentations and group discussions during poster sessions about research in respiratory medicine and tobacco from around the world
20/05/2014	08:30	10hr (18:30)	Met with other researchers, medical professionals and students attending the American Thoracic Society conference	San Diego, USA, Convention Centre	Attended various conference presentations and group discussions during poster sessions about research in respiratory medicine and tobacco from around the world; had networking meeting with Dr Smita Shah and attended the

Date	Time	Duration (end time)	Meeting/networking	Location of event	Outcome
					Health Promotion experts meeting
21/05/2014	08:30	10hr (18:30)	Met with other researchers, medical professionals and students attending the American Thoracic Society conference	San Diego, USA, Convention Centre	Attended various conference presentations and group discussions during poster sessions about research in respiratory medicine and tobacco from around the world
23/05/2014	10:30	1hr (11:30)	Met with Dr Dee Burton from City University of New York, Hunter College, Manhattan	Hunter College, Dee's office, New York, Manhattan	Met to discuss tobacco related research underway in America and how a collaboration could be formed between Adelaide and New York; Tobacco cessation interventions amongst the high risk incarcerated population were considered as a new collaborative Cochrane review option
26/05/2014	12:00	2hr (14:00)	Met with Dr Shadi Nahvi from The Albert Einstein Institute, New York, The Bronx	The Albert Einstein Institute, New York, The Bronx	Discussed the possibility of collaboration; Spoke about current practices in the New York health sector and the Albert Einstein Institute in particular with the high volume of substance abusers and process for rehabilitation; Agreed to be part of new Cochrane review
12/06/2014	10:00	1hr (11:00)	Meeting with Jeffrey Newchurch	KC Office	Discussed current research to ensure cultural appropriateness
17/07/2014	11:20	20min (11:40)	Interview with NHMRC over the phone as short listed applicant for the Translating Research In to Practice (TRIP) Fellowship	Telephone interview	Answered questions about my TRIP application from the panel of assessors; Application was successful and received funding for 2015 for the project 'Training health professionals in smoking cessation for Aboriginal and TSI Australians'
21/08/2014	11:00	1hr (12:00)	Meeting with Jeffrey Newchurch	KC Office	Discussed current research to ensure cultural appropriateness

Date	Time	Duration (end time)	Meeting/networking	Location of event	Outcome
30/09/2014	11:30	1hr (12:30)	Meeting with Jeffrey Newchurch	KC Office	Discussed current research to ensure cultural appropriateness
03/11/2014	17:30	1hr (18:30)	Meeting as part of Transforming Health with other SA Health Young Professionals Group members	North Terrace meeting room	Participated in discussion about Transforming Health with other members of the Young Professionals Group; asked a question to the Health Minister Hon. Jack Snelling about how research fits into the model and gave two examples of my work; from this summary he requested to meet again to discuss the results further (follow-up meeting with the Minister who visited TQEH specifically for research showcase occurred 23/06/2015)
16/01/2015	12:00	3hr (15:00)	Australia Day Lunch to celebrate winning the start of Australia Day festivities	Adelaide Entertainment Centre	Spoke with Maurice Henderson (Fundraising Director for the Australian Labour Party) about how to effectively raise funds for research; introduced to Frank and Kathy Seeley who were possible funders for research activities
19/01/2015	12:30	1hr (13:30)	Meeting with Maurice Henderson, Fundraising Director for the Australian Labour Party	Chianti Café, Hutt Street	Successful meeting about how to attract funding for research with suggestions for contacts
24/01/2015	08:00	14hr (22:00)	As the Young Australian of the Year attended the Australia Day celebrations in Canberra with the other finalists from around the country	Canberra, multiple locations for Australia Day celebrations including Parliament	Press interview and networking opportunities with all the finalists from around the country for Australia Day

Date	Time	Duration (end time)	Meeting/networking	Location of event	Outcome
				House	
25/01/2015	08:00	16hr (00:00)	As the Young Australian of the Year attended the Australia Day celebrations in Canberra with the other finalists from around the country; spoke with the Prime Minister Tony Abbott	Canberra, multiple locations for Australia Day celebrations including Parliament House	Networking opportunities with other finalists from around the country; Morning tea with Prime Minister Tony Abbott, spoke one-on-one about my research
26/01/2015	06:30	7.5hr (14:00)	Australia Day; radio interview; Flag raising ceremony; spoke with Prime Minister Tony Abbott	Canberra, multiple locations for Australia Day celebrations	Radio interview in morning at Parliament House in the Senate for The Press Club (ABC); Flag Raising Ceremony and had one-on-one conversation about my research with the Prime Minister
03/02/2015	08:00	1hr (09:00)	Meeting with Maurice Henderson	Chianti Café, Hutt Street	Followed up Australia Day discussions and funding opportunities; spoke about meeting with potential collaborators in Canberra for various aspects of work and the possibility of funding
03/02/2015	14:30	2hr (16:30)	Meeting with John Bouilly	BHI	Discussed Aboriginal health research and the possibility of collaboration for research investigating the link between respiratory, gastroenterology and ENT health in Aboriginal Australians
19/02/2015	14:00	30min (14:30)	Meeting with Federal Education Minister Christopher Pyne	Minister Pyne's Electoral Office	Discussed research and possibility of expanding youth program in Aboriginal health; Minister Pyne agreed to place

Date	Time	Duration (end time)	Meeting/networking	Location of event	Outcome
					an application on our behalf to the National Schools Board and the Australian Academy of Sciences about the program for tobacco prevention and healthy lifestyle amongst youth
26/02/2015	15:30	1hr (16:30)	Meeting with Manager of Credit Union SA	Credit Union SA offices, King William Road	Discussed potential collaboration to expand networks for research in Aboriginal health and schools; Credit Union offered to help create links with schools and teachers for initiatives with Aboriginal health and healthy lifestyle initiatives
26/02/2015	17:30	30min (18:00)	Meeting with Health Minister the Hon. Jack Snelling	Citi Centre Building, Hindmarsh Square, Health Minister's Office	Discussed transforming health and the impact on research, spoke about SA Young Australian of the Year and my role in SA Health
02/03/2015	09:00	1hr (10:00)	Meeting with Carly Cluse from St John's Ambulance	Cotto Espresso Bar, Woodville Road	Spoke with Carly about the possibility of collaboration and including First Aid Training in the tobacco prevention and healthy lifestyle web-site for youth
03/03/2015	10:30	1hr (11:30)	Meeting with Greg from OpenBook Howden publishers	St Mary's at OpenBook Howden	Publishing company who introduced the concept of 'augmented reality' being interactive print for use in printed resources to enhance integration with electronic resources
13/03/2015	18:15	3hr (21:15)	Networking opportunity for the Premier's Adelaide Reception and official opening of the Convention	Adelaide Convention Centre	Networking opportunity; met the Mayor of several cities in Adelaide and regional locations for possible areas in which to conduct research, particularly with Aboriginal health centres

Date	Time	Duration (end time)	Meeting/networking	Location of event	Outcome
			Centre		and communities
20/03/2015	10:00	1hr (11:00)	Meeting with the CEO of the Asthma Foundation of SA (David Bedson) and Lou Williamson	TQEH, 4A Education Room	Spoke about our research, what we do in Respiratory Medicine, my PhD and possibility for collaboration; As a result I was invited to join the MASAC Board (Medical and Scientific Advisory Committee) for the Asthma Foundation of SA
29/03/2015	17:00	1hr (18:00)	Evidence Based Medicine special interest group annual business meeting	Gold Coast Convention Centre	Discussed workings of the Evidence Based Medicine special interest group; I was elected as new Primary Chairperson for the next two years commencing from the Perth 2016 meeting
30/03/2015	15:00	1hr (16:00)	TSANZ annual Indigenous Lung Health Working Party meeting	Gold Coast Convention Centre	Discussed progress with completion of policy document for the last 12 months; next requirement for the group is to establish a plenary or symposium dedicated to Indigenous Respiratory health for the 2016 Perth conference
01/04/2015	10:00	30min (10:30)	Tobacco special interest group annual business meeting	Gold Coast Convention Centre	Stepped down as chairperson; discussed the possibility of sending a letter on behalf of TSANZ to all Universities requesting mandatory training of health professionals in smoking cessation – action will be carried over to new convenors
27/04/2015	11:00	30min (11:30)	Meeting with Annapurna Noori	Maringga Turtpandi, 1 Gilles Crescent, Hillcrest	Spoke about the work underway for Aboriginal and TSI health improvements, specifically around youth tobacco prevention

Date	Time	Duration (end time)	Meeting/networking	Location of event	Outcome
					and healthy lifestyle programs; possibility of collaboration and mentoring of new PhD students

I also attended and presented at intermittent seminars within the Basil Hetzel Institute for Translational Health Research for ‘post-graduate student presentations’ and on Wednesday afternoons for ‘Weekly seminars’. In addition I regularly attended and presented at departmental meetings including Thursday morning Unit meeting from 08:30 to 09:30 at The Queen Elizabeth Hospital. There were also regular meetings and teleconferences with post-graduate supervisors Professor Brian Smith, Professor Adrian Esterman, Professor Matthew Peters and Dr Antony Veale

Appendix 4 Log of training, seminars and workshops attended

#	Date	Time	Duration (end time)	Training/seminar/workshop	Location of event	Outcome
	25/02/2011	08:50	4hr (13:00)	University of Adelaide Induction program	Napier Building, University of Adelaide	Induction program for candidature
	16/03/2011	11:00	1hr (12:00)	Barr Smith Library meeting at University of Adelaide with Mick Draper	Barr Smith Library, UoA	Library meeting to learn literature searching skills and to identify available resources
	18/03/2011	12:00	2hr (14:00)	Uni Course – Getting started on reviewing literature	Adelaide Graduate Centre Seminar Room	Course on how to review literature
	25/03/2011	12:00	2hr (14:00)	Uni Course – Effective Writing strategies	Adelaide Graduate Centre Seminar Room	Course on how to write for reports and publications and writing structures
	30/03/2011	16:00	1hr (17:00)	Uni orientation for School of Medicine, Discipline of Medicine	Discipline of Medicine Seminar Room, Eleanor Harrald Building	Orientation for discipline of medicine – 3 publications usually expected for thesis by publication
	13/04/2011	16:00	1hr (17:00)	Higher Degree by Research thesis content detail presentation with David Callen	Discipline of Medicine Seminar Room, Eleanor Harrald Building, 6 th Floor	Guide to what content should be included in a thesis by publication, including forms to be signed, requirements before submission and guide to content
	02/05/2011	13:00	2hr (15:00)	Workshop – EndNote training session for beginners	UoA, Nexus, 10 Pulteney St, Level 2, Lab 20, Computer	Learnt beginners EndNote software for literature referencing

#	Date	Time	Duration (end time)	Training/seminar/workshop	Location of event	Outcome
					Suite 1	
	09/05/2011	14:00	2hr (16:00)	Uni Course – Preparing and presenting seminars	UoA Graduate Centre Seminar Room, Adelaide	Course on how to prepare for and present oral and poster research presentations
	18/05/2011	12:30	1hr (13:30)	Occupational Health and Safety Course Induction for the BHI	TQEH, 6A Main Building, Discipline of Surgery	Attended OH+S induction course for post-graduate students doing research at the BHI and TQEH
	19/05/2011	10:00	2.5hr (12:30)	EndNote training session – Intermediate level	UoA, Nexus, 10 Pulteney St, Level 2, Lab 20, Compu Suite 1	Learnt intermediate Endnote software for literature referencing
	02/06/2011	16:00	1hr (17:00)	Meeting with Prof Adrian Esterman for Uni Update	University of South Australia, North Tce, Adelaide	Meeting to discuss progress and to go through manuscript corrections
	15/06/2011	10:00	1.5hr (11:30)	UoA Hazard Management Course with David Callen	UoA Napier Building, Adelaide	Course about hazard management and risk assessment during candidature
	01/07/2011	09:00	8hr (17:00)	Cochrane Symposium and workshops at Monash University	Cochrane training workshop - Melbourne	Attended Cochrane symposium to learn the latest skills in conducting Cochrane reviews
	11/07/2011	10:00	2hr (12:00)	Basic statistics and research methods course	University of Adelaide Engineering South S112	Learnt basic statistics and research methods
	12/07/2011	10:00	2hr (12:00)	Basic statistics and research methods course	University of Adelaide Engineering South S112	Learnt basic statistics and research methods
	13/07/2011	10:00	2hr (12:00)	Basic statistics and research methods course	University of Adelaide Engineering South S112	Learnt basic statistics and research methods
	14/07/2011	10:00	2hr (12:00)	Basic statistics and research methods course	University of Adelaide Engineering South S112	Learnt basic statistics and research methods

#	Date	Time	Duration (end time)	Training/seminar/workshop	Location of event	Outcome
				course	Engineering South S112	
	15/07/2011	10:00	2hr (12:00)	Basic statistics and research methods course	University of Adelaide Engineering South S112	Learnt basic statistics and research methods
	15/07/2011	14:00	2hrs (16:00)	SPSS training linked with weeklong statistics course	University of Adelaide Engineering South S112	Learnt basic SPSS usage with practice data
	20/07/2011	12:00	1hr (13:00)	Occupational Health and Safety Course Induction for The Queen Elizabeth Hospital	6A Main Building, The Queen Elizabeth Hospital	Basic induction for TQEH
	01/08/2011	14:00	2hr (16:00)	How to ask questions about statistics	The University of Adelaide	Learnt basic questions to ask when determining appropriate statistics methods
	15/08/2011	13:00	4hr (17:00)	Writing a paper for publication: papers that analyse primary data	The University of Adelaide, Level 6 Grenfell Street, Adelaide Graduate Centre	Practiced writing techniques for publishing research
	27/09/2011	18:00	1.5hr (19:30)	Attended University of Adelaide presentation 'Eating for two – nutrition in pregnancy'	The University of Adelaide, Elder Hall	Networking event and information about nutrition during pregnancy as it was being considered as a component of the PhD
	08/12/2011	13:00	1hr (14:00)	Attended presentation about 'Options and processes for PhD by publication'	University of Adelaide, Discipline of Medicine Seminar Room, Eleanor Harrald Building	Gained information about processes for conducting a PhD by publication based on criteria from the Discipline of Medicine

#	Date	Time	Duration (end time)	Training/seminar/workshop	Location of event	Outcome
	13/02/2012	13:00	2hr (15:00)	Statistics for research students	University of Adelaide, Horace Lamb Lecture Theatre	Learnt basic statistics for research studies and projects
	14/02/2012	13:00	2hr (15:00)	Statistics for research students	University of Adelaide, Horace Lamb Lecture Theatre	Learnt basic statistics for research studies and projects
	15/02/2012	13:00	2hr (15:00)	Statistics for research students	University of Adelaide, Horace Lamb Lecture Theatre	Learnt basic statistics for research studies and projects
	16/02/2012	13:00	2hr (15:00)	Statistics for research students	University of Adelaide, Horace Lamb Lecture Theatre	Learnt basic statistics for research studies and projects
	17/02/2012	13:00	2hr (15:00)	Statistics for research students	University of Adelaide, Horace Lamb Lecture Theatre	Learnt basic statistics for research studies and projects
	22/02/2012	12:30	1hr (13:30)	Attended Hon. John Hill (Health Minister) presentation about hospital budgets for TQEH	TQEH, Level 2 lecture theatre	Had prepared a one page document about the results of the STOP smoking trial, approached the minister after his talk to discuss the results; he asked if it would be okay to present these results to Parliament; additional meetings organised as a result to discuss smoking cessation policy and funding for Aboriginal health in particular
	29/03/2012	09:00	12hr (21:00)	TSANZ annual scientific meeting in Canberra	Canberra Convention Centre	Watched other oral and poster presentations at the annual scientific conference, spoke with other researchers and investigators about potential

#	Date	Time	Duration (end time)	Training/seminar/workshop	Location of event	Outcome
						collaborations
	30/03/2012	09:00	12hr (21:00)	TSANZ annual scientific meeting in Canberra	Canberra Convention Centre	Watched other oral and poster presentations at the annual scientific conference, spoke with other researchers and investigators about potential collaborations
	31/03/2012	09:00	12hr (21:00)	TSANZ annual scientific meeting in Canberra	Canberra Convention Centre	Watched other oral and poster presentations at the annual scientific conference, spoke with other researchers and investigators about potential collaborations
	01/04/2012	09:00	12hr (21:00)	TSANZ annual scientific meeting in Canberra	Canberra Convention Centre	Watched other oral and poster presentations at the annual scientific conference, spoke with other researchers and investigators about potential collaborations
	02/04/2012	09:00	12hr (21:00)	Presented oral at the national ASM for TSANZ about training health professionals in smoking cessation Cochrane review	Canberra Convention Centre	Watched other oral and poster presentations at the annual scientific conference, spoke with other researchers and investigators about potential collaborations and presented oral for the Evidence Based Medicine special interest group
	03/04/2012	09:00	12hr (21:00)	Presented oral at the national ASM for TSANZ about Indigenous tobacco	Canberra Convention Centre	Presented oral, award winning presentation for the Tobacco Control prize and watched other oral and

#	Date	Time	Duration (end time)	Training/seminar/workshop	Location of event	Outcome
				cessation Cochrane review		poster presentations at the annual scientific conference, spoke with other researchers and investigators about potential collaborations
	04/04/2012	08:00	4hr (12:00)	TSANZ annual scientific meeting in Canberra	Canberra Convention Centre	Attended the final oration and spoke with other researchers and investigators about potential collaborations
	11/04/2012	12:00	1hr (13:00)	Seminar about preparing a thesis by publication presented by the school of medicine, David Callen	The University of Adelaide	Gained greater insight into the requirements of preparing a thesis by publication
	19/04/2012	13:30	2.5hr (16:00)	Managing a higher degree by research thesis with Word 2007 – Level 1 workshop	The University of Adelaide, Information Technology Training Room 2, Level 9 Gawler Place	Learnt the basic skills for writing a PhD thesis in word such as applying styles, table of contents and dealing with a large document
	17/05/2012	09:15	2.5hr (11:45)	Managing a higher degree by research thesis with Word 2007 – Level 2 workshop	The University of Adelaide, Information Technology Training Room 2, Level 9 Gawler Place	Skills training building on the Level 1 workshop from the previous month
	31/07/2012	12:15	1hr (13:15)	Grand round presentation about Diabetes and associated conditions in Indigenous health	TQEH, Level 2 seminar room	Presentation by Professor Kerin O’Dea – Professor of Population Health and Nutrition at the University of South Australia, interesting perspective of her

#	Date	Time	Duration (end time)	Training/seminar/workshop	Location of event	Outcome
						involvement in doing research as a non-Indigenous person and the perceptions of research in remote communities and how she overcame these issues
	08/08/2012	09:00	8hr (17:00)	Tobacco control forum with tobacco experts from across South Australia, organised by Jacinta Freeman (Public Health Advocacy Institute of WA) and Mike Daube (leading tobacco expert)	Greenhill Road, government building	Full day forum and workshop about tobacco policy, how to influence policy and make successful change, presentations by leading tobacco researchers from around the country including Professor Mike Daube and Indigenous researchers, Damien Shen's work was of interest in particular, who I asked to make follow-up meetings with to discuss his anti-smoking media campaigns for Indigenous populations
	10/08/2012	09:00	5.5hr (15:30)	Anglicare Research to Practice seminar – Aboriginal engagement	Adelaide Pavilion conference and function rooms, South Terrace	Presenters included Daryle Rigney (Flinders University capacity building), Ian Goodwin-Smith (Anglicare living beyond Aboriginal suicide), Paul Monaghan (UoA language revival), Sonia Waters (Anglicare about research to practice), Deirdre Tedmanson (Uni SA capacity building and Aboriginal engagement) and Klynton Wanganeen (former commissioner for Aboriginal Engagement).

#	Date	Time	Duration (end time)	Training/seminar/workshop	Location of event	Outcome
						Spoke with Sonia and Klynton about their presentations after the event and they agreed to meet with me to discuss my research further
	27/09/2012	10:00	9hr (19:00)	Cochrane Colloquium in New Zealand	New Zealand, Auckland, Hyatt Hotel	Attended the annual Cochrane Colloquium; watched presentations about meta-analysing data, evidence based medicine, how to disseminate evidence and presentation in lay summaries to enable easy reading of scientific articles
	28/09/2012	10:00	9hr (19:00)	Cochrane Colloquium in New Zealand	New Zealand, Auckland, Hyatt Hotel	Attended the annual Cochrane Colloquium; watched presentations about meta-analysing data, evidence based medicine, how to disseminate evidence and presentation in lay summaries to enable easy reading of scientific articles
	29/09/2012	10:00	9hr (19:00)	Cochrane Colloquium in New Zealand	New Zealand, Auckland, Hyatt Hotel	Attended the annual Cochrane Colloquium; watched presentations about meta-analysing data, evidence based medicine, how to disseminate evidence and presentation in lay summaries to enable easy reading of scientific articles
	30/09/2012	08:00	4hr (12:00)	Workshop as part of Cochrane Colloquium on 'How to get published	New Zealand, Auckland, Hyatt Hotel	Learnt how to write a publication, presented some of my research in front of the group (a manuscript I

#	Date	Time	Duration (end time)	Training/seminar/workshop	Location of event	Outcome
				in high impact journals' presented by the chief editor of the British Medical Journal (Richard Smith)		was working on to do with Indigenous health) and received group feedback; learnt about other forms of publishing outside of peer reviewed publications and the importance of this
	30/09/2012	10:00	9hr (19:00)	Cochrane Colloquium in New Zealand	New Zealand, Auckland, Hyatt Hotel	Attended the annual Cochrane Colloquium; watched presentations about meta-analysing data, evidence based medicine, how to disseminate evidence and presentation in lay summaries to enable easy reading of scientific articles
	01/10/2012	10:00	9hr (19:00)	Cochrane Colloquium in New Zealand	New Zealand, Auckland, Hyatt Hotel	Attended the annual Cochrane Colloquium; watched presentations about meta-analysing data, evidence based medicine, how to disseminate evidence and presentation in lay summaries to enable easy reading of scientific articles
	08/02/2013	09:30	7hr (16:30)	SAHMRI Aboriginal Health Research Workshop	Rydges South Park, Level 6 South Terrace, Adelaide	Attended the SAHMRI workshop about requirements for research in Aboriginal and TSI health, cultural sensitivity and the needs to effective research dissemination
	21/02/2013	16:00	2hr (18:00)	Introduction to qualitative social research approaches	Pulteney Street	University of Adelaide course for qualitative research approaches training on how to design and

#	Date	Time	Duration (end time)	Training/seminar/workshop	Location of event	Outcome
						analyse research
	23/03/2013	08:00	8hr (16:00)	TSANZ Darwin conference	Darwin convention centre	Attended presentations, seminars and symposiums about respiratory research studies and work
	24/03/2013	08:00	8hr (16:00)	TSANZ Darwin conference	Darwin convention centre	Attended presentations, seminars and symposiums about respiratory research studies and work
	25/03/2013	08:00	8hr (16:00)	TSANZ Darwin conference	Darwin convention centre	Attended presentations, seminars and symposiums about respiratory research studies and work and presented at the conference
	26/03/2013	08:00	8hr (16:00)	TSANZ Darwin conference	Darwin convention centre	Attended presentations, seminars and symposiums about respiratory research studies and work and presented at the conference
	27/03/2013	08:00	8hr (16:00)	TSANZ Darwin conference	Darwin convention centre	Attended presentations, seminars and symposiums about respiratory research studies and work and presented at the conference
	24/05/2013	10:00	1hr (11:00)	Information session for scholarships at the University of Adelaide	115 Grenfell Street, Adelaide	Attended seminar about scholarship information session, what is required and options for applying
	28/05/2013	19:00	2hr (21:00)	2013 Lowita O'Donoghue Oration 'Healing the fault lines: uniting politicians, bureaucrats and NGO's for improved outcomes in Aboriginal	Bonython Hall, North Terrace Adelaide	Met and spoke with Lowita O'Donoghue; interesting perspective on the current health system with a request by the speaker for more evaluation to occur alongside existing programs so that we know

#	Date	Time	Duration (end time)	Training/seminar/workshop	Location of event	Outcome
				Health'		what is working – exact statement I have made with my research
	29/05/2013	17:30	2.5hr (20:00)	Grant writing workshop University of Adelaide	IPAS seminar room, Level 2 Braggs building	Training on how to effectively write grant applications and what assessors are looking for in a good application
	30/05/2013	09:30	2hr (11:30)	SA Aboriginal Research Network meeting	Tandanya Grenfell Street	Discussed research in Aboriginal communities in South Australia; what research is underway, what needs to be done for good research practices and where to from here in new activities
	24/06/2013	15:00	1hr (16:00)	3MT (minute thesis) information session for The University of Adelaide	Faculty of Health Sciences Board Room, Barr Smith South	Information session about what is required in the 3MT competition
	10/07/2013	17:00	3 hrs (20:00)	Attended 'The Task Force Story', recalling 40 years of tertiary education for Aboriginal and TSI people presented by Sharon Meagher: Aboriginal Elder	Kerry Packer Gallery, Uni SA City West Campus	Networking and educational event; Invited by Sharon Meagher
	12/07/2013	09:00	3.5hr (12:30)	Attended NVivo10 Beginners Workshop 'A' for qualitative analyses	Nexus 10, 207 Computer Suite 4, Level 2 Pulteney St, Adelaide	NVivo used for qualitative analysis of focus groups and interviews
	19/07/2013	13:45	1hr	KC interviewed for the Catherine Helen Spence Memorial Scholarship	Department of Education and Child Development; 31 Flinders	Interview organised by Pam Quick for the Memorial Scholarship committee – application

#	Date	Time	Duration (end time)	Training/seminar/workshop	Location of event	Outcome
				for research into Aboriginal health	St, Adelaide	unsuccessful
	19/07/2013	09:00	3.5hr (12:30)	Attended NVivo10 Beginners Workshop 'B' for qualitative analyses	Nexus 10, 207 Computer Suite 4, Level 2 Pulteney St, Adelaide	NVivo used for qualitative analysis of focus groups and interviews
	23/07/2013	09:00	3hr (12:00)	Attended the Aboriginal Health Network Meeting organised by Prof Alex Brown, director of Aboriginal Health Unit, SAHMRI	Tauondi Aboriginal Community College	Networking and discussion; introduced myself to Dr Jenny Baker who agreed to meet with me to discuss the research and Kathy Mott from SAHMRI asked for my details to meet at a later date
	26/07/2013	09:00	3.5hr (12:30)	Attended NVivo10 Beginners Workshop 'C' for qualitative analyses	Nexus 10, 207 Computer Suite 4, Level 2 Pulteney St, Adelaide	NVivo used for qualitative analysis of focus groups and interviews
	29/08/2013	13:00	1hr (14:00)	Attended Adelaide University Post-graduate conference – Workshop 'Taking Culture into Account': Dr Michael Wilmore, Discipline of Media	Wine Centre of South Australia	Workshop about identifying culture in health care and the importance of this in general practice
	29/08/2013	14:30	1hr (15:30)	Attended Adelaide University Post-graduate conference – Workshop 'What health professionals need to know about social media': Dr Michael Wilmore, Discipline of Media	Wine Centre of South Australia	Workshop about the use, importance and pitfalls of social media in healthcare for use by health professionals
	27/08/2013	14:30	-	First contact with Gillian Gould via research gate – PhD student in	Internet and e-mail correspondence	Multiple e-mail and internet correspondence regarding potential collaboration, possibility of

#	Date	Time	Duration (end time)	Training/seminar/workshop	Location of event	Outcome
				Aboriginal health based at James Cook University NSW		writing articles together including Cochrane update; additional review of evidence, Indigenous specific theoretical approach to tobacco paper and possible NHMRC early career research grant
	25/09/2013	21:00	1hr (22:00)	Sent e-mails to potential participants for focus groups and people to consult with research following SAHMRI workshops	e-mail correspondence	Networking to meet and discuss current research and potential collaborations further: Dr John Bouilly – GP with interest in Aboriginal and respiratory health; Lauren Maksimovic – Evaluation Officer for the Cancer Council of SA; Jeffrey Newchurch – Aboriginal Elder with interest in men’s health research; A/Prof Jenny Baker – Associate Professor Aboriginal Health
	27/09/2013	09:30	12hr (19:30)	TSANZ SA/NT branch annual general meeting	Ayres House, North Terrace, Adelaide	Annual general meeting for respiratory related research
	17/12/2013	10:00	7hr (17:00)	R training course	The University of Adelaide	Workshop on how to analyse data using 'R'
	18/12/2013	10:00	3hr (13:00)	R training course	The University of Adelaide	Workshop on how to analyse data using 'R'
	04/04/2014	08:30	10hr (18:30)	TSANZ Adelaide conference	Adelaide convention centre	Attended presentations, seminars and symposiums about respiratory research studies and work
	05/04/2014	08:30	10hr (18:30)	TSANZ Adelaide conference	Adelaide convention centre	Attended presentations, seminars and symposiums about respiratory research studies and work

#	Date	Time	Duration (end time)	Training/seminar/workshop	Location of event	Outcome
	06/04/2014	08:30	10hr (18:30)	TSANZ Adelaide conference	Adelaide convention centre	Attended presentations, seminars and symposiums about respiratory research studies and work and presented
	07/04/2014	08:30	10hr (18:30)	TSANZ Adelaide conference	Adelaide convention centre	Attended presentations, seminars and symposiums about respiratory research studies and work and presented
	08/04/2014	08:30	10hr (18:30)	TSANZ Adelaide conference	Adelaide convention centre	Attended presentations, seminars and symposiums about respiratory research studies and work
	09/04/2014	08:00	4hr (12:00)	TSANZ Adelaide conference	Adelaide convention centre	Attended presentations, seminars and symposiums about respiratory research studies and work and presented
	16/05/2014	08:30	10hr (18:30)	Met with other researchers, medical professionals and students attending the American Thoracic Society conference	San Diego, USA, Convention Centre	Attended various conference presentations and group discussions during poster sessions about research in respiratory medicine and tobacco from around the world
	17/05/2014	08:30	10hr (18:30)	Met with other researchers, medical professionals and students attending the American Thoracic Society conference	San Diego, USA, Convention Centre	Attended various conference presentations and group discussions during poster sessions about research in respiratory medicine and tobacco from around the world
	18/05/2014	08:30	10hr (18:30)	Met with other researchers, medical	San Diego, USA, Convention	Presented and attended various conference

#	Date	Time	Duration (end time)	Training/seminar/workshop	Location of event	Outcome
				professionals and students attending the American Thoracic Society conference	Centre	presentations and group discussions during poster sessions about research in respiratory medicine and tobacco from around the world
	19/05/2014	08:30	10hr (18:30)	Met with other researchers, medical professionals and students attending the American Thoracic Society conference	San Diego, USA, Convention Centre	Presented and attended various conference presentations and group discussions during poster sessions about research in respiratory medicine and tobacco from around the world
	20/05/2014	08:30	10hr (18:30)	Met with other researchers, medical professionals and students attending the American Thoracic Society conference	San Diego, USA, Convention Centre	Attended various conference presentations and group discussions during poster sessions about research in respiratory medicine and tobacco from around the world; Had networking meeting with Dr Smita Shah and attended the Health Promotion experts meeting
	21/05/2014	08:30	10hr (18:30)	Met with other researchers, medical professionals and students attending the American Thoracic Society conference	San Diego, USA, Convention Centre	Attended various conference presentations and group discussions during poster sessions about research in respiratory medicine and tobacco from around the world
	19/06/2014	18:00	3.5hr (21:30)	SA/NT TSANZ branch scientific evening presentation dinner; Sleepy apnoea and respiratory medicine	Adelaide Pavilion	Learnt about the impact of sleep apnoea on functional capacity and mandatory reporting of apnoea on road safety

#	Date	Time	Duration (end time)	Training/seminar/workshop	Location of event	Outcome
	22/08/2014	09:00	3.5hr (12:30)	Attended NVivo10 Beginners Workshop 'A' for qualitative analyses	Nexus 10, 207 Computer Suite 4, Level 2 Pulteney St, Adelaide	NVivo used for qualitative analysis of focus groups and interviews
	29/08/2014	09:00	3.5hr (12:30)	Attended NVivo10 Beginners Workshop 'B' for qualitative analyses	Nexus 10, 207 Computer Suite 4, Level 2 Pulteney St, Adelaide	NVivo used for qualitative analysis of focus groups and interviews
	02/09/2014	09:00	8.5hr (17:30)	Aboriginal Health Research Showcase organised by Prof Alex Brown, SAHMRI	SAHMRI building, North Tce, Adelaide	Showcase of research programs of SA's institutions and organisations by senior researchers and leaders organised by SAHMRI
	03/09/2014	09:00	8.5hr (15:30)	Aboriginal Health Research Showcase with workshop components: organised by Prof Alex Brown, SAHMRI	SAHMRI building, North Tce, Adelaide	9am-1pm Presentations by up-and-coming Aboriginal and TSI researchers 1pm-5:30pm skill development workshops and discussion sessions (1 st workshop: Discussions around intercultural communication and community engagement; 2 nd workshop: Writing for publication)
	05/09/2014	09:00	3.5hr (12:30)	Attended NVivo10 Beginners Workshop 'C' for qualitative analyses	Nexus 10, 207 Computer Suite 4, Level 2 Pulteney St, Adelaide	NVivo used for qualitative analysis of focus groups and interviews
	22/09/2014	09:00	8hr (17:00)	Intercultural awareness and competency training (The University of Adelaide)	University of Adelaide, Level 1, Schultz Building	Welcome to country, who are Aboriginal and TSI people, terminology, protocols and resources
	28/03/2015	10:00	9.5hr (19:30)	TSANZ annual scientific meeting on the Gold Coast	Gold Coast Convention Centre	Watched other oral and poster presentations at the annual scientific conference, spoke with other

#	Date	Time	Duration (end time)	Training/seminar/workshop	Location of event	Outcome
						researchers and investigators about potential collaborations; Australian Cochrane Airways Group Network annual meeting; Annual General Meeting of the TSANZ; received letter of congratulations during the welcome reception for being named the Young Australian of the Year for SA
	29/03/2015	09:00	12hr (21:00)	TSANZ annual scientific meeting on the Gold Coast	Gold Coast Convention Centre	Watched other oral and poster presentations at the annual scientific conference, spoke with other researchers and investigators about potential collaborations; special interest group annual meeting for convenors; chaired poster session for joint Population Health and Tobacco special interest groups; gave two oral presentations in the Evidence Based Medicine special interest group session; attended the Evidence Based Medicine annual business meeting – elected as primary Chairperson during the meeting
	30/03/2015	08:00	12hr (21:00)	TSANZ annual scientific meeting on the Gold Coast	Gold Coast Convention Centre	Watched other oral and poster presentations at the annual scientific conference, spoke with other researchers and investigators about potential

#	Date	Time	Duration (end time)	Training/seminar/workshop	Location of event	Outcome
						collaborations; Chaired the Indigenous lung health working party meeting
	31/03/2015	09:00	12hr (21:00)	TSANZ annual scientific meeting on the Gold Coast	Gold Coast Convention Centre	Watched other oral and poster presentations at the annual scientific conference, spoke with other researchers about potential collaborations and presented poster for gastro-oesophageal reflux treatment for asthma; co-chaired oral session for Cell COPD with Brian Smith; President's Cocktail Party and Conference dinner
	01/04/2015	08:00	9hr (17:00)	TSANZ annual scientific meeting on the Gold Coast	Gold Coast Convention Centre	Watched other oral and poster presentations at the annual scientific conference, delivered an oral presentation for tobacco special interest group, chaired session, conducted business meeting, received Robert Pierce Grant-In-Aid for Indigenous research award during the Plenary and ran the Cochrane workshop post-conference



6 November 2012

Kristen Carson
The Bazil Hetzel Institute of Translational Research
37A Woodville Road
Woodville SA 5011

RE: Improving health for Aboriginal people through tobacco related research
REFERENCE NO: 04-12-472

Dear Kristen

Thank you for responding to the suggestions made by the committee to your research project, *Improving health for Aboriginal people through tobacco related research*.

At our last meeting your responses to the letter from the committee (10 October 2012) were accepted and the project can proceed. For networking purposes and spreading the word about your project, the committee suggested that you engage with other projects and structures focussed on tobacco issues, such as the SA Tackling Smoking Working Group, the Cancer Council SA and Menzies School of Health Research.

In accordance with the NHMRC guidelines, *National Statement on Ethical Conduct in Research Involving Humans*, we require at regular periods, at least annually, reports from principal researcher(s). An 'Annual Progress or Final Report' template is available at: <http://www.ahcsa.org.au/research-ethics/>

If you require any further information please do not hesitate to contact the Executive Officer or myself. We wish you well with the project and look forward to receiving a copy of your report.

Sincerely yours



MS LUCY EVANS
CHAIRPERSON

Ref: Acknowledgement/Acceptance of Suggestions/1November2012



AHREC is a sub-committee of AHC SA

9 King William Road, Unley SA 5061 - PO Box 601, Unley SA 5061
Tel: (08) 8421 2400 Fax: (08) 8421 2499 Email: office@ahcsa.org.au Website: www.ahcsa.org.au



Human Research Governance Office (TQEH/LMH/MH)
Basil Hetzel Institute
DX465101
The Queen Elizabeth Hospital
28 Woodville Road
Woodville South SA 5011
Telephone: 08 8222 8019

21 March 2013

Ms Kristin V. Carson
DX 465154; The Clinical Practice Unit
The Queen Elizabeth Hospital
28 Woodville Road
Woodville South, SA, 5011

Dear Ms Carson

HREC reference number: HREC/13/SAH/6

SSA reference number: SSA/13/TQEHLMH/44

Project title: Advancing the understanding of tobacco use, prevention, cessation and related illnesses in Indigenous populations, with particular reference to Aboriginal Australians

RE: Site Specific Assessment Review

Thank you for submitting an application for authorisation of the above project. I am pleased to inform you that authorisation has been granted for this study to commence at the following site:

- The Queen Elizabeth Hospital (TQEH)

The following conditions apply to the authorisation of this research project. These are additional to those conditions imposed by the Human Research Ethics Committee that granted ethical approval to this project:

1. Notification of extensions to ethics approval granted by the lead HREC are to be provided to the Research Governance Officer.
2. Notification of completion of the study at TQEH is to be provided to the Research Governance Officer.
3. Confidentiality of the research subjects shall be maintained at all times as required by law.

Should you have any queries about the consideration of your Site Specific Assessment form, please contact me on 08 8222 8019 or geh.ethics@health.sa.gov.au
The SSA reference number should be quoted in any correspondence about this matter.

ALISON BARR
A/Research Governance Officer (TQEH/LMH/MH)



14 March 2008

A/Professor B Smith
Respiratory Medicine
The Queen Elizabeth Hospital

The Queen Elizabeth Hospital
28 Woodville Road
WOODVILLE SOUTH SA 5011
Lyell McEwin Hospital
Haydown Road
ELIZABETH VALE SA 5112

Dear A/Professor Smith Application Number 2008012

The Ethics of Human Research Committee Chairman has considered additional information to your protocol entitled:

"Smoking Termination Opportunity for inPatients (STOP)"

The following documents have been reviewed and approved:

- CNAHS Ethics of Human Research Committee (TQEH & LMH) Application Form
- Letter of Amendment to Protocol Design [Author: Prof B Smith] dated 03 March 2008
- Patient Information Sheet and Consent Form, Version 1 dated 06 March 2008

Approval Status: **FINAL**

Period of Approval: **14 March 2008 – 14 March 2009**

***Please note the terms under which Ethical approval is granted:**

1. Researchers are required to immediately report to the Ethics of Human Research Committee anything which might warrant review of ethical approval of the protocol, including:
 - a) serious or unexpected adverse effects on participants;
 - b) proposed changes in the protocol; and
 - c) unforeseen events that might affect continued ethical acceptability of the project
2. Protocols are approved for up to twelve months only and a report is required at the end of the study or 12 month period. Extensions will not be granted without a report to the Committee.
3. Confidentiality of the research subjects shall be maintained at all times as required by law
4. All research subjects shall be provided with a Patient Information Sheet and Consent Form, unless otherwise approved by the Committee
5. The Patient Information Sheet and Consent Form shall be printed on the relevant site letterhead stating the contact details for the researchers
6. The Patient Information Sheet must state that the Executive Officer can be contacted for information regarding conduct of the study, policies and procedures, or if the participant wishes to make a confidential complaint
7. A report and a copy of any published material should be forwarded to the Committee at the completion of the project.

Dr Timothy Mathew
Chairman
Ethics of Human Research Committee (TQEH & LMH)



21 April 2009

**A/Prof B Smith
Head Respiratory Medicine
Clinical Practice Unit
THE QUEEN ELIZABETH HOSPITAL**

Attention: Kristin Carson

**Royal Adelaide
Hospital**

North Terrace
Adelaide SA 5000
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Research Ethics Committee

Level 3, Hanson Institute
Tel (08) 8222 4139
Fax (08) 8222 3035
Email:
Heather.O'Dea@health.sa.gov.au

Dear A/Prof Smith,

**Re: "Smoking termination opportunity for inpatients." (STOP) project."
Version 4 (19 June 2008).
Patient Information Sheet & Consent Form, Version 2 (18 June 2008).
To Whom it may Concern – Information Letter.**

RAH PROTOCOL NO: 080520a.

I am pleased to advise that Research Ethics Committee APPROVAL is granted to the following amendments to the above project:

- **Protocol Version 2 (4 September 2008).**
- **Patient Information Sheet & Consent Form, Version 5 (20 April 2009).**

Please quote the RAH Protocol Number on all correspondence. Research Ethics Committee deliberations are guided by the NHMRC National Statement on Ethical Conduct in Human Research 2007.

The general conditions of approval follow:

- Adequate record-keeping is important. If the project involves signed consent, you should retain the completed consent forms which relate to this project and a list of all those participating in the project, to enable contact with them in the future if necessary. The duration of record retention for all research data is 15 years.
- You must notify the Research Ethics Committee of any events which might warrant review of the approval or which warrant new information being presented to research participants, including:
 - (a) serious or unexpected adverse events which warrant protocol change or notification to research participants,
 - (b) changes to the protocol,
 - (c) premature termination of the study,
 - (d) a study completion report within 3 months of the project completion.
- The Committee must be notified within 72 hours of any serious adverse event occurring at this site.
- Approval is ongoing, subject to satisfactory annual review. Investigators are responsible for providing an annual review to the RAH REC Executive Officer each year using the Annual Review Form available at: <http://www.rah.sa.gov.au/rec/index.php>

**Dr A Thornton
CHAIRMAN
RESEARCH ETHICS COMMITTEE**

One-on-one interview guide: Doctors

INTRODUCTION:

2 minutes

Welcome/what we are trying to achieve

Thank you for agreeing to do this interview. As you know we are doing research tobacco use and quitting strategies used by Aboriginal people as well as perceptions around Aboriginal healthcare, research and health priorities. We have asked you specifically because you have identified that you regularly see Aboriginal patients in your role as a doctor. Our team is trying to understand what the best strategies might be for assisting Aboriginal tobacco users to quit and to understand some of the things that currently stop that from happening and some of the things that might help. We are also interested in other areas of health to identify priorities, barriers and facilitators to health service utilisation as well as research.

Honesty/audio taping

It is very important that we get your honest opinions and the issues and topics during the interview and remember that everything discussed in this interview and your specific opinions will remain completely anonymous. We will also be audio taping the session for transcription purposes, however only the direct research team will have access to these audiotapes. You will not be individually identified in any of our presentations or publications.

Some generic probes

You mentioned _____, tell me more about that.

You mentioned _____, what was that like for you?

You talked about _____, describe that experience in as much detail as possible.

What else happened?

What were your feelings about that?

It sounds as though you had a pretty strong reaction.

It sounds like you're saying.....

1. Types of tobacco use and general tobacco use patterns

- a) How do you perceive tobacco use in Aboriginal communities? (e.g., more males or females, adults or children, Aboriginal or non-Aboriginal, lots of people or a few, differ by socio-economic status, differ by location e.g., urban, rural and regional)
- b/c) What kinds of tobacco are being used by your patients? Does it differ by age, gender or location?
- d) According to the survey by the Australian Bureau of Statistics in 2008 45% of Aboriginal people were tobacco users in Australia with 38% being non Aboriginal smokers. Is this surprising to you, or does it sound right based on your experience? Why or why not.
- f) According to the same 2008 Australian Bureau of Statistics survey a difference was found between males and female tobacco users with more females using tobacco. Does this surprise you at all? Why or why not. And why do you think this is the case?
- g) Do you think the number of tobacco users has changed since then? Why or why not.

2. Context of tobacco use

- f) According to one Australian study almost 50% of Aboriginal youth aged 14 years and over are reporting smoking on a daily basis. Is this surprising to you or does this sound right? Why or why not?

3. Pros and cons of tobacco use

- a) What do you think your Aboriginal patients believe are the advantages of smoking? What do you think they believe are the disadvantages of smoking?
- b) What are the advantages and disadvantages of using commercial chew or chewing tobacco mixed with ash?

4. Chewing tobacco mixed with ash

- c) Do you know what types of plants are used to make the ash and where do people get this from? Why do you think Aboriginal people use it?

5. Knowledge about smoking

- a) Do you think Aboriginal people see tobacco use as harmful? Why or why not
- c) Do you think they alter their behaviour around children? Do you think it is a problem that needs to be better addressed?
- d/e) In your experience, what if any health problems do Aboriginal people associate with tobacco use? If they don't why do you think this is the case?

6. Perceptions about smoking

- c/d) Do you know of any Aboriginal pregnant women that have smoked during pregnancy? If so why do you think they continued to smoke? If they stopped, what do you think motivated them and did they take up smoking again after the pregnancy?

7. Motivation to change

- a/b) Have any of your patients given up tobacco use? If so, what was their motivation?
- c) According to one report, between 2002 and 2008 we saw the first significant decline in tobacco use in Aboriginal people going from 49% down to 45%. Does this sound right to you? What do you think the reasons for this may have been?
- d) When you consult, do you always ask your Aboriginal patients about tobacco use? Why or why not?
- e) Have you ever tried to help an Aboriginal patient to give up smoking? Where you successful? Did they ask you for help or did you probe the issue with them?
- f) What advice or resources did you offer? Did the patient utilise what you provided?
- g) Do you feel confident in providing tobacco cessation advice to Aboriginal patients?
- h) Do you think this advice coming from you makes a difference? Why or why not?

8. About quitting smoking

- a) What have you found to get in the way of successful quit attempts for Aboriginal people? How do you think this can be overcome?
- c) When you think about tobacco cessation resources and strategies, what kinds of things come to mind?
- c2) If an Aboriginal person wants to quit smoking, what do you think would be the most common approach to try and achieve this? (e.g., cold turkey, seek advice from doctor or get patches from chemist, help from family or friends)
- d) Do you know if any of your Aboriginal patients ever tried nicotine replacement therapy products to help them quit such as patches, gum, inhalers or lozenges? If so, what was their experience like? Why do you think it did/didn't work for them?
- e) Have you ever heard of Champix or Chantix (varenicline tartrate) or Zyban (bupropion)? And if so, what have you heard? Have any of your Aboriginal patients ever tried using either of these products and if so, what was their experience like?
- f) Why do you think [Champix/Zyban] did/didn't work for them?

9. Other sources for quitting smoking

- a) Have you seen any of the culturally tailored Aboriginal advertising campaigns on TV, radio or posters? Do you think they work to make Aboriginal people want to try and quit smoking? Why or why not.
- c) What do you think would help Aboriginal people to make an attempt to quit smoking (Extra support from family friends, doctors, government) and why?

PROBE: Easy or hard to access? Cost?
- d) What approach do you think could currently be considered the least helpful, if any, in helping Aboriginal people quitting and why?
- e) What community assets and strengths do you think could be used to help deliver smoking cessation/prevention messages (e.g., community forums, elders acting as role models)

10. Tobacco prevention in youth

- a) Do you have any children as patients? What is the youngest Aboriginal patient you would see? Do any of them use tobacco and have you offered any resources or advice to help them quit? If so, do you think it was successful?
- a2) Do you know of any advertising or resources (such as pamphlets, posters, community campaigns etc.) that are specifically designed to help youth stop smoking or not smoke to begin with? (In schools, community groups, outside organisations). Do you have access to any of these resources as a doctor? If so what are they and if not, do you think you should?
- b) Did you know that players from the Port Adelaide Football Club visit Aboriginal communities throughout South Australia and the Northern Territory to deliver positive health messages for kids including messages about not smoking? How do you feel about this, do you think it is a good thing and will help to deliver health messages or do you think something else should be done instead?
- c) Do you think it is something that should be done more or less? Why or why not
- f) Do you know if any of your adult patients that smoke do so inside the house or around children? Why or why don't you think this is the case?

11. Health service

- a) How do you feel about the medical care provided to Aboriginal patients? Do you think it differs from care provided to non-Aboriginal people? Why or why not?
- b) Do you think medical care for Aboriginal patients has differed over time compared to treatment of non Aboriginal patients? For example have you noticed any differential treatment because of nationality? If so, why? When (if at all) do you think this changed?
- b2) Do you think Aboriginal patients need to have different types of consultations or spoken to differently during consults compared to non-Aboriginal people? If so, can you provide some example? If not, why not?
- c) Are there any outstanding events that come to mind that you would like to share?
Bad experiences or good experiences
- d) Is there anything you believe needs to happen that currently isn't occurring as part of good health care delivery for Aboriginal people?

- g) When considering the SNAP health model, being smoking, nutrition, alcohol and physical activity do you think these issues should be combined in the one health initiative or approached separately? Why?
- h) Some doctors and nurses have reported that they do not feel they have “...the skills or confidence to talk with Aboriginal patients about tobacco, and even if they did it’s not going to work so why bother.” Do you think this statement is true in healthcare today?

12. Consults

- a) During your consults with Aboriginal people do they act any differently to non-Aboriginal people? If so can you provide some examples (e.g., do you notice an increase in lack of eye contact, disinterest, not listening, more attentive)
- d) Do you feel like what you are saying is being adequately understood by your patient? If not, can you provide some examples?
- d2) Is there anything specific to your discipline that is of greater concern for Aboriginal patients compared to non-Aboriginal patients? (E.g, greater prevalence of specific conditions or diseases and if so what are they and why are they important for Aboriginal patients in particular)
- e) Would you consider any issues related to Aboriginal health to be sensitive (as in issues that may cause grievances if discussed)? If so, what are some examples?
- f) Do you think talking about smoking, alcohol, nutrition/obesity or other drug use could be considered sensitive? Why or why not?
- i) Do you think some of the precautions healthcare providers need to take around cultural sensitivity for Aboriginal people have gone too far? Why? If so, can you provide some examples?
- j) Do you think some healthcare providers need to be more culturally sensitive to Aboriginal patients? Why or why not?
- k) Do you feel confident enough in your knowledge around cultural sensitivity for Aboriginal patients?

- l) Have you ever undergone any specific training for cultural awareness? If so what? Do you think you need to or this is important?
- m) What kinds of programs would you want to see delivered around cultural sensitivity if any? Do you think it would help you with consults for Aboriginal people?

13. Research

- a/b) Are you aware of any research initiatives active in Aboriginal health? Do you know if they are currently being implemented successfully? What are some of the barriers or facilitators that you are aware of that these researchers have used/ come across?
- b) Do you think research specifically being done with Aboriginal people is important? Why or why not?
- c) What if anything would you like to see change in relation to research being conducted in Aboriginal health?
- d) Do you think it makes a difference who is conducting the research and who is involved in delivering research questions? For example do you think there would be a difference between research delivered by an Aboriginal compared to a non-Aboriginal person? Why or why not?

14. Other health problems

- a) Do you think tobacco use is a big health problem concerning Aboriginal people today?
- b) What do you think are the biggest health problems facing Aboriginal people at the moment in their eyes (e.g., heart disease, diabetes, under nutrition, alcohol abuse?)
- b2) What do you think are the biggest health problems facing Aboriginal people at the moment in your eyes (e.g., heart disease, diabetes, under nutrition, alcohol abuse?)
- b3) What do you think are the other big problems (apart from health) facing Aboriginal people at the moment (e.g., heart disease, diabetes, under nutrition, alcohol abuse?)
- c) What is currently being done and by whom to help address these health problems?

- d) Do you think doctors or healthcare workers can do more to help? What should they be doing? How often? Why do you think this will help?
- e) Is there anyone else that you can think of that could help with these health problems? What else is needed? (E.g, more resources, buildings, training, funding)
- f) In what area do you think future funding for health should be invested?
- g) Do you think racism is occurring in healthcare practices today? If so, can you provide some examples?

15. Closing comments

- a) Is there anything else you would like to tell us about tobacco use amongst Aboriginal people?
- b) Please tell us about anything else you feel is important for us to know
- c) Validate the focus group (read out a summary of the main points discussed to make sure our interpretation is accurate and reflects the views of the audience)

Thank you for your time.

One-on-one interview guide: Key stakeholders

INTRODUCTION:

2 minutes

Welcome/what we are trying to achieve

Thank you for agreeing to do this interview. As you know we are doing research tobacco use and quitting strategies used by Aboriginal people as well as perceptions around Aboriginal healthcare, research and health priorities. We have asked you specifically because you have identified that you have a role in Aboriginal health or communities. Our team is trying to understand what the best strategies might be for assisting Aboriginal tobacco users to quit and to understand some of the things that currently stop that from happening and some of the things that might help. We are also interested in other areas of health to identify priorities, barriers and facilitators to health service utilisation as well as research.

Honesty/audio taping

It is very important that we get your honest opinions and the issues and topics during the interview and remember that everything discussed in this interview and your specific opinions will remain completely anonymous. We will also be audio taping the session for transcription purposes, however only the direct research team will have access to these audiotapes. You will not be individually identified in any of our presentations or publications.

Some generic probes

You mentioned _____, tell me more about that.

You mentioned _____, what was that like for you?

You talked about _____, describe that experience in as much detail as possible.

What else happened?

What were your feelings about that?

It sounds as though you had a pretty strong reaction.

It sounds like you're saying.....

1. Types of tobacco use and general tobacco use patterns

- a) How do you see tobacco use in Aboriginal communities? (e.g., more males or females, adults or children, Aboriginal or non-Aboriginal, lots of people or a few, differ by socio-economic status, differ by location e.g., urban, rural and regional)b/c) What kinds of tobacco are currently being used in Aboriginal communities? Does it differ by age, gender or location?
- d) According to the survey by the Australian Bureau of Statistics in 2008 45% of Aboriginal people were tobacco users in Australia with 38% being non Aboriginal smokers. Is this surprising to you, or does it sound right based on your experience? Why or why not.
- f) According to the same 2008 Australian Bureau of Statistics survey a difference was found between males and female tobacco users with more females using tobacco. Does this surprise you at all? Why or why not. And why do you think this is the case?
- g) Do you think the number of tobacco users has changed since then? Why or why not.

2. Context of tobacco use

- f) According to one Australian study almost 50% of Aboriginal youth aged 14 years and over are reporting smoking on a daily basis. Is this surprising to you or does this sound right? Why or why not?

3. Pros and cons of tobacco use

- a) What do you think Aboriginal people believe are the advantages of smoking? What do you think they believe are the disadvantages of smoking? Do you think these views differ between Aboriginal people and non-Aboriginal people?
- b) What are the advantages and disadvantages of using commercial chew or chewing tobacco mixed with ash?

4. Chewing tobacco mixed with ash

- c) Do you know what types of plants are used to make the ash and where do people get this from?
- d) Why do you think people use it?

5. Knowledge about smoking

- a) Do you think Aboriginal people see tobacco use as harmful? Why or why not? Does this view differ from non-Aboriginal people?
- c) Do you think smokers alter their behaviour around children? Do you think it is a problem that needs to be better addressed?
- d/e) In your experience, what if any health problems do Aboriginal people associate with tobacco use? If they don't why do you think this is the case?

6. Perceptions about smoking

- c/d) Do you know of any Aboriginal pregnant women that have smoked during pregnancy? If so why do you think they continued to smoke? If they stopped, what do you think motivated them and did they take up smoking again after the pregnancy?
- e) At what age do you think most Aboriginal kids start smoking? Why do you think they start at this age? (e.g., seeing adults around them smoking)
- f) Do you think it is harder for Aboriginal people to give up smoking if they use alcohol and/or other drugs? Why or why not?
- f2) Can tobacco cessation initiatives work if they don't address other health problems such as alcohol and/or other drug use? Why or why not.

7. Motivation to change

- b) How do you feel about current levels of tobacco use in the community?
- c) According to one report, between 2002 and 2008 we saw the first significant decline in tobacco use in Aboriginal people going from 49% down to 45%. Does this sound right to you? What do you think the reasons for this may have been?

8. About quitting smoking

- b) What if anything are you aware of that can get in the way of successful quit attempts for Aboriginal people? How do you think this can be overcome?
- c) When you think about tobacco cessation resources and strategies, what kinds of things come to mind?
- c2) If an Aboriginal person wants to quit smoking, what do you think would be the most common approach to try and achieve this? (e.g., cold turkey, seek advice from doctor or get patches from chemist, help from family or friends)
- e/f) Do you think smoking cessation medications such as Champix or nicotine patches are used by Aboriginal people? Do you think they work? Why or why not?

9. Other sources for quitting smoking

- a) Have you seen any of the culturally tailored Aboriginal advertising campaigns on TV, radio or posters? Do you think they work to make Aboriginal people want to try and quit smoking? Why or why not.
- c) What do you think would help Aboriginal people to make an attempt to quit smoking (Extra support from family friends, doctors, government) and why?

PROBE: Easy or hard to access? Cost?
- d) What approach do you think could currently be considered the least helpful, if any, in helping Aboriginal people quitting and why?
- e) What community assets and strengths do you think could be used to help deliver smoking cessation/prevention messages (e.g., community forums, elders acting as role models)
- f) Do you think these are more or less effective in helping people to stop using tobacco than other non-tailored tobacco initiatives and are these more or less effective in helping people to stop using tobacco than non-tailored tobacco initiatives?

10. Tobacco prevention in youth

- a) Do you know of any advertising or resources (such as pamphlets, posters, community campaigns etc.) that are specifically designed to help youth stop

smoking or not smoke to begin with? (In schools, community groups, outside organisations)

- b) Did you know that players from the Port Adelaide Football Club visit Aboriginal communities throughout South Australia and the Northern Territory to deliver positive health messages for kids including messages about not smoking? How do you feel about this, do you think it is a good thing and will help to deliver health messages or do you think something else should be done instead?
- c) Do you think it is something that should be done more or less? Why or why not
- d) Currently 2-3 players go at a time for one day and take with them stickers, drink bottles, posters etc. Do you think it would be better for 1-2 players to go over two days instead? And what items would be better for the kids? Are the posters, stickers and drink bottles the best items to use to deliver messages or would something else be better? If so, what? (e.g., mini footballs instead)
- e) What do you think would be the most effective way to engage kids? If players did: a kick and catch session, classroom visits, school assemblies, tests about what they have learnt.
- f) Do you know if tobacco users will smoke inside the house or around children? Why do/why don't you think this is the case?

11. Intervention delivery modes

- a) What kinds of activities do you think would help keep tobacco users distracted from smoking, if they were part of a group of people who were also trying to quit?

12. Health service

- a) How do you feel about the medical care provided to Aboriginal patients? Do you think it differs from care provided to non-Aboriginal people? Why or why not?
- b) Do you think medical care for Aboriginal patients has differed over time compared to treatment of non-Aboriginal patients? For example have you noticed any differential treatment because of nationality? If so, why? When (if at all) do you think this changed?

- b2) Do you think Aboriginal patients need to have different types of care or be spoken to differently during healthcare visits compared to non-Aboriginal people? If so, can you provide some example? If not, why not?
- c) Are there any outstanding events that come to mind that you would like to share?
Bad experiences or good experiences
- d) Is there anything you believe needs to happen that currently isn't occurring as part of good health care delivery for Aboriginal people?
- g) When considering the SNAP health model, being smoking, nutrition, alcohol and physical activity do you think these issues should be combined in the one health initiative or approached separately? Why?
- h) Some doctors and nurses have reported that they do not feel they have "...the skills or confidence to talk with Aboriginal patients about tobacco, and even if they did it's not going to work so why bother." Do you think this statement is true in healthcare today?

13. If stakeholder is familiar with health:

- a) In your experience, during doctor consults with Aboriginal people do you think act any differently to non-Aboriginal people? If so can you provide some examples (e.g., do you notice an increase in lack of eye contact, disinterest, not listening, more attentive)
- b) Are there any differences in healthcare provision between Aboriginal people and non-Aboriginal people? If so what are they?
- d) Do you think conversations between doctors or healthcare workers are being adequately understood by Aboriginal patients? If not, can you provide some examples?
- e) Would you consider any issues related to Aboriginal health to be sensitive (as in issues that may cause grievances if discussed)? If so, what are some examples?
- f) Do you think talking about smoking, alcohol, nutrition/obesity or other drug use could be considered sensitive? Why or why not?

- i) Do you think some of the precautions healthcare providers need to take around cultural sensitivity for Aboriginal people have gone too far? Why? If so, can you provide some examples?
- j) Do you think some healthcare providers need to be more culturally sensitive to Aboriginal patients? Why or why not?
- k) Do you feel confident enough in your knowledge about cultural awareness specific to Aboriginal Australians?
- l) Have you ever undergone any specific training for cultural awareness? If so what? Do you think you need to or this is important?
- m) What kinds of programs would you want to see delivered around cultural sensitivity if any? Do you think it would help the relationship between Aboriginal people and their healthcare delivery?

14. Research

- a/b) Are you aware of any research initiatives active in Aboriginal health? Do you know if they are currently being implemented successfully? What are some of the barriers or facilitators that you are aware of that these researchers have used/come across?
- c) Do you think research specifically being done with Aboriginal people is important? Why or why not?
- d) What if anything would you like to see change in relation to research being conducted in Aboriginal health?
- e) Do you think it makes a difference who is conducting the research and who is involved in delivering research questions? For example do you think there would be a difference between research delivered by an Aboriginal person compared to a non-Aboriginal person? Why or why not?

15. Other health problems

- a) Do you think tobacco use is a big health problem concerning Aboriginal people today?

- b) What do you think are the biggest health problems facing Aboriginal people at the moment (e.g., heart disease, diabetes, under nutrition, alcohol abuse?)
- c) What is currently being done and by whom to help address these health problems?
- d) Do you think doctors or healthcare workers can do more to help? What should they be doing? How often? Why do you think this will help?
- e) Is there anyone else that you can think of that could help with these health problems? What else is needed? (E.g, more resources, buildings, training, funding)
- f) In what area do you think future funding for health should be invested?
- g) Do you think racism is occurring in healthcare practices today? If so, can you provide some examples?

16. Closing comments

- a) Is there anything else you would like to tell us about tobacco use amongst Aboriginal people?
- b) Please tell us about anything else you feel is important for us to know
- c) Validate the focus group (read out a summary of the main points discussed to make sure our interpretation is accurate and reflects the views of the audience)

Thank you for your time.

2015

Television

1. Kristin interviewed 17th of June 2015 as an ambassador for TAFE SA, which will be used for television commercials and advertisement campaigns, You Tube, pamphlets and other TAFE brand awareness resources
2. Kristin filmed for the University of Adelaide as one of six staff/students who will be featured in the 2015/16 advertising campaigns and research/study at University initiatives. This will be aired across multiple channels including for commercials, online websites, you tube and other resources in late 2015
3. ABC Australia Day Ceremony live from Canberra Parliament House (25/01/2015) on Australia Day Eve as the SA finalist for Young Australian of the Year

Radio

4. ABC Alice Springs (01/06/2015) Kristin interviewed live for ‘Clinical Corner’ about PhD research related to the STOP trial and Champix being safe and well tolerated amongst patients with smoking related illnesses admitted to hospital (8 minute interview)
5. ABC Adelaide (27/05/2015) Kristin interviewed about PhD research related to the STOP trial and Champix being safe and well tolerated amongst patients with smoking related illnesses admitted to hospital (5 minute interview)
6. 5AA Adelaide (27/05/2015) Kristin interviewed about PhD research related to the STOP trial and Champix being safe and well tolerated amongst patients with smoking related illnesses admitted to hospital (5 minute interview)
7. Coast FM (28/05/2015) Kristin interviewed in studio live by David Hearne about experience as a national finalist for the Young Australian of the Year award and current research activities underway at The Queen Elizabeth Hospital.

8. 5AA in studio radio interview by Will Goodings (16/02/2015) selected as one of two representatives of The Queen Elizabeth Hospital and one of 8 from the state to take part in a series organised by South Australian Health that showcases people who work in health as ‘profile pieces’ to talk about the work we do in the hospitals, our own background and the extra work we do outside health within the community (20 minute interview)
9. ABC radio in studio interview with Ian Henschke (17/02/2015) as the SA Young Australian of the Year representative for the national award to talk about my experience in Canberra, how I became the recipient of the SA title and talking about my research in tobacco and smoking cessation (15 minute interview)
10. Radio National (ABC Canberra Australia Day 26/01/2015) **in studio interview for the Press Club at the Senate (Parliament House)** on a panel with fellow Young Australian of the Year finalists Yasmin Abdel-Magied and Genevieve Clay-Smith to an audience of over 500,000 listeners talking about important causes that we feel strongly about, advice for youth and what needs to change in today’s society (30 minutes)
11. Stuntfm Radio 93.7 (24/01/2015) ‘Young Aussies to be honoured’ newsfeed as per ‘The Australian’ article written on 24/01/2015
12. Coast FM (22/01/2015) Kristin interviewed in studio live by David Hearne about the transition from high school to scientist and being a finalist for the national Young Australian of the Year award.

Newspaper

13. The Daily Telegraph, Sunday the 25th of January, ‘Who will be Australian of the Year’ by Taylor Denny
14. The Sydney Morning Herald, Sunday January 25th, ‘Australian of the Year winner announced in Canberra’ article by Stephanie Peatling
15. Perth New Sunday Times, Sunday the 25th of January ‘Young Aussies to be honoured’ article by Elise Scott

16. The Australian, Saturday January 24th, ‘Young Aussies to be honoured’ article by Elise Scott – National circulation

Online articles

17. Drug Discovery and Development (01/06/2015) ‘Researcher: Controversial Stop-smoking drug Champix is safe’
<http://www.dddmag.com/news/2015/06/researcher-controversial-stop-smoking-drug-champix-safe>
18. Tealeaves (28/05/2015) ‘Stop smoking drug’ <http://tealeaves.cigarettes-herbal.eu/stop-smoking-drug/>
19. Pharmaceutical Processing (27/05/2015) ‘Study: Controversial quit-smoking drug Champix is safe’ <http://www.pharmpro.com/news/2015/05/study-controversial-quit-smoking-drug-champix-safe>
20. Medical Xpress (27/05/2015) ‘The controversial stop-smoking drug Champix is safe’ <http://medicalxpress.com/news/2015-05-controversial-stop-smoking-drug-champix-safe.html>
21. Health Canal (27/05/2015) ‘The controversial stop-smoking drug Champix is safe’ <http://www.healthcanal.com/public-health-safety/63856-the-controversial-stop-smoking-drug-champix-is-safe.html>
22. WorldNews.com (27/05/2015) ‘The controversial stop-smoking drug Champix is safe (The University of Adelaide)’
http://article.wn.com/view/2015/05/27/The_controversial_stopsmoking_drug_Champix_is_safe_The_Unive/
23. Noodles gateway to facts (27/05/2015) The University of Adelaide press release ‘The controversial stop-smoking drug Champix is safe’
<http://www.noodles.com/view/47053D5C4C8C5BAE64DDF61BEDD92FF5BDB7ED19?1683xxx1432693548>

24. The Lead: Newsleads from South Australia (27/05/2015) 'Controversial quit-smoking drug Champix is safe and effective'
<http://www.theleadsouthaustralia.com.au/industries/health/controversial-quit-smoking-drug-champix-is-safe-and-effective/>
25. The University of Adelaide News and Events (27/05/2015) 'The controversial stop-smoking drug Champix is safe'
<http://www.adelaide.edu.au/news/news78342.html>
26. Media release Wednesday the 27th of May for World No Tobacco Day. Kristin interviewed via the University of Adelaide about research related to PhD, tobacco use, smoking cessation, tobacco prevention and Aboriginal health related to smoking; Media release by Newsmaker
<http://www.newsmaker.com.au/news/35521/the-controversial-stopsmoking-drug-champix-is-safe#.VXUFDKMw-mQ>
27. Interceder 'Young Aussies to be honoured' (26/01/2015)
http://webcache.googleusercontent.com/search?q=cache:Jr4lAYyPBbgJ:interceder.net/latest_news/Jacqueline-Carson+&cd=22&hl=en&ct=clnk&gl=au
28. The Sydney Morning Herald Federal Politics 'Australian of the Year winner announced in Canberra' (26/01/2015) <http://www.smh.com.au/federal-politics/the-pulse-live/australian-of-the-year-winner-announced-in-canberra-20150125-12xsa6.html>
29. Perth New Sunday Times (25/01/2015) 'Young Aussies to be honoured'
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39. Pro Bono Australia (13/01/2015) 'Women finalists dominate Australian of the Year Awards 2015' <http://www.probonoaustralia.com.au/news/2015/01/women-finalists-dominate-australian-year-awards-2015>

2014

Television

40. Channel 9 News and several pieces aired during commercial breaks over a three week period regarding winners of the Premier's Channel 9 Young Achiever of the Year Awards. Kristin Carson highlighted as the winner of the University of Adelaide Faculty of Sciences, Science and Technology Award as well as the overall winner of the Premier's Channel 9 Young Achiever of the Year

Radio

41. 891 ABC Adelaide (30/10/2014) Kristin interviewed live on radio by Sonya Feldhoff as one of four finalists for the South Australian Young Australian of the Year for 2014.
42. ABC PM News, National (10/09/2014) Kristin interviewed by Mandie Sami over the phone, aired online and on radio; 'Indigenous Australians experience diabetes 20 years earlier' Kristin asked to response to the statistics from the AIHW about Indigenous Australian's experiencing diabetes at a much younger age and with greater prevalence than non-Indigenous Australians. Kristin interviewed from the perspective of her role as the chair of the 'Indigenous Lung Health Working party for the Thoracic Society of Australia and New Zealand'. Total air time for news piece 4.16 minutes.
<http://mpegmedia.abc.net.au/news/audio/pm/201409/20140910-pm03-atsiabshealth.mp3>
43. WWL.com AM870 and FM 105.3 'Scoot: Don't blame the TV for your bad choices' (22/04/2014; 12:39PM) <http://www.wwl.com/Scoot-Don-t-blame-the-TV-for-your-bad-choices/13069478?pid=396269>
44. KELO FM 101.9; 1320AM and 107.9FM Sioux Falls, SD (15/04/14; 12:48pm) 'Tobacco on TV tied to adult smoking rates' Kristin interviewed as tobacco expert by Reuters health about research showing the smoking on TV influences smoking in real life <http://kelofm.com/news/articles/2014/apr/15/tobacco-on-tv-tied-to-adult-smoking-rates/>

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73. Senator Scott Ryan Media (17/11/2014) ‘Media Release – Celebrating Young Australian of the Year nominees’ <http://scottryan.com.au/media/media-release-celebrating-young-australian-year-nominees>
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84. NACCHO Aboriginal Health News Alerts (25/08/2014) 'Indigenous smoking program cuts risk widening the gap' <http://nacchocommunique.com/category/3-promote-research-that-will-build-evidence-informed-best-practice/talking-about-the-smokes-tats-research-project/>
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154. WNFL 1440AM Green Bay, WI (15/04/2014) ‘Tobacco on TV tied to adult smoking rates’ <http://wnflam.com/news/articles/2014/apr/15/tobacco-on-tv-tied-to-adult-smoking-rates/>

155. WNMT 650AM Hibbing, Minnesota (15/04/2014) 'Tobacco on TV tied to adult smoking rates' <http://wnmtradio.com/news/articles/2014/apr/15/tobacco-on-tv-tied-to-adult-smoking-rates/>
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162. Basil Hetzel Institute News (April 2014) 'Kristin Carson wins Premier's Channel 9 Young Achiever Award' <http://www.basilhetzelinstitute.com.au/news-events/news>
163. Australian Super (01/04/2014) 'Australian Super is a proud supporter of the 2014 Young Achiever Awards' <http://www.australiansuper.com/campaigns/yaa>

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166. The University of Adelaide, Vice Chancellor's Blog (31/03/2014) 'Congratulations to 2014 Young Achiever of the Year' <http://blogs.adelaide.edu.au/vco/2014/03/31/congratulations-to-2014-young-achiever-of-the-year/>
167. Awards Australia Current Finalists (03/2014) 'South Australia, The Channel 9 Young Achiever Awards' <http://www.awardsaustralia.com/young-achiever-awards/sa/current-finalists/>
168. Awards Australia Current Winners (03/2014) 'South Australia, The Channel 9 Young Achiever Awards' <http://www.awardsaustralia.com/young-achiever-awards/sa/current-winners/>

2013

Television

169. Channel 9 News, Brian Smith and Kristin Carson interviewed by Jessica Stanley for the Channel 9 News Health Report. Interview scheduled for Thursday the 26th of September at 11:30am in Respiratory Medicine Department 4A for the STOP trial (Smoking Termination Opportunity for inPatients) [http://9adelaide.com.au/?page_id=111#prettyPhoto\[gallery\]/0/](http://9adelaide.com.au/?page_id=111#prettyPhoto[gallery]/0/)
170. Channel 7 News, Kristin Carson interviewed by Amelia Mulcahy for the Channel 7 Health Report during the evening news (30/04/2013; approx. 3 minutes air time) for the study 'Evaluation of Transdermal Nicotine Replacement Therapy (NRT) Activity Through Metabolic Induction'

Radio

171. ABC PM News, National (03/10/2013) Kristin interviewed by Mandie Sami over the phone, aired online and on radio; 'Indigenous people are 50 per cent more likely to die from cancer than other Australians' Kristin asked to response to the statistics from the AIHW about Indigenous Australian's being 50% more likely to die from cancer than other Australians. Kristin interviewed from the perspective of her role as the chair of the 'Indigenous Lung Health Working party for the Thoracic Society of Australia and New Zealand'. Total air time for news piece approximately 5 minutes.
<http://mpegmedia.abc.net.au/news/audio/pm/201310/20131003-PM06-ATSICANCER.mp3>
172. ABC 891 Mornings Adelaide (31/05/2013) Kristin interviewed for World No Tobacco Day for approximately 5 minutes, final follow-up for the NRT patient (see other ABC 891 interviews below) and as the Chair of the Tobacco special interest group for the Thoracic Society of Australia and New Zealand.
173. COAST FM 88.7, Kristin Carson interviewed in studio by David Hearn (16/05/2013) for approximately 15 minutes regarding background and how she became a scientist, the research titled 'training health professionals in smoking cessation', 'Evaluation of Transdermal Nicotine Replacement Therapy (NRT) Activity Through Metabolic Induction' and 'Interventions for tobacco cessation and prevention in Indigenous youth'.
174. ABC 891 Mornings Adelaide (21/05/2013), Follow-up discussion and interview from the 15/03/2013 in studio interview with Kristin Carson (interview by Ian Henschke) regarding the study 'Evaluation of Transdermal Nicotine Replacement Therapy (NRT) Activity Through Metabolic Induction'
175. Panorama on Syn (Syn.org.au), Kristin Carson interviewed over the phone (Tuesday 23/04/2013, aired online and on radio for ~10 minutes) by Producer Samantha Yapp about the research 'Review finds 'dangerous shortcomings' in anti-smoking programs aimed at Indigenous youth'.

176. ABC 891 Mornings Adelaide, Kristin Carson interviewed in studio by Ian Henschke (Monday, 15/03/2013) about the study 'Evaluation of Transdermal Nicotine Replacement Therapy (NRT) Activity Through Metabolic Induction'
177. ABC radio Darwin, Kristin Carson live interview with radio host (Monday, 25th of March 2013: approximately five minutes; Question/Answer broadcast set up) relating to media release from the Thoracic Society of Australia and New Zealand titled 'Review finds 'dangerous shortcomings' in anti-smoking programs aimed at Indigenous youth'
178. 98.9FM, Brisbane, hosted by newsreader; 25 March 2013 9:00 AM; "A national health group has called for further evaluation of anti-smoking campaigns aimed at reducing rates of smoking among young Indigenous people. The Australian reports a study by the Thoracic Society of Australia and New Zealand found almost half of Indigenous Australians aged over 14 smoking daily. Kristin Carson, Queen Elizabeth Hospital Adelaide, says there has been a lack of review of Government campaigns to reduce Indigenous youth smoking..."(32 seconds)
179. ABC Darwin, hosted by newsreader; 26 March 2013 07:08 AM "A study has cast doubt on the effectiveness of anti-smoking campaigns aimed at Indigenous youth as the programs aren't being monitored. The study was presented at a Thoracic Society of Australia meeting in Darwin, Kristin Carson, Senior Research Scientist, says considering the amount of investment by the Council of Australian Governments, it's alarming that evaluation proceedings aren't running alongside such programs..." (40 seconds)
180. ABC Darwin, hosted by newsreader; 26 March 2013 07:56 AM "A study on the effectiveness of anti-smoking campaigns aimed at Indigenous youth says evaluation is needed to find out if the programs are working. The study was presented at a Thoracic Society of Australian and New Zealand's annual scientific meeting in Darwin. Kristin Carson, Senior Research Scientist, says it's impossible to tell whether any programs are working in Indigenous communities ..." (45 seconds)

181. ABC Western Queensland, Longreach hosted by newsreader; 26 March 2013 08:33 AM “A study on the effectiveness of anti-smoking campaigns aimed at Indigenous youth says evaluation is needed to find out if the programs are working. The study was presented at a Thoracic Society of Australia and New Zealand’s annual scientific meeting in Darwin. Kristin Carson, Senior Research Scientist says it’s impossible to tell whether any programs are working in Indigenous communities...” (41 seconds)
182. ABC Western Queensland, Longreach hosted by newsreader; 26 March 2013 12:33 PM “A study on the effectiveness of anti-smoking campaigns aimed at Indigenous youth says evaluation is needed to find out if the programs are working. The study was presented at a Thoracic Society of Australia and New Zealand's annual scientific meeting in Darwin. Kristen Garson(*), Senior Research Scientist, says it's impossible to tell whether any programs are working in Indigenous communities...” (46 seconds)
183. 4K1G Townsville, hosted by newsreader; 26 March 2013 16:01 PM “A study by Thoracic Society of Australia and New Zealand found almost half of Indigenous Australians aged over 14yo smoke daily. Kristin Carson from the Queen Elizabeth Hospital says there's been a lack of reviews of government campaigns to reduce Indigenous youth smoking” (32 seconds)
184. ABC Wide Bay, Bundaberg, Hosted by Rachel Loakes; 26 March 2013 12:33 PM “A study on the effectiveness of anti-smoking campaigns aimed at Indigenous youth says evaluation is needed to find out if the programs are working. The study was presented at a Thoracic Society of Australia and New Zealand’s annual scientific meeting in Darwin. Kristin Carson, Senior Research Scientist says it’s impossible to tell whether any programs are working in Indigenous communities...” (46 seconds)

Newspaper

185. The Australian, Monday March 25 2013, Page 5 ‘Anti-smoking efforts deemed a failure’, article by Jamie Walker (135.52cm²) – National circulation

186. NT News, Monday March 25 2013, Page 3 ‘Project ‘harmful’’ link also available online <http://ntnews.newspaperdirect.com/epaper/viewer.aspx#>

Online articles

187. Oncology Central Editor’s pick (18/11/2013) <https://oncology-central.com/content/article/is-cancer-risk-still-reduced-if-you-give-up-smoking-in-later-life>
188. You Tube Nine News (05/10/2013) ‘Doctors are calling for a permanent anti-smoking officer to be based in all public hospitals’ Brian Smith and Kristin Carson interviewed by Channel 9 News for the STOP smoking program (see publication list Thorax Smith et.al. 2013 manuscript)
http://www.youtube.com/watch?v=Vx3UZEfwZsU&feature=c4-overview&list=UUhAumjy26uts_hvywCSdgvQ
189. Channel 9 News online: 9Adelaide (05/10/2013) ‘No smoking’ Brian Smith and Kristin Carson interviewed by Channel 9 News for the STOP smoking program (see publication list Thorax Smith et.al. 2013 manuscript)
[http://9adelaide.com.au/?page_id=111#prettyPhoto\[gallery\]/1/](http://9adelaide.com.au/?page_id=111#prettyPhoto[gallery]/1/)
190. ABC PM (03/10/2013) ‘Indigenous people are 50 per cent more likely to die from cancer than other Australians’ Kristin interviewed by Mandie Sami in relation to the statistics from the AIHW about Indigenous Australian’s being 50% more likely to die from cancer than other Australians. Kristin interviewed from the perspective of her role as the chair of the ‘Indigenous Lung Health Working party for the Thoracic Society of Australia and New Zealand’.
<http://www.abc.net.au/pm/content/2013/s3861795.htm>
191. WCH Foundation (5/09/2013), ‘2013 Young Investigator Award semi-finalists announced!’ <http://stage-wchfoundation.dbgtechnologies.com/news-and-stories/applications-are-now-open-for-the-2013-young-investigator-award-via>
192. Seven News (30/04/2013), Kristin Carson interviewed for Channel 7 News by Amelia Mulcahy ‘Study looks at nicotine patches’

<https://au.news.yahoo.com/sa/a/16944560/study-questions-use-of-nicotine-patches/> and <https://www.youtube.com/watch?v=hQarqTrGGIM>

193. YouTube (30/04/2013) '7News – Study looks at nicotine patches' http://www.youtube.com/watch?v=hQarqTrGGIM&list=UU5T7D-Dh1eDGtsAFCuwv_Sw&index=7
194. Yahoo AU News (30/04/2013) 'Study questions use of nicotine patches' Kristin Carson interviewed for Channel 7 News; by Melissa Wildy <http://au.news.yahoo.com/a/-/newshome/16944560/study-questions-use-of-nicotine-patches/>
195. Ausmed Education (24/04/2013), article written by Kristin Carson 'Anti-smoking campaigns failing Indigenous youth' <http://www.ausmed.com.au/the-nursing-blog/entry/anti-smoking-campaigns-failing-indigenous-youth>
196. World News Australia (SBS), (17/04/2013), article written by Kristin Carson 'Anti-smoking campaigns failing Indigenous youth' <http://www.sbs.com.au/news/article/1756956/Anti-smoking-campaigns-failing-Indigenous-youth>
197. Crikey Independent Media, Independent Minds: Croaky (19/04/2013) 'Anti-smoking campaigns failing Indigenous youth' <http://blogs.crikey.com.au/croakey/2013/04/19/anti-smoking-campaigns-failing-indigenous-youth/>
198. The Conversation, 17/04/2013, article written by Kristin Carson 'Anti-smoking campaigns failing Indigenous youth' <http://theconversation.com/anti-smoking-campaigns-failing-indigenous-youth-13072>
199. Interceder (19/04/2013), 'Anti-smoking campaigns failing Indigenous youth' http://interceder.net/latest_news/kristin-carson
200. Blogotariat: Oz Blogs News Commentary (19/04/2013) 'Anti-smoking campaigns failing Indigenous youth' <http://www.blogotariat.com/node/984649>

201. Tobacco News (Industries News), (16/04/2013), ‘Anti-smoking campaigns failing Indigenous youth’ <http://www.industriesnews.net/story?sid=s213886081&cid=46>
202. All News Australia (ALLNewsAU), (17/04/2013), article written by Kristin Carson ‘Anti-smoking campaigns failing Indigenous youth’ <http://www.allnewsau.com/news/anti-smoking-campaigns-failing-indigenous-youth>
203. Invited news article (17/04/2013) by the editors of ‘The Conversation’ 800 words written by Kristin Carson; <http://theconversation.com/anti-smoking-campaigns-failing-indigenous-youth-13072> ‘Dangerous shortcoming in multi-million dollar anti-smoking campaigns for Indigenous youth’
204. Alltop news (17/04/2013) ‘Anti-smoking campaigns failing Indigenous youth’ <http://news.alltop.com/>
205. ABC blogs (15/04/2013) by Michaela Andreyev; Mornings with Ian Henschke ‘Quit smoking research project at Queen Elizabeth Hospital’ http://blogs.abc.net.au/sa/2013/04/quit-smoking-research-project-at-queen-elizabeth-hospital.html?site=adelaide&program=adelaide_mornings (Audio available at: <http://blogs.abc.net.au/files/quit-smokeing.mp3>)
206. Stop Smoking Solutions (15/04/2013) ‘Quit smoking research project...’ <http://stopsmokingsolutions.net/?s=kristin+carson&x=10&y=8>
207. National Indigenous Radio Service (25/03/2013), ‘Ant-smoking campaigns a failure’ <http://www.nirs.org.au/blog/NEWS/article/28901/Ant-smoking-campaigns-a-failure.html>
208. Northern Territory News (NT News online) (25/03/2013) ‘Project ’harmful’’ <http://ntnews.newspaperdirect.com/epaper/viewer.aspx> ‘MEDICAL experts have warned that the multimillion-dollar Coalition of Australian Government’s anti-smoking program for indigenous youth has some “alarming shortcomings”. Researcher Kristin Carson said the paucity of data on the effectiveness of the anti-

tobacco initiatives could result in decades of harm to indigenous families and huge health costs.’

209. Media release, 24 March 2013, Thoracic Society of Australia and New Zealand, Annual Scientific Meeting, Darwin; ‘Review finds ‘dangerous shortcomings’ in anti-smoking programs aimed at Indigenous youth’. Kristin Carson interviewed by Trevor Gill following oral presentation of ‘Interventions for tobacco prevention in Indigenous youth: A Cochrane review and a narrative synthesis’.
210. The Australian online, March 25 2013, ‘Almost half of all Indigenous people older than 14 smoke daily’ <http://www.theaustralian.com.au/news/health-science/almost-half-all-indigenous-people-older-than-14-smoke-daily/story-e6frg8y6-1226604569755>
211. NACCHO Aboriginal Health News Alerts, March 25 2013, ‘Almost half all Aboriginal people older than 14 smoke daily’ (<http://nacchocommunique.com/category/3-promote-research-that-will-build-evidence-informed-best-practice/>)
212. Port Adelaide Football Club website (23/01/2013) ‘Outer Army cheers for the QEH’ <http://www.portadelaidefc.com.au/news/2013-01-23/armys-donation>
2012

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213. National Electronic Library for Medicines NHS, September 19 2012, ‘RCT: Varenicline plus counselling over counselling alone for smoking cessation amongst inpatients (STOP) <http://www.nelm.nhs.uk/en/NeLM-Area/News/2012---September/19/RCT-Varenicline-plus-counselling-over-counselling-alone-for-smoking-cessation-amongst-inpatients-STOP/>
214. High Beam Research (01/07/2012) ‘Varenicline plus counselling elevates quit rate’ <http://www.highbeam.com/doc/1G1-299536173.html>
215. Preventive Health Alert (May 2012) Library Services Department of Health and Ageing ‘Interventions for smoking cessation in Indigenous populations’

[http://www.anpha.gov.au/internet/anpha/publishing.nsf/Content/689910073F14D02BCA25793B001D861A/\\$File/Preventive%20Health%20Alert%20May%202012.pdf](http://www.anpha.gov.au/internet/anpha/publishing.nsf/Content/689910073F14D02BCA25793B001D861A/$File/Preventive%20Health%20Alert%20May%202012.pdf)

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<http://www.clinicalpsychiatrynews.com/specialty-focus/pain-and-addiction/single-article-page/varenicline-plus-counseling-elevates-smoking-quit-rate/f59d276ad153d3686b369b948ed53e26.html>
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(<http://www.pslgroup.com/news/content.nsf/medicalnews/852571020057CCF685257A02006F4AEE?OpenDocument&id=&count=10>)
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(<http://www.smokefree.com/smokefreecom/cessation-training>)
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(<http://www.newswise.com/articles/doctors-need-training-to-help-smokers-quit>)
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NOTE:

This publication is included on pages 654 - 706 in the print copy of the thesis held in the University of Adelaide Library.

GRANT PROPOSAL – TRIP FELLOWSHIPS
FOR FUNDING COMMENCING IN 2015

Application ID: 1092680
CI Last Name: Carson

Research Translation Proposal (maximum of 7 pages including references)

1. Provide a description of the gap between evidence and practice that you wish to address.

Since 2008 the Australian government has funded initiatives in excess of AU\$2.34 billion aimed at eliminating the Indigenous inequality gap and improving Aboriginal and Torres Strait Islander (TSI) health, with anti-tobacco programs being an important part of the strategy (van der Sterren and Knoche, 2011, COAG Reform Council, 2012). Yet our extensive research over the past five years (primarily through my PhD) has identified a *considerable gap between the production of these culturally-tailored smoking cessation and tobacco abuse prevention resources and their practical utilisation on the frontline of clinical care* (Carson et al., 2014b, Carson et al., 2014a, Carson et al., 2014c). Moreover, our recently published systematic analyses have identified a *paucity of data pertaining to the evaluation of these programs* by the Australian Government and other organisations (Carson et al., 2012a, Carson et al., 2013a, Carson et al., 2012b, Carson et al., 2013b), the results of which have subsequently received considerable amounts of media attention with broadcasts through 14 radio segments across Australia, several newspaper articles (including page 5 of The Australian) and over 20 online news websites in 2013 alone. Our research has also identified that *many of the healthcare workers and some doctors are reporting that they do not believe they have the skills or ability to offer smoking cessation/prevention initiatives to patients*, and perhaps more importantly, admit to the attitude of *'even if I did, it's not going to work so why bother'* (Carson et al., 2012c, Carson et al., 2013b, Carson et al., 2014b).

2. Include justification of the evidence-practice gap (i.e. robust existing research) and explain why it is important to address this gap.

Justification of the evidence-practice gap: My *extensive research evaluations* over the past four years, several of which have been published in *one of the highest ranked international journals in evidence based medicine research* (Cochrane Database of Systematic Reviews is ranked 11 out of 151 journals in the field of Medicine; 2012), have led to the identification of an important evidence translation gap. *Potentially effective smoking cessation resources* that have been well-funded and developed with extensive community consultation to enhance cultural relevance are *not being used by health professionals as part of clinical care*. The reasons cited for this include a lack of confidence and ability to deliver smoking cessation and prevention messages, being unaware of the resources and how to access them and a lack of knowledge around smoking cessation and tobacco abuse prevention options (Carson et al., 2014b, Carson et al., 2014a, Carson et al., 2014c, Carson et al., 2012c). The lack of methodologically rigorous evaluations for existing government funded smoking cessation and tobacco prevention initiatives revealed in our Cochrane reviews is also of great concern, particularly considering that *we identified a potential for harm* among the tobacco abuse prevention programs for Indigenous youth (Carson et al., 2012b). More participants reported smoking following the tobacco prevention program in the intervention group of one study, in comparison to the control group who received no tobacco prevention program at all. Furthermore, by continuing to invest funding and other resources into ineffective programs an opportunity cost for potentially effective initiatives ensues. *Until methodologically rigorous evaluations occur alongside Indigenous tobacco cessation and prevention interventions, we can begin to redirect funding into the initiatives most likely to improve quit attempts and prevent youth from smoking.*

Why it is important to address this gap: Increasing offers of support for smoking cessation and utilising every opportunity to discuss anti-tobacco messages with smokers are essential to fostering long-term successful quit attempts (Carson et al., 2013c). This is even more important in the Indigenous Australian setting where the prevalence of tobacco use is still almost three times that of the non-Indigenous population, with 45% of Aboriginal and TSI peoples aged 15 years and over reporting smoking on a daily basis (Australian Bureau of Statistics, 2011), compared to 18% for non-Indigenous Australians. Consequently, Aboriginal and TSI Australians are over represented in

the burden of tobacco-related morbidity and premature mortality. *Tobacco use among Indigenous Australians is reported to contribute to 80% of all lung cancer deaths, 37% of ischemic heart disease, 21% of chronic obstructive pulmonary disease, 9% of all strokes and 5% of low birth-weight babies* (van der Sterren and Knoche, 2011). Approximately 80% of the Indigenous mortality gap (in terms of potential years of life lost) can be attributed to chronic disease and an analysis of 11 risk factors related to death and illness among Indigenous Australians calculated that *tobacco smoking accounted for 12.1% of the entire burden of disease, which was more than any other risk factor and more than the burden attributable to alcohol and illicit drugs combined* (van der Sterren and Knoche, 2011). Subsequently, national statistics report that Aboriginal and TSI people are twice as likely to be admitted to hospital compared to the non-Indigenous population, despite likely under-reporting of Indigenous separation statistics (van der Sterren and Knoche, 2011), with Indigenous health care expenditure accounting for 3.3% of national expenditure and 8.5% of all government expenditure in 2008-9, or AU\$3.60 for every \$1.00 spent per non-Indigenous Australian (Australian Institute of Health and Welfare, 2011). When we then consider that recent estimates of the economic impact from *an 8% reduction in the prevalence of tobacco smoking in Australia would result in: 158,000 fewer incident cases of disease, 5000 fewer deaths, 2.2 million fewer lost working days, 3000 fewer early retirements and would reduce health sector costs by AU\$491 million* (Magnus et al., 2011), it is clear that by addressing this evidence-practice gap we can make a substantial impact on Indigenous quality of life, morbidity and mortality as well as reduce Australian health care expenditure through reduced health service utilisation.

3. Describe what will be implemented as part of your proposal.

The funding received through this TRIP Fellowship will be used to support a multi-site cluster randomised delayed intervention (DI) controlled trial for Aboriginal and/or TSI health professionals (HPs) across 6 South Australian community groups (four urban and two regional with geographical separation large enough to reduce the risk of potential contamination between groups) to either:

1. Training program for HPs including two half-day skills workshops in **a)** MI techniques for smoking cessation and tobacco prevention, **b)** a seminar about the latest cessation and tobacco prevention options, and **c)** guidance to optimise the use of *culturally-tailored and community-driven (local)* tobacco programs, plus a booster session and feedback at one month, OR
2. Delayed intervention control where communities have data collection at the same time as the intervention populations however the training intervention commences three months later.

We have successfully pioneered these three intervention components into the clinical inpatient settings and built this application on the *foundation of in depth pilot investigations* over the past six years with *widespread community input and participation* (including my personal consultation with over 100 Aboriginal Elders, key community stakeholders and researchers to ensure that the work being done is believed to be important and worthwhile in the eyes of Aboriginal people). Through this proposal I aim to determine if training HPs who work with Aboriginal communities in smoking cessation and prevention techniques, when compared with the DI controls, will; **AIM 1:** increase quit attempts and duration of smoking abstinence amongst their patients, as measured by self-reported continuous smoking abstinence and 7-day point prevalence, and **AIM 2:** increase the likelihood of a HP **a)** talking about tobacco prevention measures with families and youth, **b)** suggesting strategies to prevent smoking amongst youth, **c)** offering cessation counselling to their patient, **d)** asking about setting a quit date, **e)** offering a follow-up appointment, **f)** providing self-help material, **g)** referring to local health services **h)** offering smoking cessation medications, as measured by a self-reported pre/post comparison questionnaire, patient survey, qualitative interview data and examination of electronic and hard-copy patient case notes, and **AIM 3:** prove cost effective subsequent to reduced morbidity and premature mortality, as measured by electronic South Australian DRG data (five years pre-study and 12 months post) supplemented

by review of HP records, SA Department of Health Data and PBS/MBS data sets, and **AIM 4:** improve the knowledge, skills and attitudes of HPs toward smoking cessation and tobacco abuse prevention in Aboriginal communities as measured by pre/post enrolment HP and patient questionnaires, supplemented by qualitative interview data and review of medical records.

4. Describe how you propose to implement the intervention.

Implementation of the intervention will occur with assistance from the associate investigators and research personnel named on this application. The evidence-based intervention has already been developed and pilot tested, based on our previous randomised controlled smoking cessation study (Smith et al., 2013), information produced from our Cochrane reviews (Carson et al., 2014b, Carson et al., 2014c, Carson et al., 2013c) and following in depth community consultation with over 100 Indigenous Australians. This intervention also utilises the existing culturally-tailored smoking cessation and tobacco abuse prevention resources that have been funded and developed by the COAG and other local research projects (i.e. the translating research into practice focus of this application). *Each community group will receive a total of two, half day workshops (total eight hours contact time over one month)*, with each half day workshop incorporating all three components of the intervention (a-c) listed above, to ensure greater dissemination of techniques in case of missed sessions.

Cluster randomisation will occur by random number generator software with stratification to urban and regional locations. A statistician has calculated the *sample size of 240 per study arm (n=480 in total)*, providing 80% power to detect a difference between the group proportions of 0.08 whilst also taking adjustments for clustering effects, drop-outs and participants lost to follow-up. With an estimated minimum of 20 HPs recruited per community group, each professional would only need to recruit and maintain contact with four patients each over the three month follow-up period, which is decidedly achievable and practical.

5. Define the group/s whose behaviour the intervention seeks to change, and describe how the group/s will be engaged in the process.

The first ‘Closing the Gap’ performance report released by the COAG (Council of Australian Governments) in 2012, examined the progress observed over the past five years for each state and territory in Australia individually (COAG Reform Council, 2012). Out of all the states and territories assessed, South Australia (SA) was the only location whose predicted performance at the beginning of the COAG implementation program was worse than the projected indicators. Moreover, between 1998 and 2010 no significant decreases in Aboriginal mortality were observed in SA, as occurred in other areas such as Queensland and the Northern Territory. Based on this trend line, SA will not meet the 2031 health improvement targets unless Indigenous death rates begin to fall faster, thus making SA the ideal state in which to conduct this investigation.

The six participating community groups have been chosen for practical reasons as I have already built strong collaborations and connections with all sites selected for participation. Extensive engagement has already occurred over the past six years as described above and under the ‘community engagement’ paragraph for the ‘Indigenous health criteria’ reported below.

Health professionals (defined as healthcare workers, nurses, doctors, dentists, physiotherapists or community care workers) will be recruited via existing community contacts (e.g., through suggestions from Aboriginal Elders and leaders of community groups who support the planned research) and through healthcare centres (e.g., healthcare workers associated with our Respiratory physicians or referred by healthcare management staff). Preliminary enquiries across all six sites have already identified several HPs willing to participate in the study, increasing feasibility.

Self-reported ‘regular’ smokers (to determine, patients are asked: “if smokes are available would you smoke on a daily basis?”) will be recruited by the above mentioned HPs to participate in the study. These HPs will undergo brief training in patient consent procedures for recruitment of

smokers and partial collection of patient data (information that can be obtained from patient records will be collected by me to reduce questionnaire burden). *We will ensure that NHMRC guidelines and frameworks for the ethical conduct of Aboriginal and TSI health research are adhered to.*

6. Describe the methods you will use to monitor the effect your project is having on closing the nominated evidence-practice gap.

Utilising a randomised controlled trial design to examine the intervention model (as described in point 3) that may potentially close the evidence-practice gap (as described in point 1) provides methodological rigour to facilitate monitoring of outcomes for this proposals objectives. Data will be used to monitor the effect of this project. Collection of this data will occur at baseline, one and three months for HPs as well as baseline and three months for patients (in addition to 12 month data collection for economic objectives). This will include: demographics, smoking history, importance and motivation to quit smoking, receptiveness to counselling, medical history, social situation (including employment, education, housing and family setting), stressors, and cravings (for cessation of tobacco use) and demographics, attitude toward smoking and intention to smoke, knowledge about the health effects of tobacco use and beliefs about smoking (for prevention of tobacco use). These tools have been widely used and validated, facilitating comparisons of new findings with the published literature. Patient outcome data will be collected by the HPs during their consultations for both the intervention group and DI control group, with data obtainable via medical record review collected by myself, associate investigators and research assistant available during the implementation phase of this proposal. I will also be responsible for collection of the qualitative data as I have experience in designing, conducting, analysing and interpreting qualitative interview data, which will also be validated by one of the two Elders named as associate investigators on this application to ensure cultural competence regarding the interpretation of the data. I will collect data for hospital utilisation and intervention cost effectiveness using a pilot tested Access database that was used to analyse the same data for the STOP smoking trial (Smith et al., 2013).

Statistical analyses that will be employed to monitor each of the four aims (described in point 3) include: **AIM 1:** Baseline characteristics will be compared between study arms using t-tests for means (or non-parametric equivalent), or chi-squared tests for categorical variables. Primary analysis comparing quit rates at three months will be by log binomial multilevel mixed-effects generalized linear model, with adjustment for clustering by community. The results presented will follow the CONSORT statement proforma, and will be on an intention to treat basis. The statistical package Stata 13, with intention to treat, will be used for all analyses; **AIM 2:** For each outcome (a-h) a t-test comparison between each study arm will be undertaken (or non-parametric if non-normally distributed data). If randomisation is successful, adjustment for different characteristics between the groups will not be necessary. Qualitative participant analyses will use methodology utilised in our previous publications and pilot analyses. As per our previous focus groups and interviews, data will be entered into NVivo software version 10, utilising thematic categories based on the Triandis behavioural modelling theory:

Probability of act = [habit + intention] x [motivation x facilitating conditions]*

**Intention = social factors (subjective culture) + affect + perceived consequences*

AIM 3: A detailed cost effectiveness evaluation will occur alongside this trial, supervised by my mentor Professor Smith, having trained in Health Economics at the University of Newcastle, NSW. The model will compare outcomes and costs for the intervention compared to the DI control and will incorporate epidemiological data on natural disease progression of smokers and ex-smokers from disease profiles split by gender and/or region (urban/regional or remote). The economics models will be time dependent Markov models containing ex-smoker tunnel sequences (Briggs A and Sculpher M, 1998). Downstream data on smoking cessation maintenance and natural disease progression for smokers and ex-smokers will be drawn from the epidemiological literature and National data sets (AIHW and ABS). Costs will include the direct costs of the intervention

(pharmaceutical, counselling and follow up) and the costs of associated health service use (inpatient frequency and duration, other health service use as captured by the PBS and MBS data sets). Costs and outcomes will be discounted at 5% per annum according to current PBAC guidelines (Commonwealth Department of Health and Ageing, 2002). Analyses will report the discounted cost per life year gained (\$/LY) and the discounted cost per quality adjusted life year gained (\$/QALY) at trial end and extrapolated over a 15 year time horizon. Sensitivity analysis will be performed.

AIM 4: HP performance analyses will be the same as hypothesis 2a-h.

7. Describe how you will know whether the project has contributed to closing the nominated evidence-practice gap.

Considering that our extensive preliminary research has identified that no methodologically rigorous evaluations for tobacco abuse prevention programs have occurred in Australia and only one trial of nicotine patches (with numerous methodological flaws) has been conducted (in the Northern Territory) for smoking cessation programs, completion and publication of this trial in itself will be a substantial step toward closing the evidence-practice gap. Publication of the results will provide an evidence-base on which future practice and research can be built, shaping the next phase of tobacco programs for Aboriginal and TSI people Australia-wide.

This methodologically rigorous and pre-specified evaluation (developed through practical experience in another multi-centre smoking cessation randomised controlled trial (Smith et al., 2013)) will allow us to determine whether our intervention has the potential to close the nominated evidence-practice gap. Moreover, by implementing this research in a randomised controlled trial design (with the control group also receiving the intervention after completion of the investigation period), we will be making an immediate impact (with translation of evidence-based research into clinical practice) across a large group of health services in South Australia and subsequently an even larger pool of Aboriginal and TSI people who use those services. Thus, the benefit of this investigation will be immediately seen across the South Australian community groups participating and importantly, the benefits of the training and skills taught during the intervention are sustainable beyond the life of the trial. If my evaluation proves the intervention successful, *this program can be easily implemented to provide a nation-wide cost-effective means of improving Aboriginal and TSI health* by facilitating greater access to community resources and quit services, whilst concurrently building community capacity.

8. Describe how you plan to disseminate the results of your work.

I have a successful track record in dissemination of evidence based research, producing over 35 peer reviewed publications, co-author on over 60 conference abstracts, interviewed for over 140 media citations (television, radio, newspaper, magazines and online news websites) and influenced policy and practice both locally and internationally on several occasions, all in the past four years alone (see CV). Dissemination of the results for this work will occur through: presentation of the findings at local and national meetings and conferences (including several where I am already an active member or chairperson and have shared research findings in the past resulting in successful uptake of the findings to influence the next phase of practice and research); publication in peer reviewed journal articles; engaging with the media and dissemination of the results through as many channels as possible (television, radio, newspaper, online etc.); preparation of an evidence based case report and petition to the Australian government that further action is required (type of action will depend on the findings of the randomised controlled trial), which already has the backing of a recognised charitable organisation being the Thoracic Society of Australia and New Zealand (TSANZ); Moreover, the President of the TSANZ is also an associate investigator on this application and will assist with dissemination of this work for policy and practice. Discussions about the results with influential doctors, scientists, health care workers, policy makers and consumers to share the findings and determine how best to use the information from the ‘grass

roots' level; Plus additional channels that are likely to present themselves during the course of the investigation. We will also share the results with the Indigenous contributors who participated in the research (healthcare workers, patients, family members and the broader Indigenous community) at several fora chosen by them.

9. What new knowledge and skills will this project provide to enhance your potential as a leader in your field of expertise?

As a researcher developing a field of expertise in smoking cessation and tobacco abuse prevention for Indigenous Australians, I have yet to perform a fully-powered randomised controlled trial among this cohort. Indeed, as mentioned above there is only one such study that has ever been performed in Australia (only for smoking cessation; no studies have evaluated tobacco abuse prevention) and that study has several limitations that have been discussed in my publications (Carson et al., 2012a, Carson et al., 2013b). Completion, publication and dissemination of this work will not only enhance my potential as a leader in this field, but also potentially produce a sustainable positive impact for tobacco use on a population over-represented in morbidity and premature mortality. The research outlined in this proposal will provide me with the *practical skills (development of techniques that are successful in mobilising participants, organisations, policy makers and other professionals), knowledge (through learning the barriers and facilitators for recruitment of subjects and implementation of interventions)* and an evidence base needed to implement a smoking cessation and tobacco abuse prevention study in South Australian Indigenous communities, which I can then use as the *foundation for a National approach, as is my intention*. To date, all of my Indigenous specific work has been through systematic reviews of interventions and through qualitative data analyses, which was determined to be necessary before a practical randomised controlled trial can occur, as per recommendations from several influential Aboriginal Elders. The ground work for this trial has now been established upon a strong evidence-base that I have generated. It is now time to take this work to the next level and attempt to translate this evidence into standard care.

10. Please outline any additional resources you have secured, or will need to secure, and how you will obtain them.

The Port Adelaide Football Club Outer Army has made several donations through fundraising activities over the past three years, all of which are accessible to cover costs associated with this research project. The Respiratory Medicine Department of The Queen Elizabeth Hospital has a substantial pool of funds available exclusively for research activities that can also be called upon for any incidental costs that may arise during the study to safeguard successful completion. Approval to access these funds for the purpose of this trial have already been secured. Additionally, a full time research assistant already employed within the department will be available to assist during the recruit, intervention implementation and data collection periods. A statistician (Professor Adrian Esterman) who is also my PhD supervisor and collaborator on multiple past publications will assist with the data analysis. Two Aboriginal Elders, Jeffrey Newchurch and Ruth Miller, who are both associate investigators on this proposal, will oversee the study's conduct and assist with intervention implementation and participant recruitment. Professor Brian Smith (my primary PhD supervisor, mentor for this application and employer at The Queen Elizabeth Hospital) will also provide guidance and assistance where needed throughout the entire TRIP Fellowship program.

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Indigenous Health Criteria: Community engagement: Two named investigators on this application are Aboriginal Elders, one of whom has expertise in smoking cessation strategies through her former role as Tackling Smoking co-ordinator for the Aboriginal Health Council of South Australia. Over the past six years our team of researchers have engaged, consulted and collaborated with Aboriginal and TSI communities, Elders, expert researchers, doctors and healthcare workers who consult with Aboriginal patients and key community stakeholders across Australia. These intensive one-on-one discussions have occurred with over 100 Aboriginal and/or TSI Elders, researchers and health professionals from organisations including but not limited to: the Aboriginal Health Council of South Australia, Cancer Council of South Australia, the Port Adelaide Football Club, The Queen Elizabeth Hospital, Menzies School of Health Research, Murray Mallee Community Health, The University of South Australia, The University of Adelaide, Flinders University, Flinders Medical Centre, the Royal Adelaide Hospital, Lyell McEwin Hospital, Prince Alfred Hospital, Poche Centre for Indigenous Health, Aboriginal and Torres Strait Islander School of Health, SAHMRI (South Australian Health and Medical Research Council – Prof Alex Brown), Nunkuwarrin Yunti Health Centre, Nganampa Health Council and Tauondi Aboriginal Community College (full list of engagement with individual names, where permission has been granted by the individual, can be made available on request). In addition, Respiratory Specialists named as associate investigators on this application collectively collaborate with health professionals and consult patients across all six communities included in this application through clinics and outreach services. Moreover, this proposal includes a specific approach of training existing health professionals recognised in their communities, which is a different approach to a policy-based intervention. We are engaging with communities that want to participate using their preferred health professional as a vector. Therefore it can be considered complementary.

Benefit: This smoking cessation and healthy lifestyle program can be easily implemented nation-wide with little expense. Health professionals participating in this research will also gain new skills, knowledge and build confidence in their abilities to offer smoking cessation and prevention advice, motivational interviewing, as well as gain access to a broader range of culturally-tailored and community-driven resources that can be used in everyday practices. In addition, patients of the health professionals will benefit through increased and enhanced opportunities to quit smoking, with improved access to support services, resources and other smoking cessation and prevention aids such as counselling, pharmacotherapy and pamphlets. Moreover, the majority of resources that will be used in this program have already been developed with extensive community consultation and participation, with the purpose of this proposal to simply facilitate greater dissemination of these resources to community members, with health professionals as the vector.

Sustainability and transferability: Considering the expertise, experience and position of investigators on this application, translation into standard clinical practice and policy is exceedingly achievable, with the potential for high impact changes to health service delivery by health professionals. The simple intervention model proposed in this application has the potential to produce sustainable community benefits and lead to major health improvements in Aboriginal and TSI communities through reductions in smoking. As described in our proposal, even an 8% reduction in the prevalence of tobacco smoking in Australia would result in 158,000 fewer incident cases of disease, 5000 fewer deaths, 2.2 million fewer lost working days, 3000 fewer early retirements and would reduce health sector costs by AU\$491 million. Moreover, the training provided to health professionals through this research will produce sustainable skills that will survive beyond the life of the investigation and can be transferred to priorities other than tobacco.

Building capacity: In 2010 the South Australian Department of Health State-wide Service Strategy Division stressed the need to support the jobs and health of Aboriginal Health Workers. Building capacity through offering a low-intensity but high-impact training in the latest smoking cessation strategies will contribute toward capacity building, by offering long-term and sustainable skills that can be utilised throughout the health professional's career. This training will benefit the

health professionals (the majority of which are likely to be of either Aboriginal and/or TSI heritage as identified through our pilot investigations) by 1) enhanced skills, knowledge and confidence for the delivery of smoking cessation strategies, 2) development of general motivational interviewing techniques that can be applied to other scenarios and 3) additional skills to include in Curriculum Vitae's. For non-Indigenous health professionals, they will learn cultural sensitivity and awareness, which was reported by all participants in pilot investigations (Indigenous and non-Indigenous alike) to currently be lacking in existing health practices. Finally, if proven successful the results from this research will be used to make a case to the Australian Government for wide-spread National implementation of this program that will require funding for additional health professionals who will need to be trained (up-skilling) in motivational interviewing techniques with knowledge around tobacco use and smoking cessation. In addition, building on the multi-faceted intervention model in this proposal, we hope to apply for NHMRC funding to evaluate a broader healthy life-style program that incorporates other leading risk factors for disease and premature mortality including nutrition, exercise, obesity, alcohol and other social, environmental and personal factors.

Priority: As highlighted in our research proposal, tobacco use among Aboriginal and TSI Australians has been recognised as the number one cause of chronic conditions and disease among Aboriginal Australians (SA Department of Health, 2010). In particular, smoking cessation and tobacco abuse prevention for Aboriginal Australians was identified as a key national health priority. Yet despite being over represented in the burden of tobacco-related morbidity and mortality, very little research has been successfully conducted to evaluate and/or enhance the uptake of smoking cessation pharmacotherapies and other tobacco related initiatives for Indigenous Australians, as evident in our recent publications. Without repeating the full background to this proposal, tobacco use among Indigenous Australians is reported to contribute to 80% of all lung cancer deaths, 37% of ischemic heart disease, 21% of chronic obstructive pulmonary disease, 9% of all strokes and 5% of low birth-weight babies. Thus reducing the prevalence of tobacco use among Aboriginal and TSI Australians is a considerable priority. However, despite these harrowing statistics, tobacco use is considered by most to be only one in a myriad of other health, social, lifestyle and environmental issues faced by Indigenous Australians, reducing its priority in the eyes of some Aboriginal and TSI people, as evident in our pilot investigations. In addition, tobacco use in the Aboriginal and TSI setting is more complicated than simply addiction or habit. As such, our study which has been in development over the past three years has been designed to take these complexities into account, through incorporating existing community-driven health programs. Our intervention coupled with these broader healthy lifestyle programs, will enhance quit smoking attempts by addressing the 'syndrome' of needs rather than merely isolating tobacco. This study intervention also endeavours to improve facilitation and dissemination of local health initiatives to the broader community of professionals, who may not be aware of the breadth of services and resources available to them (as evident in our pilot research).

Significance: South Australia was the only location where predicted performance at the beginning of the COAG implementation program was worse than the projected indicators and where the lack of significant decreases in Aboriginal mortality mean that SA will not meet the 2031 health improvement targets unless Indigenous death rates begin to fall faster. Tobacco cessation is known to markedly influence morbidity and premature mortality, thus the potential to produce a substantial health benefit across a large group of Indigenous Australians is realistic and achievable through the research proposed in this TRIP Fellowship application. In addition, optimising the delivery of existing culturally-tailored and community-driven health programs will not only improve the chances of smoking cessation and tobacco abuse prevention among participants in this trial, but also aid dissemination of existing efforts that have been comprehensively developed and often extensively funded, though too-often underutilised within the health sector and Indigenous communities.



Australian Government

National Health and Medical Research Council

TRIP Fellowships - Assessor Snapshot Report - APP1092680

2014_TRIP Fellowships_funding_commencing_2015

Applicant & Citizenship: (CIA) Kristin Carson - Australia

Application Title: Training health professionals in smoking cessation and tobacco abuse prevention for Aboriginal Australians

Institution(s) Participating (A-PInst):	The University of Adelaide
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Actual Institutions (A-IAct)	Department
Aboriginal Health Council of SA	Multiple areas for liaison and consultation including tobacco co-ordinators
Cancer Council SA	Multiple areas where Indigenous specific resources are developed
Central Adelaide Local Health Network Incorporated trading as Royal Adelaide Hospital	Multiple departments where Indigenous healthcare professionals work
Central Adelaide Local Health Network Incorporated trading as The Queen Elizabeth Hospital (TQEH)	Clinical Practice Unit
Flinders Medical Centre	Multiple departments where Indigenous healthcare professionals work
Lyell McEwin Hospital	Multiple departments where Indigenous healthcare professionals work
Murray Mallee Community Health Service	Multiple departments where Indigenous healthcare professionals work
Southern Fleurieu Health Service	Multiple departments where Indigenous healthcare professionals work
The University of Adelaide	School of Medicine

Guide to Peer-Review Areas (A-RC): Indigenous Health, Population Health, Health Promotion

Broad Research Area (A-RC): Health Services

Field of Research (A-RC): PUBLIC HEALTH AND HEALTH SERVICES - Aboriginal and Torres Strait Islander Health

Research Keywords/Phrases (A-RC): smoking cessation, addiction prevention, Aboriginal health, translational research, health care utilisation

Health Care Profession	Tertiary Qualifications	Indigenous Focus	Do you wish to be considered for a Co-funded Fellowship?
Other	The Diploma of Laboratory Technology (Pathology Testing) provided me with the foundation necessary for understanding medical technology and research related to health. This qualification has been sufficient in allowing me to be employed as a Senior Medical Research Scientist within The Queen Elizabeth Hospital and enrolment into the University of Adelaide for a PhD in Medicine (supplemented by a large track record of on the job research experience and academic output).	Yes	Yes

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B-EI: Eligibility Information

Health Care Professional

What is your health care profession? **Other**

If 'Other' is selected above, identify the type of health care profession below. Guidance on requirements in relation to health care profession is provided in the 'Advice and instructions to applicants' document and the TRIP funding rules.

I am a Senior Medical Research Scientist, which encompasses multiple health care professional roles including clinical trial manager and policy maker (i.e. policy discussions). I am responsible for the research projects of over 25 health professionals in South Australia (including doctors, advanced trainees, nurses, physiotherapists, students and laboratory technicians) along with over 40 research projects. I also have a number of policy roles within SA Health and other organisations.

Tertiary Qualifications

Applicants must hold, as a minimum, a relevant Bachelor's degree or equivalent tertiary qualification. The qualifications entered in your RGMS CV (under CV-QAP) will be listed on the assessor snapshot report for this application. Describe how the qualifications you hold meet the minimum requirements of this application.

The Diploma of Laboratory Technology (Pathology Testing) provided me with the foundation necessary for understanding medical technology and research related to health. This qualification has been sufficient in allowing me to be employed as a Senior Medical Research Scientist within The Queen Elizabeth Hospital and enrolment into the University of Adelaide for a PhD in Medicine (supplemented by a large track record of on the job research experience and academic output).

Employing Institution (Upload)

See separate attachment titled: [APPID1092680_Carson_Employing Health Care Authority Statement of Support.pdf](#)

CV-CD: Career Disruption (last 5 years only)

Duration	Career Disruption	Explanation
-		

B-AEST: Application Executive Summary (TRIP)

Being in a position to change people's lives and actually see those changes taking place in clinical practice is what drives me. I have had to work harder than most to become recognised as a scientist, finishing year 12 only three points shy of a fail. Yet this early adversity has actually given me an advantage, teaching me to challenge existing infrastructure and concepts and most importantly to think outside of the box. In 2012 following a hospital budget discussion I approached the Health Minister at the time, Hon. John Hill, to ask a question about what is being done to improve Aboriginal Health in South Australia and reduce the current disease burden. The outcome of this discussion was an invitation to visit parliament house on multiple occasions to discuss tobacco related initiatives and dissemination of state funding based on my research. This resulted in several changes to the state-wide hospital tobacco policy to include alternative forms of smoking cessation medication apart from nicotine replacement therapy, as well as a request for the findings from my work to be presented to Parliament House and 12-months of funding to continue my research.

From an academic output perspective I have produced over 35 peer-reviewed publications, written a chapter for a hard-cover published book on Health Disparities, co-authored over 60 scientific conference abstracts and have over 140 media citations (including television, radio, newspaper, magazine and online news websites), all in the past four years alone. My commitment and leadership strengths have seen me elected as the Chairperson for the Tobacco and Addictive Substances Special Interest Group for the Thoracic Society of Australia and New Zealand (TSANZ) since 2012 and more recently as one of the youngest Editorial Board Members for the Cochrane Database of Systematic Reviews (ranked 11 out of 151 journals in the Medicine, General and Internal category). In March this year I was the recipient of the Channel 9 Premier's Young Achiever of the Year and the University of Adelaide Faculty of Sciences, Science and Technology Award winner during the same award ceremony. The connections and collaborations I have made through these avenues is what I call upon to influence policy and practice change. I have learnt that without a solid network of influential and passionate people, successful research translation is not possible.

I have the capability, drive and proven track record of success in translating research into practice and policy on a local and international level. Through the opportunity the TRIP Fellowship provides, I intend to apply my knowledge and skills in translational research to benefit a population with the greatest burden of morbidity and premature mortality within Australia, being Aboriginal Australians. Current statistics estimate that approximately 45% of Aboriginal people aged 14 years and over are reporting smoking daily, compared to 17% in the non-Indigenous setting. Since 2008 the Australian government has invested AU\$2.34 billion to reduce this gap and others like this in Indigenous health, yet progress is slow. My proposed Fellowship will provide arguably the first methodologically rigorous evaluation of tobacco prevention and cessation for Aboriginal Australians, through a multi-centre cluster randomised delayed-intervention controlled trial (RCT). The pilot tested intervention that has been developed from systematic examination of the global evidence, community participation and practical cost-effective considerations will combine: training workshops in motivational interviewing techniques coupled with provision of the latest evidence for tobacco related research, and instructions on how to access existing culturally-tailored and community developed resources. However, to make a national contribution to Indigenous health, we first have to prove that this intervention strategy will indeed be effective and this well-powered RCT will provide this evidence.

B-GP: Grant Proposal

See separate attachment titled: APPID1092680_Carson_Grant Proposal.pdf

B-RTO: Research Translation Output

Comment on up to four of your significant publications, papers, reports and other contributions with a focus on the last five years that demonstrate the quality of your research translation output.

On an international level my research in patient self-management of asthma (protocol published, review In Press) has been utilised by the National Institute of Health and Clinical Excellence as the foundation of their clinical indicators to underpin their 2014 guideline for the 'Quality and outcomes framework for asthma clinical care' across the United Kingdom. The same research was also used to inform 'Quality Outcome Measures' for paediatric asthma action plans for the non-profit Primary Care Medical Home Group in the United States of America. My research examining physical training for asthma has determined that exercise is safe among asthmatics and can actually reduce their risk of future exacerbations. This work has received extensive media attention around the world with publication in several languages. My research examining the effectiveness of 'training health professionals in smoking cessation' has identified that one-off group training sessions of a short duration are just as effective as an intense one-on-one training session in teaching functional techniques to health professionals that can be used to help smokers quit. The intervention for this TRIP application has been designed based on this evidence, coupled with one of my other Cochrane reviews, 'Interventions for smoking prevention in Indigenous youth'. Significant gaps in the evaluation of existing heavily-funded tobacco programs intended to encourage young Indigenous Australian's not to smoke were identified, with no studies identified from Australia. Importantly my analyses revealed that some programs overseas are actually causing more harm than good with a greater uptake of tobacco use among youth in the intervention group compared to the control. Subsequently, this research has been broadcast across several radio stations Australia-wide, been featured in 'The Australian' and triggered funding for me to produce a policy document for the Australian and New Zealand School of Government.

B-RTL: Research Translation Leadership

Provide details of your success in building your profile as a leader in research translation. Guidance on how to complete this section is provided in the advice and instructions to applicants.

I have personally fostered collaborations with over 50 researchers world-wide including Iran, Netherlands, Ireland, the USA and the UK, resulting in an invitation for a 4-week sabbatical in London at Saint George's Hospital and Oxford University for 2015. Since 2010 I have published over 35 peer-reviewed articles, many in high impact journals, contributed to over 60 scientific abstracts and produced over 140 media citations. Since 2011 I have completed over three dozen peer reviews for scientific journals including two for the Journal of the American Medical Association, and reviewed four grant applications for funding (three international). I am one of the youngest ever researchers elected as Chair of a special interest group with for the Thoracic Society of Australia and New Zealand (TSANZ) and I have been elected as one of the youngest Editors for the Cochrane Library. In 2012 I also founded the TSANZ Indigenous Lung Health Working party, gaining not only the support but also the involvement of the current President and CEO. When starting in Respiratory Medicine in 2008, my role was to recruit patients and collect data for one study. The department produced on average three papers and three abstracts each year. I have since evolved this position to one of a leader within the unit and in the past two years the department has produced an average of 14 peer reviewed publications and eight conference presentations, with six peer reviewed publications and 23 accepted scientific conference abstracts already produced in 2014, all of which I have personally facilitated. I am now responsible for over 40 research projects and the research activities of 25 staff (including doctors, consultants, advanced trainees, registrars, interns, and PhD students) for the Respiratory Medicine Department and Clinical Practice Unit at The Queen Elizabeth Hospital. Subsequently, in 2013 eight doctors from other hospitals approached me to assist them with their research projects.

B-COL: Collaboration

Past collaborations, including your role and any resulting outcomes (e.g. publications, patents, translation into policy or practice, primary health care).

My collaborations through the Thoracic Society of Australia and New Zealand have allowed me to influence several policy and practice documents. For example through my position as chairperson for the tobacco special interest group I have been able to use evidence from my Cochrane reviews to underpin evidence based changes for several documents, including: the 'National Tobacco Strategy 2012-18', 'Options to introduce new tobacco product content controls and new disclosure requirements for tobacco products 22 Feb 2013' by the Department of Health and Ageing and I provided feedback on the 'Protecting children from tobacco fact-sheet' developed by the Action on Smoking and Health Council.

My collaboration on the STOP (Smoking Termination Opportunity for inPatients) trial started in 2008 when I was employed during the design phase. Over a four year period I supervised a team of three researchers to help recruit 392 patients admitted to one of three South Australian hospitals with acute smoking related illnesses and randomised them to either smoking cessation treatment with varenicline tartrate (Champix) plus Quitline counselling or Quitline counselling alone. The final outcome of this study (Thorax 2013) was a statistically significant difference in continuous smoking abstinence at 12 month follow-up in the medication group (31%) compared to the counselling alone group (21%), both of which were exceptionally superior to the standard unassisted hospital quit attempt of 3%. An economic analysis also revealed a substantial saving to the health system of \$6,646.00 per successful quitter over the 12 month study period through reduced length of hospital stay and readmission with a direct saving of \$684,538.00. This work has since been featured on Channel 9 news and presented at over 30 fora including selection into the 'Late Breaking Clinical Trials' oral session for the American Thoracic Society conference.

Current collaborations, including your role and any resulting outcomes (e.g. publications, patents, translation into policy or practice, primary health care).

A multi-centre randomised cross-over trial comparing light-weight battery-powered portable oxygen concentrators to oxygen cylinders is currently underway, though preliminary investigations have found equivalent efficacy between devices, with longer term cost-effectiveness and patient preference for the battery-powered device. I presented these results at the Thoracic Society of Australia and New Zealand conference in 2013 and subsequently a case report is underway to recommend that hospitals purchase these devices for clinical practice. Incidentally, during recruitment we also uncovered that patients were not being re-assessed for oxygen requirements after the initial prescription, resulting in more than 60% of the 100+ patients screened no longer meeting the criteria for oxygen therapy. This has initiated an immediate review of practice across South Australia and re-assessment of all existing patients to determine oxygen need.

Through consultation with over 100 Aboriginal Elders, key community stakeholders and researchers across Australia, I have built a large network of collaborators with an interest in Indigenous health. Many of these individuals are involved in current projects as part of my PhD which involve focus groups in cohorts of Aboriginal smokers, ex-smokers and non-smokers to produce a better understanding of the barriers and facilitators surrounding successful smoking cessation attempts.

Collaborations I have built outside of employment include successful partnerships with researchers from Iran, producing three peer-reviewed publications to date, with two additional articles in press and three others in production. My skills in evidence based medicine research have also helped me foster collaboration with a team of cardiologists at The Queen Elizabeth Hospital, producing two publications in leading cardiac journals on tako-tsubo cardiomyopathy already in 2014 with another currently in production.

B-SM: Supervision and Mentoring (TRIP)

Highlight your contribution to research translation through teaching, supervision and mentoring, including any notable positions and/or achievements that have arisen from your supervision and mentoring activities

I have successfully collaborated with over 60 researchers from around the world (including The Netherlands, Iran, The UK, Scotland and all states and territories within Australia) to produce over 35 peer-reviewed publications in four years alone. My role for 18 of these publications has been the facilitation of the research team, training of new researchers (particularly around evidence based research for the Cochrane reviews), designing the protocol and performing data analyses as well as writing up the manuscripts and supervising the work through to publication. My training of new researchers and facilitation of new author teams has resulted in my election as an Editorial Board member for the Cochrane Library, through the Airways group based in London. On a local level I have been able to inspire several staff within the Respiratory Department to consider doing research alongside their clinical work, resulting in a record number of scientific abstracts for our unit to present at the Thoracic Society of Australia and New Zealand conference (17 for 2014; previous record was 7 in 2013). Two of these teams of new researchers received awards for best presentations during the conference, one for the nursing special interest group and the other for chronic obstructive pulmonary disease. Moreover, all staff members who participated in the 2014 conference are already underway with their research projects for the 2015 conference.

Since 2013 I have been responsible for several staff members embarking on further study, including two PhD students and two Masters students. After convincing them to undertake the additional workload and research, I helped them design a research project, select outcomes, establish a workable timeline and start the work. All four students are currently ahead of schedule for completion and following completion of my PhD I will be added as a post-doctoral supervisor on all four projects.

B-SMS: Supervision and Mentoring Summary (TRIP)

Student's/Staff name	Years involved	Supervisory role	Level	Completed	Student's/Staff current role	Additional comments
Karen Royals	2	Co-Supervisor	Masters	No	Clinical Practice Consultant and Respiratory Nurse at The Queen Elizabeth Hospital	I encouraged Karen to commence a Masters degree and am in the process of designing her research proposal. I will also be supervising the research activities through to completion and submission of her thesis. I have supervised Karen on other research activities over the past year, which will be used as the foundation of her Masters degree.
Kathryn Lawton	1	Co-Supervisor	Masters	No	Respiratory Clinical Practice Consultant and Nurse at The Queen Elizabeth Hospital	I encouraged Kathy to commence a Masters degree and am in the process of designing her research proposal. I will also be supervising the research activities through to completion and submission of her thesis.
Khin Hnin	1	Mentor	PhD	No	Respiratory Clinician at Flinders Medical Centre and PhD student	I helped to design Khin's PhD work and I was responsible for her considering to become a PhD student. I still provide ongoing input into her PhD work.

Rachada To-A-Nan	2	Mentor	PhD	No	PhD student with the Therapeutics Research Group, Basil Hetzel Institute for Translational Health Research	Although Rachada is doing her PhD with another research unit at the Basil Hetzel Institute for Translational Health Research, she approached me to assist her with her PhD work as her progress was slow due to a lack of structure in the design. I have worked with Rachada on another research trial (manuscript in production) and have subsequently joined her PhD supervisory team as a mentor over the past two years. She is expected to complete in early 2015.
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Zafar Usmani	6	Co-Supervisor	PhD	No	Respiratory & Sleep Physician at the Queen Elizabeth Hospital and the Lyell McEwin Hospital and PhD student	I have worked with Zafar for over six years on various research projects (many published). It was through one of these Cochrane reviews 'Pharmacological interventions for the treatment of anxiety in patients with COPD' that we identified the gap in the existing literature and have subsequently developed a methodologically rigorous and well-powered randomised controlled trial to address this gap. I then encouraged Zafar to use this work to complete a PhD in Medicine at the University of Adelaide. Since mid-2013 he has recruited 12 of the 100 participants he needs for this trial to date and expects to complete his PhD (through part time study) in 2019.
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B-CFF: Co-funded Fellowship

Co-funded Fellowship

Do you wish to be considered for a co-funded Fellowship? Yes

Co-funding Partner Organisation/s

Select the Co-funding partner organisation/s you wish to nominate. You may nominate more than one co-funding partner.	Cancer Australia - Lung and Gynaecological Cancers
If 'Other' is selected above, enter the name of the co-funding partner organisation(s) in the text box below.	

Relevance to Co-funding Organisation/s

Outline the relevance of your project to the aims of the co-funding organisation/s.

On the 3rd of October 2013 I was interviewed for ABC PM news (radio) about the latest statistics released by the Australian Institute of Health and Welfare, which found that Indigenous people are 50 per cent more likely to die from cancer than other Australians. Lung cancer was the most commonly diagnosed cancer and the evidence is clear that tobacco smoking is the leading contributor to lung cancer development. Considering that tobacco use among Indigenous Australians is twice that of the non-Indigenous, reducing tobacco use will logically reduce the incidence of lung cancer within this population. A lot of funding has been invested into this area, however, my PhD work has uncovered that the resources developed from this funding are not making it to the frontline of clinical care. My proposed project uses a randomised controlled trial to examine an intervention that combines tobacco cessation and prevention education workshops using the latest literature as the evidence base (through partnership with Cancer Council SA and based on my published evaluations) that is culturally tailored for the Indigenous setting. It also provides training to health professionals across a range of disciplines in motivational interviewing techniques and finally we identify existing community-owned and initiated health improvement programs and demonstrate how to access and utilise these existing resources on the frontline of clinical management. By training health professionals who see Aboriginal patients, this approach can provide long-term sustainable benefit to a broad range of community members that require little investment from our end (and later the government if national roll-out is determined to be feasible) and the skills will be maintained beyond the life of the research project. This trial will be the first in Australia to produce a methodologically rigorous evaluation of a tobacco cessation and prevention program specifically designed to improve Indigenous health

B-NM: Nomination of Mentors

Project Mentor

Professor Brian James Smith

Director of Respiratory Medicine The Queen Elizabeth Hospital

4A Main Building; The Queen Elizabeth Hospital; 28 Woodville Road, Woodville South, SA, 5011

brian.smith@health.sa.gov.au 08 8222 7966 08 8222 6041

Project Mentor Statement of Support (Upload)

See separate attachment titled: [APPID1092680_Carson_Project Mentor_Statement of Support.pdf](#)

B-PDP: Professional Development Plan

Course/Activity name	Type of course	Institute	Other Organisation (Non Institution)	Duration of course	Contribution to skills	Additional comments
'R' statistics workshop	Adelaide University Course	The University of Adelaide	Researcher Education Development Unit	Two, 6 hour workshops	<p>This 'R' statistics workshop will provide me with a basic insight into how to navigate this freely available statistical package that can be used for statistical analysis of data. To become familiar with this program will give me more options for data analysis and will help improve my overall statistics skills.</p> <p>Considering that my statistical abilities are currently quite poor, this course will help me to improve in this area, as to date the majority of analyses for my larger research projects (such as the STOP smoking trial) have been done by external statisticians.</p>	

Aboriginal Health Conference	National Conference		Aboriginal Health Conference	The conference goes for two days in July each year.	This conference provides me with a unique opportunity to meet and talk with other academics and research related professionals that work in Indigenous Health. As I have yet to attend the Aboriginal Health conference, the potential to learn from other health professionals and academics in the area will greatly improve my abilities to translate research in this field. My intention is to network with as many people as possible during this conference to build my profile as a researcher in Aboriginal and Torres Strait Islander health as well as learn how to improve my work for this Fellowship application and into the future. I also intend on presenting the results from this Fellowship research during the Aboriginal Health conference.	
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Advanced STATA programming 152	Statistical analysis course using STATA		(SDAS) Survey Design and Analysis Services Pty Ltd	Seven week, five lecture	<p>As a research scientist, having an expert grasp of data analysis procedures are fundamental. For this reason learning STATA as my primary data analysis platform across the Fellowship period will provide me with a fundamental skill which I am currently lacking that puts me at a significant disadvantage compared to other scientists. The opportunity provided through this Fellowship in terms of time allocation for professional development activities and the funding to attend these courses is something that I am unlikely to get a chance to complete in my current position at The Queen Elizabeth Hospital.</p> <p>The advanced programming 152 course will follow-on from the 151 course and will teach how to add new commands to Stata for those who understand the basics of Stata programming. This course covers advanced issues of programming in the Stata language, focusing on writing commands for general use.</p>	
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Attendance at the Thoracic Society of Australia and New Zealand (TSANZ) conference	National conference		Thoracic Society of Australia and New Zealand	Six days each year	Attendance at this conference will facilitate an opportunity for networking with leading researchers, doctors and other professionals from across Australia and New Zealand. In addition, the TSANZ Indigenous Lung Health Working Party which I Chair occurs annually at these meetings, and will be used to brainstorm ideas with eminent professionals with a similar passion for Indigenous health. This network will also be used to disseminate research findings and the society will provide influential backing for a case study to be made to the Australian government following completion of the research outlined in this proposal. I also plan to present the results of this research at the conference, which I hope will provide me with the opportunity to network with a larger range of influential academics and receive constructive feedback on my research.	
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<p>Australian Smoking Cessation Conference</p>	<p>National Conference</p>		<p>Australian Smoking Cessation Conference</p>	<p>The conference goes for 3 days every year in November.</p>	<p>Attendance at this conference will provide me with an opportunity to meet and network with experts in tobacco use, cessation and prevention from across Australia. In addition to presenting the results from the work produced from this Fellowship proposal, I also hope to see the work being produced by these tobacco experts across Australia and gain feedback and learn from their expertise. In addition, I hope to get advice from them about how best to disseminate research findings and considering that I have yet to attend the Australian smoking Cessation Conference there is much I can learn from these experts in my field.</p>	
<p>Basic statistics and research methods</p>	<p>Adelaide University Course</p>	<p>The University of Adelaide</p>	<p>Researcher Education Development Unit</p>	<p>5 weekly 2 hour workshops</p>	<p>This course will help me to gain a better understanding of statistical methods for my research. As my statistical abilities are currently quite poor, this course will help me to improve in these areas. This course will be of particular use when it comes to to analyse the data from this Fellowship trial, as to date the majority of analyses for my larger research projects (such as the STOP smoking trial) have been done by external statisticians.</p>	

Cultural competency training	Adelaide University Course	The University of Adelaide		4 hours each year	This course will help me to obtain a better understanding around cultural competency and learn appropriate methods that I can employ within my current research activities. It will improve my awareness of cultural aspects that need to be considered for conducting research in Aboriginal and Torres Strait Islander health in Australia and will help me to identify issues that may be considered sensitive. This course is fundamental to anyone doing research or undertaking academic pursuits within Aboriginal health.	
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Introduction to STATA 101	Statistical analysis course using STATA		(SDAS) Survey Design and Analysis Services Pty Ltd	6 week four lecture course	As a research scientist, having an expert grasp of data analysis procedures are fundamental. For this reason learning STATA as my primary data analysis platform across the Fellowship period will provide me with a fundamental skill which I am currently lacking that puts me at a significant disadvantage compared to other scientists. The opportunity provided through this Fellowship in terms of time allocation for professional development activities and the funding to attend these courses is something that I am unlikely to get a chance to complete in my current position at The Queen Elizabeth Hospital. The Introduction to STATA 101 is a net course will provide an introductory, six-week (4 lectures) course that will teach me how to use Stata interactively. Through a combination of lectures, example applications, and carefully chosen problems, the course covers the basic commands necessary to be most productive in the Stata environment.	
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Introduction to STATA programming 151	Statistical analysis course using STATA		(SDAS) Survey Design and Analysis Services Pty Ltd	Seven week, five lecture course	<p>As a research scientist, having an expert grasp of data analysis procedures are fundamental. For this reason learning STATA as my primary data analysis platform across the Fellowship period will provide me with a fundamental skill which I am currently lacking that puts me at a significant disadvantage compared to other scientists. The opportunity provided through this Fellowship in terms of time allocation for professional development activities and the funding to attend these courses is something that I am unlikely to get a chance to complete in my current position at The Queen Elizabeth Hospital.</p> <p>The introduction to STATA 151 will follow-on from the 101 course and teach Stata data-analysis using key programming topics such as macro processing, program flow of control, using ado-files, programming ado-files, Monte-Carlo simulation and bootstrapped standard errors.</p>	
Introduction to statistical comparisons	Adelaide University Course	The University of Adelaide	Researcher Education Development Unit	6 hours	<p>This workshop will provide me with an overview of basic statistical analysis procedures for comparing groups of individuals. It will help me grasp and understand the basic concepts of statistical procedures so that I may choose the correct analysis and interpretation tool for computer output when it comes to analyse data.</p>	

<p>Introduction to survival analysis 631 using STATA</p>	<p>Statistical analysis course using STATA</p>		<p>(SDAS) Survey Design and Analysis Services Pty Ltd</p>	<p>Seven week, five lecture course</p>	<p>As a research scientist, having an expert grasp of data analysis procedures are fundamental. For this reason learning STATA as my primary data analysis platform across the Fellowship period will provide me with a fundamental skill which I am currently lacking that puts me at a significant disadvantage compared to other scientists. The opportunity provided through this Fellowship in terms of time allocation for professional development activities and the funding to attend these courses is something that I am unlikely to get a chance to complete in my current position at The Queen Elizabeth Hospital.</p> <p>The introduction to survival analysis 631 course will teach me how to effectively analyse survival data using Stata. This will cover censoring, truncation, hazard rates, and survival functions. Topics include data preparation, descriptive statistics, life tables, Kaplan–Meier curves, and semiparametric (Cox) regression and parametric regression.</p>	
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<p>Introduction to univariate time series 461 using STATA</p>	<p>Statistical analysis course using STATA</p>		<p>(SDAS) Survey Design and Analysis Services Pty Ltd</p>	<p>Seven week, five lecture course</p>	<p>As a research scientist, having an expert grasp of data analysis procedures are fundamental. For this reason learning STATA as my primary data analysis platform across the Fellowship period will provide me with a fundamental skill which I am currently lacking that puts me at a significant disadvantage compared to other scientists. The opportunity provided through this Fellowship in terms of time allocation for professional development activities and the funding to attend these courses is something that I am unlikely to get a chance to complete in my current position at The Queen Elizabeth Hospital.</p> <p>The introduction to univariate time series 461 course will cover topics such as using time-series data in Stata, moving averages and exponential smoothers, ARMA processes, the autocorrelation and partial autocorrelation functions, ARIMA and ARMAX models, regression analysis, unit roots, and ARCH models. The optional fifth lecture introduces Stata's multivariate time-series features.</p>	
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Questionnaire design for higher degree researchers	Adelaide University Course	The University of Adelaide	Research Education Development Unit	2.5 hours	This workshop will provide me with the knowledge and understanding of the elements of questionnaire design. I will improve upon the concept of variables and its types, their importance and implications in questionnaire development. This will greatly assist me when it comes to designing and distributing my own questionnaires as part of this study and future reserach trials.	
SPSS training linked to 'basic statistics course'	Adelaide University Course	The University of Adelaide	Researcher Education Development	2 hours	This workshop will provide me with some hands-on training in SPSS statistical software package. It will teach me how to enter data, create simple charts and calculate data summaries. SPSS is a vital for analysis of research data, and this course will provide basic exposure to the coding and analysis platform. This will be particularly important for me as to date the majority of analyses for my larger research projects (such as the STOP smoking trial) have been done by external statisticians, leaving my statistical abilities lacking.	

Society for Research on Nicotine and Tobacco	International Conference		Society for Research on Nicotine and Tobacco	4 days in the second year of the Fellowship	Attendance at this conference will facilitate an opportunity for networking with leading researchers, doctors and other professionals from across America and the world. It will give me the opportunity to learn from some of the leading researchers and academics Internationally, which is important for Indigenous health as much of the existing research is being produced in America with the American Indian populations. I also aim to present the findings from this research at the conference, which I hope will provide me with the opportunity to network with a larger range of influential academics and receive constructive feedback on my research.	
Statistics for research students	Adelaide University Course	The University of Adelaide	Researcher Education Development Unit	5 weekly 2 hour workshops	This course will follow on from the other University of Adelaide research statistics course, with more detailed descriptions of research methodology to help me to gain a better understanding of statistical methods for my research. As my statistical abilities are currently quite poor, this course will help me to improve in these areas. This course will be of particular use when it comes to to analyse the data from this Fellowship trial, as to date the majority of analyses for my larger research projects (such as the STOP smoking trial) have been done by external statisticians.	

The right questions about statistics	Adelaide University Course	The University of Adelaide	Researcher Education Development Unit	1 hour a week for 8 weeks	This workshop will teach me how to identify the types of questions that I need to ask in order to decide what statistical procedures are appropriate for my research. It will also help me to acquire a better understanding of statistical procedures and help me to decide the most appropriate methods to display statistics.	
Writing a paper for publication	Adelaide University Course	The University of Adelaide	Research Education Development Unit	Four hours	The course is focused on ‘packaging’ results, identifying the most appropriate journals, identifying likely expectations of referees, and strategies for writing and revising. I believe it will help me to highlight and improve upon on my issues with structure, information flow and writing style. Overall, the course is planned to help me become a better writer.	

CV-EH: Employment History (last 5 years only)

Employer, Job Title	Type, Duration	Current?
The Queen Elizabeth Hospital; Clinical Practice Unit - Respiratory Medicine, Senior Research Officer and Cochrane Coordinator	: 2008 -	Yes

CV-A: Appointments (last 5 Years only)

Type	Organisation	Title	Role	Period	Current
Appointment	Thoracic Society of Australia and New Zealand	Tobacco and Addictive Substances Special Interest Group	Elected Chair	2013 -	Yes
Appointment	Thoracic Society of Australia and New Zealand	Indigenous Lung Health Working Party	Founding member	2013 -	Yes
Appointment	The Cochrane Collaboration	Editorial Board Member Cochrane Airways Group	Invited Editorial Board Member	2013 -	Yes
Appointment	Australian Bureau of Statistics	SA Health Statistical Liason Officer	Invited Statistical Liason Officer	2013 -	Yes
Appointment	Thoracic Society of Australia and New Zealand	Tobacco and Addictive Substances Special Interest Group	Elected Deputy Convenor	2012 - 2013	No
Honorary Appointment	South Australian Health and Medical Research Institute	Aboriginal and Torres Strait Islander Health Working Party	Invited Member	2011 -	Yes
Appointment	The Central Northern Adelaide Health Service	Smoke Free Policy steering committee	Invited Member	2010 -	Yes
Appointment	The Queen Elizabeth Hospital	Smoke Free Policy steering committee	Invited Member	2009 -	Yes

CV-Pub: Publications

CIA (K. Carson) - Journal Articles (Original Research)

- 1 Ameer F, Carson KV, Usmani ZA, Smith BJ *Ambulatory oxygen for chronic obstructive pulmonary disease* **Cochrane Database of Systematic Reviews** (2014) 5 - P01667521 **Grants -**
Deposited in an open access institutional repository - Yes

- 2 Shokouhi S, Sayemhiri K, Carson KV, Alimoghadam K *Effects of aGVHD and cGVHD on survival rate in patients with Acute Myeloid Leukemia after Allogenic Stem Cell Transplantation* **Hematology** (2014) 19 2 - P01670489 **Grants -**
Deposited in an open access institutional repository - Yes

- 3 Singh K, Carson KV, Shah R, Sawhney G, Singh B, Parsaik A, Usmani ZA, Horowitz JD. *Meta-analysis of Clinical Correlates of Acute Mortality in Takotsubo Cardiomyopathy* **American Journal of Cardiology** (2014) 113 8 - P01667551 **Grants -**
Deposited in an open access institutional repository - No

- 4 Nazarzadeh M, Bidel Z, Ayubi E, Khirollah A, Carson KV, Sayemhiri K *Determination of the social related factors of suicide in Iran: a systematic review and meta-analysis* **BMC Public Health** (2013) - P01667742 **Grants -**
Deposited in an open access institutional repository - Yes

- 5 Shokouhi S, Sayemhiri K, Carson KV, Alimoghadam K *Effects of aGVHD and cGVHD on survival rate in patients with Acute Myeloid Leukemia after Allogenic Stem Cell Transplantation.* **Virology Journal** (2013) - P01667497 **Grants -**
Deposited in an open access institutional repository - Yes

- 6 Carson KV, Chandratilleke MG, Picot J, Brinn MP, Smith BJ *Physical training for asthma* **Cochrane Database of Systematic Reviews** (2013) 9 - P01667670 **Grants -**
Deposited in an open access institutional repository - Yes

- 7 Usmani ZA, Carson KV, Heslop K, Esterman AJ, De Soyza A, Smith BJ *Psychological therapies for the treatment of anxiety disorders in chronic obstructive pulmonary disease.* **Cochrane Database of Systematic Reviews** (2013) 8 - P01667725 **Grants -**
Deposited in an open access institutional repository - Yes

- 8 Carson KV, Smith BJ, Brinn MP, Peters M, Fitridge R, Koblar S, Jannes J, Veale A, Goldsworthy S, Litt J, Edwards D, Esterman AJ *Safety of a course of varenicline tartrate and counselling over counselling alone for smoking cessation: A 52 week randomised controlled trial for inpatients (STOP Study)*. **Journal of Substance Abuse Treatment** (2013) - P01667487 **Grants** -
Deposited in an open access institutional repository - Yes
- 9 Smith BJ, Carson KV, Brin MP, Labiszewski NA, Peters M, Fitridge R, Koblar S, Jannes J, Veale A, Goldsowrthy S, Litt J, Edwards D, Esterman AJ *Smoking Termination Opportunity for inPatients (STOP): Superiority of a course of varenicline tartrate plus counselling over counselling alone for smoking cessation: A 12-month randomised controlled trial for inPatients*. **Thorax** (2013) - P01667771 **Grants** -
Deposited in an open access institutional repository - Yes
- 10 Nazarzadeh M, Bidel Z, Carson KV *The association between tramadol hydrochloride misuse and other substances use in an adolescent population: Phase 1 of a prospective survey*. **Addictive Behaviours** (2013) - P01667694 **Grants** -
Deposited in an open access institutional repository - Yes
- 11 Carson KV, Labiszewski NA, Brin MP, Esterman AJ, Peters MJ, Wood-Baker R, SMith BJ *Consumer guidelines for chronic disease management: Protocol*. **Cochrane Database of Systematic Reviews** (2012) 9 - P01667846 **Grants** -
Deposited in an open access institutional repository - Yes
- 12 Wong CX, Carson KV, SMith BJ *Home care by outreach nursing for chronic obstructive pulmonary disease*. **Cocharane Database of Systematic Reviews** (2012) 4 - P01667909 **Grants** -
Deposited in an open access institutional repository - Yes
- 13 Carson KV, Brinn MP, Peters M, Veale A, Esterman AJ, Smith BJ *Interventions for smoking cessation in Indigenous populations (Review)* **Cochrane Database of Systematic Reviews** (2012) 1 - P01668062 **Grants** -
Deposited in an open access institutional repository - Yes
- 14 Carson KV, Labiszewski NA, Brinn MP, Veale A, Chang AB, Esterman AJ, Smith BJ *Interventions for tobacco prevention in Indigenous youth* **Cochrane Database of Systematic Reviews** (2012) 8 - P01667882 **Grants** -
Deposited in an open access institutional repository - Yes

- 15 Brinn MP, Carson KV, Esterman AJ, Chang AB, Smith BJ *Mass media interventions for preventing smoking in young people (Review)* **Evidence Based Child Health: A Cochrane Review Journal** 2012 (2012) - P01668078 **Grants -**
Deposited in an open access institutional repository - Yes
- 16 lim WJ, Mohammed AR, Carson KV, Mysore S, Labiszewski NA, Wedzicha JA, Rowe BH, Smtih BJ *Non-invasive positive pressure ventilation for treatment of respiratory failure due to severe acute exacerbations of asthma: Cochrane systemactic review* **Cochrane Database of Systematic Reviews** (2012) - P01667763 **Grants -**
Deposited in an open access institutional repository - Yes
- 17 Chandratilleke MG, Carson KV, Picot J, Brinn MP, Smith NJ *Physical training for asthma* **Cochrane Database of Systematic Reviews** (2012) 5 - P01667902 **Grants -**
Deposited in an open access institutional repository - Yes
- 18 Carson KV, Verbiest MEA, Brinn MP, Crone MR, Esterman AJ, Assendelft WJJ, Smith BJ *Training health professionals in smoking cessation (Review)* **Cochrane Database of Systematic Reviews** (2012) 5 - P01667891 **Grants -**
Deposited in an open access institutional repository - Yes
- 19 Roy A, Schultz TJ, Carson KV, Smith BJ, Powell H, Wilson A, Walters EH *Asthma self-management education with either regular health care professional review or written action plans or both for asthma - Protocol* **Cochrane Database of Systematic Reviews** (2011) 12 - P01668106 **Grants -**
Deposited in an open access institutional repository - Yes
- 20 Carson KV, Brinn MP, Labiszewski NA, Esterman AJ, Chang AB, Smith BJ *Community interventions for preventing smoking in young people* **Cocharane Database of Systematic Reviews** (2011) 7 - P01668165 **Grants -**
Deposited in an open access institutional repository - Yes
- 21 Wong CX, Carson KV, Smith BJ *Home care by outreach nursing for chronic obstructive pulmonary disease* **Cochrane Database of Systematic Reviews** (2011) 3 - P01668171 **Grants -**
Deposited in an open access institutional repository - Yes

- 22 Carson KV, Brinn MP, Veale A, Esterman AJ, Smith BJ *Interventions for smoking cessation in Indigenous populations. Protocol* **Cochrane Database of Systematic Reviews** (2011) 11 - P01668176 **Grants -**
Deposited in an open access institutional repository - Yes
- 23 Carson KV, Labiszewski NA, Brinn MP, Veale A, Chang AB, Esterman AJ, Smith BJ. *Interventions for smoking prevention in Indigenous youth. PROTOCOL.* **Cochrane Database of Systematic Reviews** (2011) 9 - P01668126 **Grants -**
Deposited in an open access institutional repository - Yes
- 24 Usmani ZA, Carson KV, Cheng JN, Esterman AJ, Smith B *Pharmacological interventions for the treatment of anxiety disorders in chronic obstructive pulmonary disease* **Cochrane Database of Systematic Reviews** (2011) - P01668117 **Grants -**
Deposited in an open access institutional repository - Yes
- 25 Brinn MP, Carson KV, Esterman AJ, Chang AB, Smith BJ *Mass media interventions for preventing smoking in young people* **Cochrane Database of Systematic Reviews** (2010) - P01668181 **Grants -**
Deposited in an open access institutional repository - Yes
- 26 Usmani ZA, Cheng JN, Smith B, Carson KV *Pharmacological interventions for the treatment of anxiety and panic in chronic obstructive pulmonary disease. Protocol.* **Cochrane Database of Systematic Reviews** (2010) 4 - P01668186 **Grants -**
Deposited in an open access institutional repository - Yes
- CIA (K. Carson) - Accepted for Publication**
- 27 To-A-Nan R, Carson KV, Bond C, King C, Smith BJ *Community pharmacy interventions for smoking cessation* **Cochrane Database of Systematic Reviews** (2014) 6 - P01667580 **Grants -**
Deposited in an open access institutional repository - Yes
- 28 Carson KV, Sayemhiri K, SayemhiriF, Brinn MP, Esterman AJ, Chang AB, Smith BJ *Mass media interventions for preventing smoking in young people* **Cochrane Database of Systematic Reviews** (2014) 6 - P01667542 **Grants -**
Deposited in an open access institutional repository - Yes

- 29 Carson KV, Smith BJ, Brinn MP, Peters M, Fitridge R, Koblar S, Jannes J, Veale A, Singh K, Goldsworthy S, Litt J, Edwards D, Esterman AJ *Safety of a course of varenicline tartrate and counselling over counselling alone for smoking cessation: A 52 week randomised controlled trial for inpatients* **Nicotine and Tobacco Research** (2014) - P01845088 **Grants** -
Deposited in an open access institutional repository - No
- 30 Singh K, Usmani Z, Carson K, Sawhney G, Shah R, Horowitz J *Systematic review and meta-analysis of incidence and correlates of recurrence of Takotsubo Cardiomyopathy* **International Journal of Cardiology** (2014) In Press (May) - P01845087 **Grants** -
Deposited in an open access institutional repository - No
- 31 Carson KV, Chang AB, Brinn MP, Peters M, Nikitins I, Shah S, Veale A, Esterman AJ, Smith BJ *Tobacco use cessation and prevention initiatives for Indigenous populations: A systematic review.* **Evidence Base** (2014) - P01667627 **Grants** -
Deposited in an open access institutional repository - Yes
- CIA (K. Carson) - Journal Articles (Review)**
- 32 Carson KV, Usmani ZA, Smith BJ *Non-invasive ventilation in Acute Severe Asthma: Current evidence and future needs* **Current Opinion in Pulmonary Medicine (Asthma Special Edition January 2014)** (2014) - P01669887 **Grants** -
Deposited in an open access institutional repository - Yes
- 33 Carson KV, Brinn MP, Robertson T, To-A-Nan R, Esterman AJ, Peters M, Smith BJ *Current and emerging pharmacotherapeutic options for smoking cessation* **Substance Abuse, Research and Treatment** (2013) - P01669895 **Grants** -
Deposited in an open access institutional repository - Yes
- 34 Carson KV, Usmani ZA, Robertson T, Mysore S, Brinn MP *Smoking cessation interventions for lung cancer management* **Lung Cancer Management** (2013) - P01669891 **Grants** -
Deposited in an open access institutional repository - Yes
- CIA (K. Carson) - Books/Chapters**
- 35 Carson KV, Robertson T, Brinn MP, Peters M, Veale A, Esterman AJ, Smith BJ *Tobacco use, prevention and cessation for Indigenous populations around the world: A systematic review and narrative synthesis.* **Health Disparities: Epidemiology, Racial/Ethnic and Socioeconomic Risk Factors and Strategies for Elimination.** (2013) 1-38; Chapter 1 P01669906 **Grants** -
Deposited in an open access institutional repository - Yes

CIA (K. Carson) - Editorials

36 Carson KV, Jurisevic MA, Smith BJ *Is cancer still reduced if you give up smoking in later life?* **Substance Abuse, Research and Treatment** (2013)
2 5 357-68 P01669900 **Grants -**
Deposited in an open access institutional repository - Yes

CV-TPP: Translation into Policy/Practice (last 5 years only)

Type: Policy **Year of Research Results:** 2014

Funding Source: NHMRC: No Other Australian Source: Yes International Source: No

Research: Through an application submitted to the Australian and New Zealand School of Government I received a grant for \$10,000.00 to write a policy document for publication within their journal 'Evidence Base: A journal of evidence reviews in key policy areas', that will be used to underpin policy and practice for Indigenous tobacco cessation and prevention initiatives. The policy document is titled 'Smoking cessation and tobacco abuse prevention in Indigenous populations' and combines evidence from systematic literature that incorporate multiple channels of grey literature to strengthen the evidence and provide a large resource pool on which to base future programs, policy and practice initiatives.

Organisations Affected: The articles published in 'Evidence Base' are designed for public sector decision-makers and is a 'broker' between the public sector, academics and other policy specialists.

Year of Change: 2014

Changes: As this article is scheduled for publication in July 2014, the majority of changes will not yet be known. However, the evidence produced from this document has already been used by the Thoracic Society of Australia and New Zealand's Indigenous Lung Health Working Party to direct the next phase of research and priority areas for future funding programs and dedication of resources.

Outcomes:

Type: Policy **Year of Research Results:** 2013

Funding Source: NHMRC: No Other Australian Source: No International Source: No

Research: Provided feedback on the 'Protecting children from tobacco fact-sheet' developed by the 'Action on Smoking and Health Council'

Organisations Affected: Action on Smoking and Health Council

Year of Change: 2013

Changes: -

Outcomes:

Type: Policy **Year of Research Results:** 2013

Funding Source: NHMRC: No Other Australian Source: No International Source: No

Research: Letter to the New Zealand Government for 'Announcement of plain packaging for tobacco' on behalf of the Thoracic Society of Australia and New Zealand (TSANZ) in my role as deputy convenor of the Tobacco Special Interest Group; congratulating them on the announcement and offering support on behalf of the TSANZ.

Organisations Affected: New Zealand Government

Year of Change: 2013

Changes: -

Outcomes:

Type: Policy **Year of Research Results:** 2013

Funding Source: NHMRC: No Other Australian Source: No International Source: No

Research: Provided feedback on the consultation paper from the Department of Health and Ageing for 'Options to introduce new tobacco product content controls and new disclosure requirements for tobacco products 22 Feb 2013' on behalf of the Thoracic Society of Australia and New Zealand in my role as deputy convenor of the Tobacco Special Interest Group; Lung Health Alliance submission submitted to Allen and Clarke Policy Regulatory Specialists for Governmental consideration.

Organisations Affected: Deapartment of Health and Ageing

Year of Change: 2013

Changes: -

Outcomes:

Type: Policy **Year of Research Results:** 2012

Funding Source: NHMRC: No Other Australian Source: No International Source: No

Research: Provided feedback on the submission entitled: 'Comments on the National Tobacco Strategy 2012-18' on behalf of the Thoracic Society of Australia and New Zealand in my role as deputy convenor of the Tobacco Special Interest Group.

Organisations Affected: Thoracic Society of Australia and New Zealand (TSANZ)

Year of Change: 2012

Changes: -

Outcomes:

Type: Policy **Year of Research Results:** 2012

Funding Source: NHMRC: No Other Australian Source: No International Source: No

Research: Founder and acting chair of the 'Indigenous Respiratory Health Working Party' associated with the Thoracic Society of Australia and New Zealand and supported by the current President of the society: Professor Matthew Peters. The aim of the working party is to: consolidate existing practice initiatives for tobacco cessation and prevention tailored for Indigenous populations across Australia and New Zealand, interpret the existing evidence and provide recommendations for future evaluations, policy and research, provide position statements on behalf of the society to local governments and organisations, and to seek funding for administration, small scholarships and grants to be used by TSANZ members and Indigenous community members.

Organisations Affected: Thoracic Society of Australia and New Zealand (TSANZ)

Year of Change: 2012

Changes: -

Outcomes:

Type: Practice **Year of Research Results:** 2013

Funding Source: NHMRC: No Other Australian Source: No International Source: No

Research: Through the methodological tailoring of a Cochrane systematic meta-analysis titled 'Asthma self-management education with regular healthcare professional review or written action plans or both for adults'

In addition, in 2013 the results from this same review also informed Quality Outcome Measures for paediatric asthma action plans for the non-profit Primary Care Medical Home Group in the USA, who regularly report on certain evidence-based Quality Measures to primary care providers in North Carolina.

Evidence from our review resulted in an upgrade of asthma action plans from 'Best practice' (generally accepted as good care, but not regularly tracked) to an 'Official quality measure' (tracked via chart audits and report status of practices compared to benchmarks).

Organisations Affected: Cochrane Airway Group

Year of Change: 2013

Changes: -

Outcomes:

Type: Practice **Year of Research Results:** 2011

Funding Source: NHMRC: No Other Australian Source: No International Source: No

Research: Through the methodological tailoring of a Cochrane systematic meta-analysis titled 'Asthma self-management education with regular healthcare professional review or written action plans or both for adults' (First author Kristin Carson), completed in collaboration the UK based Cochrane Airways group, we contributed to the development of indicators for the NICE (National Institute for Health and Clinical Excellence) quality and outcomes framework for asthma clinical care in the UK.

Organisations Affected: Cochrane Airways Group

Year of Change: 2011

Changes: -

Outcomes:

CV-CN: Contribution to the NHMRC (last 5 years only)

Contribution Role	Year	Number of times

CV-JR: Editorial Responsibilities (last 5 years only)

Entry type	Journal/Publication Name	Role	Duration	Number of Articles (for Peer Review only)
Peer Reviewer - Journal Article	Primary Care Respiratory Journal	Guest	21/04/2014 -	1
Peer Reviewer - Journal Article	BMJ Open	Guest	10/03/2014 -	1
Peer Reviewer - Journal Article	Pediatrics	Guest	03/02/2014 -	1
Peer Reviewer - Journal Article	International Journal of Environmental Research and Public Health	Other	10/06/2013 -	3
Peer Reviewer - Journal Article	Substance Abuse and Rehabilitation	Other	09/09/2013 -	2
Peer Reviewer - Journal Article	Australian and New Zealand Journal of Public Health	Other	07/10/2013 -	1
Peer Reviewer - Journal Article	Journal of the American Medical Association (JAMA)	Other	12/11/2013 -	2
Member of an Editorial Board - Journal/Book	Cochrane Database of Systemtic Reviews		01/12/2013 -	
Peer Reviewer - Journal Article	Preventive Medicine	Other	02/04/2013 -	2
Peer Reviewer - Journal Article	Thorax	Other	11/02/2013 -	3
Peer Reviewer - Journal Article	Addiction	Other	01/01/2013 -	4
Peer Reviewer - Journal Article	BMC Nursing	Other	12/08/2013 -	1
Peer Reviewer - Journal Article	Cochrane Database of Systematic Reviews	Other	12/03/2012 -	4
Peer Reviewer - Journal Article	British Medical Journal (BMJ)	Other	23/07/2012 -	1

CV-P: Patents

Patent: , Status:
Registered in names of (Inventors):
Description of patent:
Applicability/Impact:

CV-CE: Community Engagement (last 5 years only)

Title/Topic	Form of Engagement	Audience	Representing Whom	Location	Frequency	Duration	Did this involve Aboriginal or Torres Strait Islander Peoples?
Premier's and Channel 9 Young Achiever of the Year presentations to schools and universities	Oral presentations and discussion fora	School students, university students and early career researchers	University of Adelaide and Awards Australia for the Young Achiever Awards	Multiple locations including The University of Adelaide, Kildare College, The Royal Adelaide Hospital and the Australian Society of Medical Research among other forums	11+ times	1/3/2014 - //	No
National Science Week (Science Alive)	Interactive display explaining tobacco related research at The Queen Elizabeth Hospital and collaborating institutions, with youth able to do basic breath testing through a Smokerlyser and spirometer	Youth attending National Science Week	The Basil Hetzel Institute for Translational Health Research	Adelaide show grounds	Annually	7/8/2014 - 9/8/2014	No
Speaker and Member of the Advantage SA Speakers in Schools Programme	Connecting school students with young professionals who provide first hand advice and share their experiences about the benefits of building a career in South Australia.	School Students	Advantage SA Speakers in Schools Programme	South Australia		//2013 - //	Yes

Engagement with mainstream media including television (channel 7 and 9 news), radio (14 occasions), newspaper (4 including 'The Australian'), magazines (2) and over 100 online media citations	Multiple media channels including television, radio, magazines, newspapers and online sources	Lay audiences and the general public	Multiple organisations including hospitals, universities and the Thoracic Society (TSANZ)	Interviews conducted in multiple states/territories and broadcast across Australia and Internationally in over a dozen different languages	11+ times	//2011 - //	Yes
Indigenous Health in communities	Engaged with Aboriginal and Torres Strait Islanders to ensure the work being done in Indigenous health will meet the needs of community members.	Aboriginal and Torres Strait Elders, key stakeholders, community leaders & policy makers	Myself. Work relates to my PhD	Australia		//2010 - //	Yes

CV-RF: NHMRC Research Funding (last 5 years only)

App ID	Title	Funding Type & Grant Type	Your Role	First Year Funded	No of Years	Total Amount (\$AUD)	% P/W
		,					

CV-ORF: Other Research Funding (last 5 years only)

App ID	Funding Organisation	Domestic/ International	Funding Source	Peer Reviewed	Your Role	First Year Funded	No of Years	Total Amount (\$AUD)	% P/W
ANZSOG	Australian and New Zealand School of Government Grant	Domestic	Government	Yes	CIA; A policy document will be produced in addition to a journal article for 'Evidence Base'	2013	1	\$10,000.00	1
N/A	The Queen Elizabeth Hospital Research Foundation	Domestic	Research Institution	Yes	Co-investigator & coordinator: upregulatory effects of the transcutaneous administration of nicotine	2011	3	\$20,000.00	3

CV-PM: Professional Memberships

Organisation	Duration	Current
Thoracic Society of Australia and New Zealand: Tobacco and Addictive Substances Special Interest Group	2013 -	Yes
Thoracic Society of Australia and New Zealand: Elected Chair of the Indigenous Respiratory Health Working Party	2013 -	Yes
Cochrane Airways Group; Invited Editorial Board Member	2013 -	Yes
Child Health Group (Cochrane Collaboration)	2013 -	Yes
Australian Satellite of the Cochrane Airways Group (ASCAG)	2013 -	Yes
SA Health Young Professionals Group	2013 -	Yes
Healthy Development Adelaide (The University of Adelaide)	2013 -	Yes
SA Aboriginal Health Research Network	2013 -	Yes
SA Health Young Professionals Group	2013 -	Yes
Thoracic Society of Australia and New Zealand: Deputy Covenor of the Tobacco and Addictive Substances Special Interest Group	2012 - 2013	No
Prognosis Methods Group (Cochrane Collaboration)	2012 -	Yes
Aboriginal and Torres Strait Islander Health working party; Invited member	2011 -	Yes

Depression, Anxiety and Neurosis Group (Cochrane Collaboration)	2010 -	Yes
The Thoracic Society of Australia and New Zealand	2010 -	Yes
Tobacco Addiction Group (Cochrane Collaboration)	2010 -	Yes
The Central Northern Adelaide Health Service Smoke Free policy steering committee: Invited member	2010 -	Yes
The Queen Elizabeth Hospital Smoke Free policy steering committee: Invited member	2009 -	Yes
Airways Group (Cochrane Collaboration)	2009 -	Yes

cv-w: Workload (Current)

(CIA) Ms Kristin Carson

Weekly Load (average hours/week)

Teaching	Clinical	NHMRC Research	Other Research
0	0	0	32

Administrative Responsibilities (average hours/week)

Administrative Commitment: 6

Responsibilities: Responsible for the research projects of over 25 health professionals (40 projects),. Number of policy roles within SA Health and other organisations.

CV-QAP: Qualifications, Awards and Prizes

Type	Title	Institution/ Organisation	Year
Diploma	Diploma in Laboratory Technology (Pathology Testing)	Tafe SA	2007
Certificate	Certificate 3 in Laboratory Skills	Tafe SA	2004
Award	The Janet Elder International Travel Scholarship	The Thoracic Society of Australia and New Zealand	2014
Award	The University of Adelaide Faculty of Sciences, Science and Technology Award Winner for the Young Achiever Awards	Awards Australia	2014
Award	Premier's and Channel 9 Young Achiever of the Year	Awards Australia; Recipient of the Young Achiever of the Year Award from over 200 applications and across eight categories	2014
Award	Development Activity titled 'Leaders in Lung health and Respiratory Services'	Young Professionals Group Development Grant Program Award	2013
Award	Young Investigator Award; Barriers and enablers for the use of smoking cessation pharmacotherapy in Aboriginal and Torres Strait Islander populations: A qualitative synthesis; Finalist	South Australian and Northern Territory Branches of the Thoracic Society of Australia and New Zealand	2013
Award	Catherine Helen Spence (CHS) Memorial Scholarship Finalist	Government of South Australia	2013
Award	South Australian Young Investigator Award Semi-Finalist	Women's and Children's Hospital Foundation Young Investigator Award	2013
Award	Presentation title: Interventions for tobacco prevention in indigenous youth: A Cochrane review and narrative synthesis; Winner	South Australian and Northern Territory Branches of the Thoracic Society of Australia and New Zealand	2012
Award	Presentation title: Interventions for tobacco cessation in Indigenous populations: A Cochrane meta-analysis; Finalist	South Australian and Northern Territory Branches of the Thoracic Society of Australia and New Zealand	2011
Award	Research Titled: Community interventions for the prevention of smoking in young people	Cochrane Airways Group Network	2008
Award	Women's and Children's Hospital Customer Service Recognition Award	Women's and Children's Hospital	2007
Prize	Presentation title: Interventions for tobacco cessation in Aboriginal Australians and other Indigenous populations	Thoracic Society of Australia and New Zealand, Canberra ASM	2012

CV-CP: Conference Participation (last 5 years only)

Thoracic Society of Australia and New Zealand (TSANZ) Conference; National;

Role: Year: 2014

Conference Presentation Summary:

Management of Bronchiectasis: A Retrospective Hospital Audit of Patient Care Compared to British Thoracic Society Guidelines

Thoracic Society of Australia and New Zealand (TSANZ) Conference; National; Australia

Role: Speaker selected from abstract **Year:** 2014

Conference Presentation Summary:

Accepted abstract - poster presentation

Smoking during pregnancy and tobacco abuse prevention in Aboriginal and Torres Strait Islander youth: A qualitative analysis.

Thoracic Society of Australia and New Zealand (TSANZ) Conference; National; Australia

Role: Speaker selected from abstract **Year:** 2014

Conference Presentation Summary:

Accepted abstract - oral presentation

Barriers and enablers to the use of smoking cessation pharmacotherapy in Aboriginal and Torres Strait Islander populations: A qualitative analysis.

Thoracic Society of Australia and New Zealand (TSANZ) Conference; National; Australia

Role: Speaker selected from abstract **Year:** 2014

Conference Presentation Summary:

Accepted abstract - oral presentation

Respiratory health service delivery and utilisation by Aboriginal and Torres Strait Oslander Australians: A qualitative analysis of the barriers and enablers to optimal medical management.

European Respiratory Society; International; Germany

Role: Year: 2014

Conference Presentation Summary:

Community interventions for preventing smoking in young people

European Respiratory Society; International; Germany

Role: Year: 2014

Conference Presentation Summary:

Gastro-oesophageal reflux treatment for asthma in adults and children: A Cochrane Systematic review

European Respiratory Society; International; Germany

Role: **Year:** 2014

Conference Presentation Summary:

Prolonged antibiotics for non-cystic fibrosis purulent bronchiectasis in children and adults: A Cochrane review

American Thoracic Society; International; United States

Role: **Year:** 2014

Conference Presentation Summary:

Accepted abstract

Smoking cessation interventions for Indigenous populations worldwide: A Cochrane systematic review

American Thoracic Society; International; United States

Role: **Year:** 2014

Conference Presentation Summary:

Accepted abstract

Asthma self-management education with either regular healthcare professional review or written action plan or both in adults: A Cochrane review

Thoracic Society of Australia and New Zealand (TSANZ) Conference; ;

Role: **Year:** 2014

Conference Presentation Summary:

Accepted abstract

Cost effectiveness of portable oxygen concentrators compared to portable oxygen cylinders: A multi-centre RCT.

Thoracic Society of Australia and New Zealand (TSANZ) Conference; ;

Role: **Year:** 2014

Conference Presentation Summary:

Accepted abstract

Continuous positive airway pressure for obstructive sleep apnoea: A Cochrane systematic review

Thoracic Society of Australia and New Zealand (TSANZ) Conference;

Role: **Year:** 2014

Conference Presentation Summary:

Accepted abstract

Physical training for asthma: A Cochrane systematic review

Thoracic Society of Australia and New Zealand (TSANZ) Conference;

Role: **Year:** 2014

Conference Presentation Summary:

Accepted abstract

Failure to pass the step test: Qualifying criteria in a multicentre randomised cross-over study of portable oxygen for patients with COPD

Thoracic Society of Australia and New Zealand (TSANZ) Conference;

Role: **Year:** 2014

Conference Presentation Summary:

Accepted abstract

Quality of life among participants of a multi-centre RCT comparing portable oxygen concentrators to portable oxygen cylinders.

Thoracic Society of Australia and New Zealand (TSANZ) Conference;

Role: **Year:** 2014

Conference Presentation Summary:

Accepted abstract

Evaluation of the hospital smoke free implementation policy: A cross-sectional cohort analysis in South Australia.

Thoracic Society of Australia and New Zealand (TSANZ) Conference;

Role: **Year:** 2014

Conference Presentation Summary:

Accepted abstract

Compliance with the British Thoracic Society guidelines in the management of pneumothoraces.

Thoracic Society of Australia and New Zealand (TSANZ) Conference;

Role: **Year:** 2014

Conference Presentation Summary:

Accepted abstract

Mass media interventions for preventing smoking in young people: A Cochrane systematic review

Thoracic Society of Australia and New Zealand (TSANZ) Conference; ;

Role: **Year:** 2014

Conference Presentation Summary:

Accepted abstract

Nurse specialist care for bronchiectasis: A Cochrane systematic review

Thoracic Society of Australia and New Zealand (TSANZ) Conference; ;

Role: **Year:** 2014

Conference Presentation Summary:

Accepted abstract

Triggers resulting in relapse: Cohort analysis from Smoking Termination Opportunity for inpatients (STOP) trial.

Thoracic Society of Australia and New Zealand (TSANZ) Conference; ;

Role: **Year:** 2014

Conference Presentation Summary:

Accepted abstract

Preference for battery powered portable oxygen concentrators versus portable cylinders in patients with COPD: Evaluation of an equipment survey.

Thoracic Society of Australia and New Zealand (TSANZ) Conference; ;

Role: **Year:** 2014

Conference Presentation Summary:

Accepted abstract

Prolonged antibiotics for purulent bronchiectasis: A Cochrane systematic review

Tehran addiction congress, 2013, Tehran, Iran; ;

Role: **Year:** 2013

Conference Presentation Summary:

Poster presentation

is Tramadol a gateway drug for substance abuse among adolescents?

Thoracic Society of Australia and New Zealand (TSANZ) March 2013, Darwin; ;

Role: Year: 2013

Conference Presentation Summary:

Oral presentation

Portable oxygen cylinders versus battery operated concentrators for COPD: A randomised cross-over study.

Thoracic Society of Australia and New Zealand (TSANZ) March 2013, Darwin; ;

Role: Year: 2013

Conference Presentation Summary:

Oral presentation

Interventions for tobacco prevention in Indigenous youth: A Cochrane review and a narrative synthesis.

Health Services Research Association of New Zealand, December 2013, Wellington; ;

Role: Year: 2013

Conference Presentation Summary:

Oral presentation

Cost Effectiveness of an inpatient smoking cessation intervention for patients with tobacco related illness (SWTOP trial): A multi-centre randomised controlled study.

Thoracic Society of Australia and New Zealand (TSANZ) March 2013, Darwin; ;

Role: Year: 2013

Conference Presentation Summary:

Oral presentation

Non-invasive positive pressure ventilation for the treatment of respiratory failure due to severe acute exacerbations of asthma: A Cochrane meta-analysis

Thoracic Society of Australia and New Zealand (TSANZ) March 2013, Darwin; ;

Role: Year: 2013

Conference Presentation Summary:

Oral presentation

Lung volume reduction surgery for diffuse emphysema: A Cochrane meta-analysis

The Queen Elizabeth Hospital, Basil Hetzel Institute for Translational Health Research: Research Day Conference, October 2013, Adelaide; ;

Role: Year: 2013

Conference Presentation Summary:

Oral presentation

Interventions for tobacco prevention in Indigenous youth: A Cochrane review and narrative synthesis.

Postgraduate Research Conference; National Wine Centre, August 2013, Adelaide; ;

Role: Year: 2013

Conference Presentation Summary:

Poster presentation

Interventions for tobacco use prevention in Indigenous youth: A Cochrane review and a narrative synthesis.

Thoracic Society of Australia and New Zealand (TSANZ) March 2013, Darwin; ;

Role: Year: 2013

Conference Presentation Summary:

Oral presentation

Cost effectiveness of an inpatient smoking cessation intervention for patients with tobacco related illnesses (STOP) Trial: A multi-centre RCT (Award winning oral 'The Tobacco Control Prize' for the best oral presentation)

Thoracic Society of Australia and New Zealand (TSANZ) March 2013, Darwin; ;

Role: Year: 2013

Conference Presentation Summary:

Invited presentation: Outreach nursing care in COPD (25 minutes + 5 minutes question time)

Invited by Professor Brian Smith, Chair of the COPD Special Interest Group, TSANZ

Thoracic Society of Australia and New Zealand (TSANZ) March 2013, Darwin; ;

Role: Year: 2013

Conference Presentation Summary:

Poster presentation

Ambulatory oxygen for chronic obstructive pulmonary disease: A Cochrane meta-analysis

Thoracic Society of Australia nad New Zealand (TSANZ) March 2012, Canberra; ;

Role: Year: 2012

Conference Presentation Summary:

Invited presentation: Interventions for smoking cessation in Indigenous populations: A Cochrane systematic review. (Oral presentation 30 minutes)

Invited by Dr Peter Franklin, Chair of the Tobacco Special Interest Group, TSANZ

Thoracic Society of Australia and New Zealand (TSANZ) March 2012, Canberra; ;

Role: Year: 2012

Conference Presentation Summary:

Invited presentation: Interventions for smoking cessation in Aboriginal Australians: A Meta-analysis. (Oral presentation 30 minutes)

Invited by Dr Peter Franklin, Chair of the Tobacco Special Interest Group, TSANZ

Thoracic Society of Australia and New Zealand (TSANZ) March 2012, Canberra; ;

Role: Year: 2012

Conference Presentation Summary:

Oral presentation

Training health professionals in smoking cessation: A Cochrane Systematic Review

ATS May 2012, San Francisco, California; ;

Role: Year: 2012

Conference Presentation Summary:

Oral presentation

Superiority of varenline tartrate plus counselling over counselling alone smoking cessation: A 52 week randomized controlled trial.

(NOTE: Of all abstracts submitted for the 2012 ATS, this research was one of only seven selected for an oral presentation in the 'Late breaking clinical trials' session, chaired by Dr David Hau, Chair of the International Conference Committee (ATS International conference 'Highlights for Clinicians'))

WONCA (World Organisation of National Colleges, Academics and Academic Associations of General Practitioners/Family Physicians) Europe, March 2012, Singapore; ;

Role: Year: 2012

Conference Presentation Summary:

Oral presentation

Training health Professionals in Smoking Cessation: A Systematic Review

Thoracic Society for Australia and New Zealand (TSANZ) March 2012, Canberra; ;

Role: Year: 2012

Conference Presentation Summary:

Oral presentation

Community interventions for the prevention of smoking in young people: A Cochrane systematic review

Basil Hetzel Institute for Translational Health Research (20 minutes) July 2011, Adelaide; ;

Role: Year: 2011

Conference Presentation Summary:

Oral presentation

Interventions for smoking cessation and tobacco prevention in Indigenous populations: Core components for post-graduate studies for the University of Adelaide.

Thoracic Society of Australia and New Zealand (TSANZ) March 2011, Perth; ;

Role: Year: 2011

Conference Presentation Summary:

Oral presentation

Physical training for asthma a meta-analysis.

The Adelaide University, Faculty of Health Sciences Post-graduate research conference: National Wine Centre, August 2011, Adelaide; ;

Role: Year: 2011

Conference Presentation Summary:

Poster presentation

Interventions for smoking cessation in Indigenous populations: A meta-analysis

ATS 2011, Denver Colorado; ;

Role: Year: 2011

Conference Presentation Summary:

Oral presentation

Varenicline tartrate and counseling versus counseling alone in a randomized controlled trial for inpatient smoking cessation: 6 month interim results.

The Queen Elizabeth Hospital, Basil Hetzel Institute for Translational Health Research: Research Day Conference, October 2011, Adelaide; ;

Role: Year: 2011

Conference Presentation Summary:

Oral presentation

Interventions for smoking cessation in Indigenous populations: A meta-analysis.

ATS 2011, Denver, Colorado; ;

Role: Year: 2011

Conference Presentation Summary:

Oral presentation

A meta-analysis (Cochrane Review) of pharmacological interventions for the treatment of anxiety disorders in COPD.

Thoracic Society or Australia and New Zealand (TSANZ) March 2011, Perth; ;

Role: Year: 2011

Conference Presentation Summary:

Oral presentation

Mass media interventions for the prevention of smoking in young people: A systematic review.

Chest Conference, October 2011, Honolulu Hawaii; ;

Role: Year: 2011

Conference Presentation Summary:

Oral presentation

Physical training for asthma a meta-analysis.

Thoracic Society of Australia and New Zealand (TSANZ) ASM 2010, Brisbane; ;

Role: Year: 2010

Conference Presentation Summary:

Oral presentation

Home care by outreach nursing for Chronic Obstructive Pulmonary Disease: A Systematic Review

Thoracic Society of Australia and New Zealand (TSANZ) ASM 2010, Brisbane; ;

Role: Year: 2010

Conference Presentation Summary:

Oral presentation

A meta-analysis (Cochrane Review) of pharmacological and psychological interventions for anxiety and depression in COPD

Thoracic Society of Australia and New Zealand (TSANZ) ASM 2010, Brisbane; ;

Role: Year: 2010

Conference Presentation Summary:

Oral presentation

Varenicline tartrate and counseling versus counseling alone in a randomized controlled trial for inpatient smoking cessation : 3 month interim results.

The Queen Elizabeth Hospital, Basil Hetzel Institute for Translational Health Research: Research Day, October 2010, Adelaide; ;

Role: Year: 2010

Conference Presentation Summary:

Poster presentation

Pharmacological interventions for the treatment of anxiety disorders in patients with COPD: A systematic review. (Award winning poster - David Horowitz Award)

Expression of Interest

Reference number: 161217

Submitted By: Kristin Carson, kristin.carson@health.sa.gov.au

Project Title: Randomised controlled trial of a novel web and app-based interactive healthy lifestyle program for youth, with a particular focus on Aboriginal and TSI populations

CHIEF INVESTIGATOR

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CHIEF INVESTIGATOR QUALIFICATIONS

Dip Lab Med	TAFE SA	(2007)
Cert III Lab Skills (Pathology Testing)	TAFE SA	(2004)

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RECIPIENT

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WHERE THE PROJECT WILL BE CARRIED OUT

RESEARCH OFFICE CONTACT

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PERSON AUTHORISING EXPRESSION OF INTEREST

Professor Brian Smith
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Level: Department Head

PROJECT DETAILS

PROJECT DISCIPLINE

Education, Allied Health

SIGNIFICANCE

Cigarette smoking is the leading causes of preventable death in the world. Aboriginal and Torres Strait Islander (TSI) Australians start smoking at a much young age (around 9 years) with a 2.5 fold increase in smoking prevalence compared to the non-Indigenous. This project uses a novel multi-media, multi-faceted web-based tobacco prevention, healthy lifestyle and role-model intervention that will be used to change behaviour, attitudes and improve knowledge around these important issues, ultimately helping to reduce the gap in Indigenous disadvantage in Australia.

RESEARCH CATEGORIES

Community Based Study

EARLY CAREER GRANT

No

PROJECT DURATION

1 Year

BUDGET ESTIMATE

\$75,000

SUMMARY OF AIMS, HYPOTHESES, BRIEF RESEARCH PLAN AND BUDGET

AIMS

The ultimate aim of this research is to conduct the first methodologically rigorous multi-centre randomised delayed-intervention controlled trial in Australia for healthy lifestyle initiatives amongst Aboriginal and Torres Strait Islander (TSI) Australians. The primary focus for the intervention is tobacco prevention and cessation; however our pilot investigations and the work conducted throughout my PhD have found that you cannot hope to address tobacco use without also addressing broader lifestyle issues including nutrition, alcohol, physical activity, abuse and career development (motivation and skills training). As such, the aims of the current project are to develop a web-based interactive intervention that will generate increased enthusiasm, enhanced knowledge and increased desire to access the web-site and app. The intervention developed through funding from this grant will then be used to underpin a NHMRC project grant for the 2017 funding round. This interactive intervention can be easily implemented into school curriculum for mass dissemination.

HYPOTHESES

Funding obtained from this grant will be used to develop the intervention for a multi-centre cluster randomised controlled clinical trial of the web-based intervention compared to a delayed-intervention control. NHMRC funding will be requested in 2017 following development of the intervention.

Therefore the hypothesis at this 'intervention development stage' is that: the web-based intervention model will result in increased enthusiasm, enhanced knowledge (about the healthy lifestyle program content) and desire to use the interactive web-based intervention compared to use of existing care (being pamphlets, books and other core curriculum teacher resources) when compared by children in a focus group setting.

BRIEF RESEARCH PLAN

Funding from this grant will be used to create and evaluate the interactive web-based intervention aimed at reducing tobacco use and other improving knowledge, behaviours and attitudes around other healthy lifestyle initiatives and career development. Already we have secured the support of several high profile partners including Credit Union SA (who will help to facilitate uptake of the program within school curriculum), St John Ambulance (who will provide tutorials for basic first aid skills training), Bravehearts (founder Hetty Johnson (QLD Australian of the Year) will provide content on how to recognise abuse, what to do and who to contact when this happens), ABC television will film the intervention as it is being developed to do a BTN (Behind The News) story and SDF Illuminate (run by TAS Young Australian of the Year will integrate our curriculum to existing school curriculum across Australia for ease of amalgamation later) amongst several others.

Several high-profile role models have also agreed to take part in the intervention by doing video chats with students and agreeing to be filmed talking about the healthy lifestyle issues as well as motivational speeches. These include Adam Goodes (2014 Australian of the Year), Jessica Mauboy (singer who has Indigenous Australian heritage), Patty Mills (NBA basketballer and Indigenous Australian), all eight of the Young Australian of the Year winners from 2015 and several players from the Port Adelaide Football club amongst several others.

In addition, three educational games will be developed through Holopoint Interactive Pty Ltd by technical director Richard Taylor. These will be in the style of Fruit Ninja, Candy Crush and the traditional card game 'snap' but instead of slicing the fruit kids will need to slice the cigarettes and avoid the smoke. For the candy crush simulation, kids will crush the junk food and collect the fruit's and vegetables. In the snap simulation, Professor Ghil'ad Zuckermann who is the Chair of Linguistics and Endangered Languages for the University of Adelaide will help to create a game using traditional Aboriginal and Torres Strait Islander words (that fit with the healthy lifestyle theme) to match them to the English words. A quote for these three games have estimated the cost of producing these apps that can be used for the web-site as well as iphones, androids and ipads to be \$45,000.00.

In addition, hard copy resources will also be produced to supplement the web-based intervention. This hard copy resources will also use a new and exciting technology called augmented reality, which can be seen here <http://tinyurl.com/OBH-InteractivePrint>. This technology will animate still images using iphones, ipads and androids for no cost to the viewer (app is free to download and content free to view). However, showcases of this technology have already sparked a huge amount of interest and is likely to really engage youth in the resources to improve uptake of the intervention. The expected cost to create the interactive images and generate the resources has been quoted as \$35,000.00. The additional expenditure of \$5,000.00 will be covered by TQEH.

RELATED RESEARCH

This is a novel area with limited research being done in this field. We have undertaken several Cochrane reviews in the area including Mass media interventions for preventing smoking in young people, Community interventions for preventing smoking in young people and Interventions for tobacco prevention amongst Indigenous youth, none of which include web-based interventions. All existing research in this area specifically tailored for Indigenous youth has had a focus on pamphlets, television and radio with little to know web-based components. Moreover, we have recently updated the 'mass media' Cochrane review (in write-up phase) and found that there are no methodologically rigorous investigations using web-based interventions to prevent smoking in youth, despite the fact that youth are more engaged with social media sites (such as Facebook and twitter etc) than any other form of media. The use of social media and interactive web-based interventions was also our concluding recommendation from the Cochrane review when it was published back in 2010.

Early intervention into adolescent smoking has the potential to drastically reduce the prevalence of smoking in society, as it is the youth that will one day form the adult population. Although there have been successful past initiatives which have targeted youth smoking, these initiatives are not working as well as they once did according to the 2012 Surgeon General's Report. Youth have advanced dramatically since these interventions were first introduced and have become desensitized to some of the past campaigns employed eg. graphic ads on television. Furthermore, mainstream campaigns have not been as effective with Indigenous youth as non-Indigenous youth, these interventions have not been appropriately or culturally tailored for this population as identified in the Indigenous specific Cochrane review. Although there is somewhat of a knowledge base as to what causes other Indigenous youth groups around the world to start smoking, the determinants that predispose Indigenous Australian youth to initiate and maintain smoking are lacking, as too are the pathways that can be implemented to deter or reduce smoking consumption amongst them.

BUDGET ESTIMATE

\$75,000

“Our deepest fear is not that we are inadequate. Our deepest fear is that we are powerful beyond measure. It is our light, not our darkness that most frightens us. We ask ourselves, who am I to be brilliant, gorgeous, talented, fabulous? Actually, who are you not to be? You are a child of God. Your playing small does not serve the world. There is nothing enlightened about shrinking so that other people won’t feel insecure around you. We are all meant to shine, as children do. We were born to make manifest the glory of God that is within us. It’s not just in some of us; it’s in everyone. And as we let our own light shine, we unconsciously give other people permission to do the same. As we are liberated from our own fear, our presence automatically liberates others.”

~ Marianne Williamson, from ‘A return to Love’