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Transform-Us! cluster RCT: 18-month and 30-month effects on children's physical activity, sedentary time and cardiometabolic risk markers

Jo Salmon ,[1] Lauren Arundell,[1] Ester Cerin,[2] Nicola Dawn Ridgers,[3] Kylie D Hesketh,[1] Robin M Daly,[1] David Dunstan,[1,4] Helen Brown,[5] Jacqui Della Gatta,[6] Paul Della Gatta,[1] Mai J M Chinapaw,[7] Lauren Shepphard,[8] Marj Moodie,[9] Clare Hume,[10] Vicki Brown ,[9] Kylie Ball,[1] David Crawford[1]

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For numbered affiliations see end of article.

Correspondence to
Professor Jo Salmon, School of Exercise and Nutrition Sciences, Deakin University Institute for Physical Activity and Nutrition, Geelong 3220, Victoria, Australia;
jo.salmon@deakin.edu.au

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ABSTRACT

Objective To test the efficacy of the *Transform-Us!* school- and home-based intervention on children's physical activity (PA), sedentary behaviour (SB) and cardiometabolic risk factor profiles.

Methods A 30-month 2×2 factorial design cluster randomised controlled trial delivered in 20 primary schools (148 Year 3 classes) in Melbourne, Australia (2010–2012), that used pedagogical and environmental strategies to reduce and break up SB, promote PA or a combined approach, compared with usual practice. Primary outcomes (accelerometry data; n=348) were assessed at baseline, 18 and 30 months. Secondary outcomes included body mass index (BMI) and waist circumference (WC) (n=564), blood pressure (BP) (n=537) and biomarkers (minimum n=206). Generalised linear mixed models estimated the interactive effects of the PA and SB interventions on the outcomes. If there was no interaction, the main effects were assessed.

Results At 18 months, there were intervention effects on children's weekday SB (−27 min, 95% CI: −47.3 to −5.3) for the PA intervention, and on children's average day PA (5.5 min, 95% CI: 0.1 to 10.8) for the SB intervention. At 30 months, there was an intervention effect for children's average day SB (−33.3 min, 95% CI: −50.6 and −16.0) for the SB intervention. Children's BMI (PA and SB groups) and systolic BP (combined group) were lower, and diastolic BP (PA group) was higher. There were positive effects on WC at both time points (SB intervention) and mixed effects on blood parameters.

Conclusions The *Transform-Us!* PA and SB interventions show promise as a pragmatic approach for reducing children's SB and adiposity indicators; but achieving substantial increases in PA remains challenging.

Trial registration ISRCTN83725066; ACTRN12609000715279.

WHAT ARE THE FINDINGS?

⇒ Over 2.5 years, the *Transform-Us!* intervention had stronger effects on children's sedentary behaviour than physical activity and there were beneficial effects on children's adiposity for both intervention approaches.

HOW MIGHT IT IMPACT ON CLINICAL PRACTICE IN THE FUTURE?

⇒ For schools and parents, it is important to support children in reducing their sedentary behaviour as well as promoting and encouraging physical activity throughout the day.

INTRODUCTION

Regular physical activity is beneficial to children's physical, social and mental health,[1] yet global estimates of children's physical activity show that the majority of them fail to meet the recommended 60+ min of moderate-intensity to vigorous-intensity physical activity every day.[2] Some countries have developed 24-hour movement guidelines for children which recommend limiting sedentary behaviours, such as screen time, to less than 2 hours a day in addition to breaking up sitting regularly throughout the day.[3 4] Television viewing has been linked with higher levels of adiposity.[5] Yet there is mixed evidence, primarily from observational studies, of associations between volumes of sitting and children's health.[6 7] As children spend most of their waking hours at home and school (70% of which is spent sitting[8]), these settings have been identified as obvious targets for reducing and breaking up sitting and promoting physical activity.

Aside from targeting physical education, some of the most effective approaches to promoting children's physical activity have been changes to the school environment (eg, provision of sports equipment,[9] playground line markings[10]) and engagement with parents (eg, information nights to target home-based physical activity[11]). However, two meta-analyses of multicomponent school-based interventions that used device-based measures of children's physical activity found very small (5 min)[12] or no[13] increases in physical activity compared with controls. Strategies to reduce and break up classroom sitting by incorporating an active curriculum into class lessons (eg, 'active mathematics'[14]), delivering guided activity breaks during class time[15] and changing the classroom environment (eg, height adjustable desks, activity permissive classrooms[16]) have all had short-term beneficial impacts on children's sitting time of up to 1 hour per day. However, in the home setting, few interventions have reduced children's overall

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sedentary behaviour, with results dependent on parental involvement.[17] Long-term interventions delivered at school and home targeting both increases in children's physical activity and reductions in sedentary behaviour are also lacking.

The long-term impact of reducing the total volume of daily sitting or frequently interrupting or breaking up sitting compared with promoting physical activity on children's cardiometabolic health is unknown. Non-traditional risk factors, such as inflammatory markers, which have been shown to relate to atherosclerosis, endothelial dysfunction and metabolic syndrome in youth, are particularly understudied.[18–21] Such evidence is important for informing whether interventions should continue to target primarily moderate-intensity to vigorous-intensity physical activity, or if a dual focus on promoting physical activity as well as reducing and breaking-up sitting is optimal for health.

The *Transform-Us!* school-based and home-based intervention was developed to determine the impact of strategies to promote children's moderate-to-vigorous physical activity versus reduce sedentary behaviour or a combination of these strategies, on behavioural and health outcomes.[22] Preliminary evidence from the programme at 6 months found significant positive intervention effects on children's moderate-to-vigorous physical activity during school recess,[23] and less weekday sedentary time minutes compared with the control (usual practice).[24] The primary aim of this paper was to determine the efficacy of the independent and combined intervention approaches to promoting physical activity and reducing sedentary behaviour on children's moderate-to-vigorous physical activity and sedentary time after 18 and 30 months compared with usual practice. Secondary aims were to determine the effects of these approaches on children's body mass index (BMI), waist circumference, systolic and diastolic blood pressure and a range of blood biomarkers.

METHODS

Study design

Transform-Us! was a 30-month 2×2 factorial design cluster randomised controlled trial (RCT) delivered in 20 primary schools with additional home intervention components in Melbourne, Victoria, Australia, between February 2010 and December 2012. The study protocol has been published[22] and registered with the Australian New Zealand Clinical Trials Registry Number. Findings are reported according to the Consolidated Standards of Reporting Trials extension for cluster RCTs. Participants were not involved in the design, or conduct, or reporting, or dissemination plans of our research, however, staff from the Department of Education and Training provided input into and feedback on the intervention content.

Participants

Government, Catholic and Independent co-educational primary schools within 50 km of the Melbourne Central Business District in the first (low), third (mid) and fifth (high) quintiles of socioeconomic status (SES) areas according to the Australian Bureau of Statistics' Socio-Economic Index for Areas (suburb disadvantage score),[25] with an enrolment exceeding 300 students and at least two Year 3 classes were eligible to be selected for the study (n=219 schools). All children in Year 3 at baseline (aged 8–9 years), apart from children in the control schools, received the programme. Only those with written parental consent provided after school recruitment participated in the evaluation of the programme. Parents could elect for their child to complete any combination of behavioural and cardiometabolic health assessments.

Randomisation and masking

Schools in low (n=74), mid (n=74) and high (n=71) SES areas were randomly ordered with probabilistic weighting according to enrolment number.[22] Eight low-SES (from 41 attempted contacts to schools via phone, fax or email), 11 mid-SES (45 attempts) and 1 high-SES school (41 attempts) agreed to participate. Key reasons for schools declining to participate included lack of time or interest. Due to difficulties recruiting schools from high SES areas, the high and mid SES strata were combined for randomisation. After recruitment, schools within each of the two strata were then randomly allocated to one of four groups using computer-generated blocks of four by a statistician not involved in the trial. The four groups were: SB-I targeting reductions in sedentary behaviour; PA-I targeting increases in physical activity; PA+SB I combined PA-I and SB-I strategies; and control (C) was a usual curriculum (practice) control group. Schools were notified of their group allocation after baseline data collection.

Procedures

Intervention

The intervention, which has been described in detail previously,[22] was delivered over 2.5 school years from July 2010 to December 2012. Strategies were based on social cognitive theory,[26] behavioural choice theory[27] and ecological systems theory.[28] The programme was delivered by classroom teachers and targeted physical activity and sedentary behaviours in the school and home settings. It incorporated a mix of educational, pedagogical, behavioural, social and environmental strategies.[22] We had involvement of teachers and staff from the Department of Education and Training in Victoria, Australia, as well as the Australian Council for Health, Physical Education and Recreation Victoria in the design of the intervention content for schools as well as assistance with the development of the professional development for teachers. We have maintained long-term partnerships with personnel from these organisations and have now expanded involvement to more than 17 key stakeholder partners.

Teachers in each of the intervention conditions received a half-day face-to-face professional development (PD) session delivered by members of the research team, which provided strategies for incorporating the intervention elements into their teaching (eg, how to deliver standing lessons and active breaks). Because children typically change classes and teachers each calendar year in Australia, Year 3 teachers underwent a PD session at the beginning of the intervention (62 out of 77 teachers attended) and Year 4 teachers received the PD at the beginning of 2011 (63 out of 66 teachers attended). The materials were provided to absent teachers by an attending teacher. Year 3 teachers were followed up after 3 months and Year 4 teachers after 6 months, to troubleshoot any difficulties and ensure intervention fidelity. These sessions involved a morning tea at each of the intervention schools to discuss any difficulties with implementing the programme. Teachers who were successfully implementing *Transform-Us!* provided assistance and suggestions to teachers who had encountered barriers. These sessions did not align with data collection points. In 2012, all Year 5 teachers were provided with the written materials but did not receive a face-to-face PD or mid-year follow-up.

Year 3 teachers in the SB-I group were asked to deliver nine key learning messages per year to children (eg, impact of sedentary behaviour on health, self-monitoring, goal setting). Year 4 and 5 teachers were asked to repeat and reinforce these learning messages to the children and extended lesson plans were

provided. Nine newsletters were sent to parents each year (18 in total) that reinforced these messages and promoted family involvement. The newsletters were delivered evenly in each year (two per school term across three terms, and three in one term). Depending on the parent newsletter distribution method at the school, either print versions of the *Transform-Us!* newsletters were provided to the teacher who then passed them onto children in the class to take home, or the newsletters were emailed to the relevant school contact person for inclusion in the e-newsletters to parents.

Teachers were asked to deliver a 30-min standing/active lesson every day by modifying how they delivered their usual curriculum (eg, active maths). Each SB-I classroom received six standing easels to help facilitate standing lessons. Teachers were asked to break up children's prolonged sitting (approximately every 30 min) with a 2-min standing/active break. They were asked to adapt standard homework tasks to break up sitting and incorporate standing at home.

Year 3 teachers in the PA-I group were also asked to deliver nine key learning messages to children (which were reinforced in Years 4 and 5) that were focused on physical activity. Class-sets of pedometers were provided to support delivery of some of the lessons. Parents were sent nine newsletters each year (18 in total) that reinforced these messages and teachers set children physically active homework tasks (eg, go for a walk with parents and count letterboxes in their street). Classroom sets of physical activity (eg, balls, skipping rope) and novel circus equipment (eg, juggling balls, ribbons) were provided each year of the intervention. Asphalt line markings were painted in the school playground in the first year of the intervention, signage promoting physical activity was placed around the school and teachers were asked to encourage and support children's physical activity during recess and lunch breaks.[22]

The PA+SB I group received a combination of the PA-I and SB-I strategies (ie, their nine key learning messages each year targeted both physical activity and sedentary behaviour). The C group was a usual curriculum control condition. At study completion, C schools were provided with all the intervention curriculum and supporting materials (without the teacher face-to-face PD).

Data collection

Data collection occurred at baseline (T1: February–June 2010) and again at the end of each calendar year during the trial: November–December 2010 (T2), November–December 2011 (T3; 18 months, mid-intervention) and November–December 2012 (T4; 30 months, post-intervention). Data were collected after randomisation by trained research staff who were blinded to intervention group allocation at baseline only. T2 primary outcome data have been previously reported.[23 24] Accelerometry, adiposity, blood pressure and child survey measures were assessed on-site at each school at each time point. Biomarkers were collected at a local commercial pathology clinic from a subsample of children at baseline and T3 (18 months) only.

Outcomes

Primary outcomes

Primary outcomes included the average minutes per weekday and average minutes per day (including weekday and weekend day data) in sedentary and moderate-intensity to vigorous-intensity physical activity, and the average frequency of breaks in sedentary time per weekday and per day (including weekday and weekend day data); all determined from accelerometry. Breaks in sedentary time were included as an indicator of effectiveness of the intervention to interrupt children's sitting time.[29] The average weekday and average day minutes in sedentary and moderate-intensity to vigorous-intensity physical activity and frequency of breaks in sedentary time were calculated by summing the minutes or breaks on valid weekdays or valid days (respectively) and dividing by the number of days. Children wore an ActiGraph GT3X (Pensacola, Florida, USA) for eight consecutive days during school term on their right hip using an adjustable nylon belt. Children were asked to wear the accelerometer during waking hours except during water-based activities (swimming and bathing). This device has acceptable validity and reliability for assessing physical activity and sedentary time in paediatric populations.[30] The normal frequency filter was selected and the epoch length was 15 s.[31]

Data were downloaded using ActiLife software (ActiGraph) and analysed using a customised Excel macro. Non-wear time was defined as 20 min or more of consecutive zeros.[31] For a day to be considered valid, children were required to have worn the accelerometer for a minimum of 8 hours on weekdays or 7 hours on weekend days.[32] Children with at least three valid weekdays for average weekday variables, or at least three valid weekdays and one valid weekend day for average day variables were included in the analyses. Age-specific cut-points[33] were used to determine the time spent in moderate-intensity and vigorous-intensity physical activity. Sedentary time was defined as ≤25 counts per 15 s.[34] The frequency of breaks in sedentary time was defined as the number of times that the accelerometer counts exceeded 25 counts per 15 s epoch.[29]

Secondary outcomes

Adiposity

Children's height (cm) and weight (kg) were measured twice at each time point with a portable stadiometer (SECA 220, Los Angeles, California, USA) and digital scales (Wedderburn Tanita, Melbourne, Victoria, Australia) to the nearest 0.1 cm and 0.1 kg, respectively, and used to calculate BMI (kg/m^2). Waist circumference (cm) was assessed twice using a flexible steel tape at the narrowest point between the bottom rib and the iliac crest, in the midaxillary plane. A third measure was taken if there was a discrepancy of over 1 cm or 1 kg for any of the measures, with the average for each used in the analysis. BMI (kg/m^2) z-scores were calculated by subtracting the sex-age population median (based on US data as Australian norms were not available) from children's raw BMI scores.[35]

Blood pressure

Resting blood pressure was assessed using an automatic digital blood pressure monitor (OMRON HEM-907, Australia) measured in accordance with standard procedures and recommendations.[36] After 2 min of quiet seated rest, systolic and diastolic blood pressure (mm Hg) were measured on the right arm with a paediatric cuff. Three measurements were taken at 1 min intervals on two occasions, 1 week apart (total of six readings). The first measurement was discarded from each visit and the average was calculated from the remaining four measurements.

Biomarkers

Parents consenting to the blood collection were provided with EMLA anaesthetic cream for their child and instructed to attend a local pathology clinic to provide an overnight fasted morning blood sample. The following cardiometabolic risk biomarkers were assessed at a National Association of Testing Authorities/

Royal College of Pathologists Australasia accredited pathology laboratory: fasting plasma glucose (mmol/L); insulin (uU/mL); cholesterol (mmol/L); high density lipoprotein cholesterol (mmol/L); low density lipoprotein cholesterol (mmol/L); triglycerides (mmol/L); high sensitive C-reactive protein (CRP) (mg/L); and serum 25-hydroxy vitamin D (nmol/L). The remaining serum samples were transported to Deakin University and stored at −80 °C until analysed for the following biomarkers (between February and October 2013) using Milliplex immunoassay kits (Millipore, Billerica, Massachusetts, USA): inflammatory markers interleukin (IL)-2, IL-6, IL-8, IL-10 pg/mL; tumour necrosis factor alpha (TNF-α) pg/mL; adipokines adiponectin and resistin (pg/ml); neurobiological marker (brain-derived neurotrophic factor (BDNF, pg/mL)); endothelial markers (soluble intercellular adhesion molecule 1 (pg/mL); plasminogen activator inhibitor 1 (PAI-1, pg/mL); soluble vascular cellular adhesion molecule 1 (pg/mL); and soluble E-selectin (ng/mL)). All assays were performed according to manufacturer's instructions and all samples were run in duplicate. In order to allow accurate within-subject comparisons, baseline and follow-up samples from the same child were analysed on the same plate. To minimise inter-plate variability, all kits were from the same batch and plate layouts were designed so that each experimental group was equally represented on each plate. Plate layouts were designed in a blinded fashion by a third party.

Covariates and demographic data

Demographic data

At baseline, child age (date of birth) and sex were self-reported by children in a survey or collected from parental proxy-reports when missing from the child report. A season variable was created based on the date of each data collection point.

Statistical analysis

Detailed power calculations are presented in the protocol paper.[22] Briefly, a moderate and similar intervention effect size (~0.32) for all three intervention arms was expected on the primary and secondary health outcomes. The sample size was based on an anticipated mean difference in moderate-intensity to vigorous-intensity physical activity of 8 min per day (SD 18 min) and a BMI difference of 1.9 kg/m^2 (SD 0.25), but was also sufficient to detect differences in other primary and secondary outcomes. The number of participants needed to detect a standardised mean difference of 0.32 with 0.8 power for sedentary behaviour (SB-I) and physical activity (PA-I) alone and in combination (SB+PAI) relative to controls was 340 in total (17 per school). Assuming a retention rate of 91% with 20 participating schools, and a school clustering effect of 0.018,[37] the minimum number of participants needed was approximately 520.

To examine primary intervention effects on average weekday and average day sedentary and physical activity outcomes, and secondary intervention effects on health outcomes at 18 and 30 months, Generalised Linear Mixed Models (GLMMs) were used with appropriate best fitting (according to Akaike Information Criterion values) variance and link functions (in this case, Gaussian variance and identity or logarithmic link functions; Gamma variance and logarithmic link functions). Intervention effects were estimated according to the intention-to-treat principle whereby all participants with valid baseline outcome data were included in the analyses without performing imputations because it has been shown that the application of longitudinal GLMMs on available data yields similar estimates to those based on multiple imputed data sets.[38] These analyses were based on the assumption that data were missing at random.[39]

All models of primary and secondary intervention effects were adjusted for school SES (low vs medium/high), child's age and sex, number of valid days of accelerometry data and average daily minutes of wear time (primary outcomes only), baseline and season in which the assessment was conducted. Six-month outcomes data were included in the models to assist the estimation of intervention effects at other time points (ie, to maximise the amount of data per participant), but were not reported in this paper as they have been previously reported.[23 24] Schools were treated as second-level random factors, while participants and their teachers were treated as first-level partially-crossed random factors (participants had different teachers at different time points) nested within schools. Dummy variables representing times of assessment (reference: baseline), physical activity (PA) intervention, which was the combined PA-I and PA+SBI groups (reference: no PA intervention; that is, SB-I and C groups combined), and sedentary behaviour (SB) intervention, which was the combined SB-I and PA+SBI groups (reference: no SB intervention; that is, PA-I and C groups combined) were entered in the GLMMs together with two-way and three-way interaction terms of time, PA intervention and SB intervention. The three-way interaction term estimated the synergistic or antagonistic interactive effects of the PA and SB interventions on the outcomes. If these data did not provide sufficient evidence of an interaction ($p>0.05$), the three-way interaction term was excluded from the model and the additive (main) effects of the PA and SB interventions were re-assessed.

To address problems arising from examining intervention effects at multiple time points (where applicable), we used an overall p value for specific main or interaction effects so that if the overall p value was >0.05 (ie, insufficient evidence of statistical significance), none of the corresponding multiple time-point comparisons would be considered statistically significant (irrespective of their individual p values). Using the above models, linear contrasts were used to estimate the intervention effects on a specific outcome at a specific time point (18 months or 30 months). For example, a main intervention effect of 10 min/day of physical activity for the PA intervention at 30 months would indicate that, after adjusting for baseline physical activity, the participants receiving the PA intervention (PA-I and PA+SBI groups combined) accrued, on average, 10 more min/day of physical activity at 30 months than their non-PA counterparts (C and SB-I groups combined). All estimates were accompanied by 95% CIs and a probability level of 0.05 was used for all statistical tests. Statistical analyses of this study are consistent with the checklist for statistical assessment of medical papers (CHAMP statement).[40] All analyses were performed in R V.3.4.3 using the packages lme4,[41] lmerTest,[42] and car.[43]

RESULTS

Between February and June 2010, 593 parents of the 1606 children eligible to receive the programme provided informed written consent at baseline for their child to participate in at least one evaluation assessment (37% response rate). The flow of the participants through the study for the primary outcome (physical activity and sedentary variables) is presented in figure 1. In total, 141 children (24%) dropped out of the study or were unavailable at data collection. The main reasons were leaving the school (n=45 at 18 months and n=55 at 30 months) or absence during data collection due to illness (n=13 at 18 months and n=28 at 30 months). A total of 481 children provided accelerometer

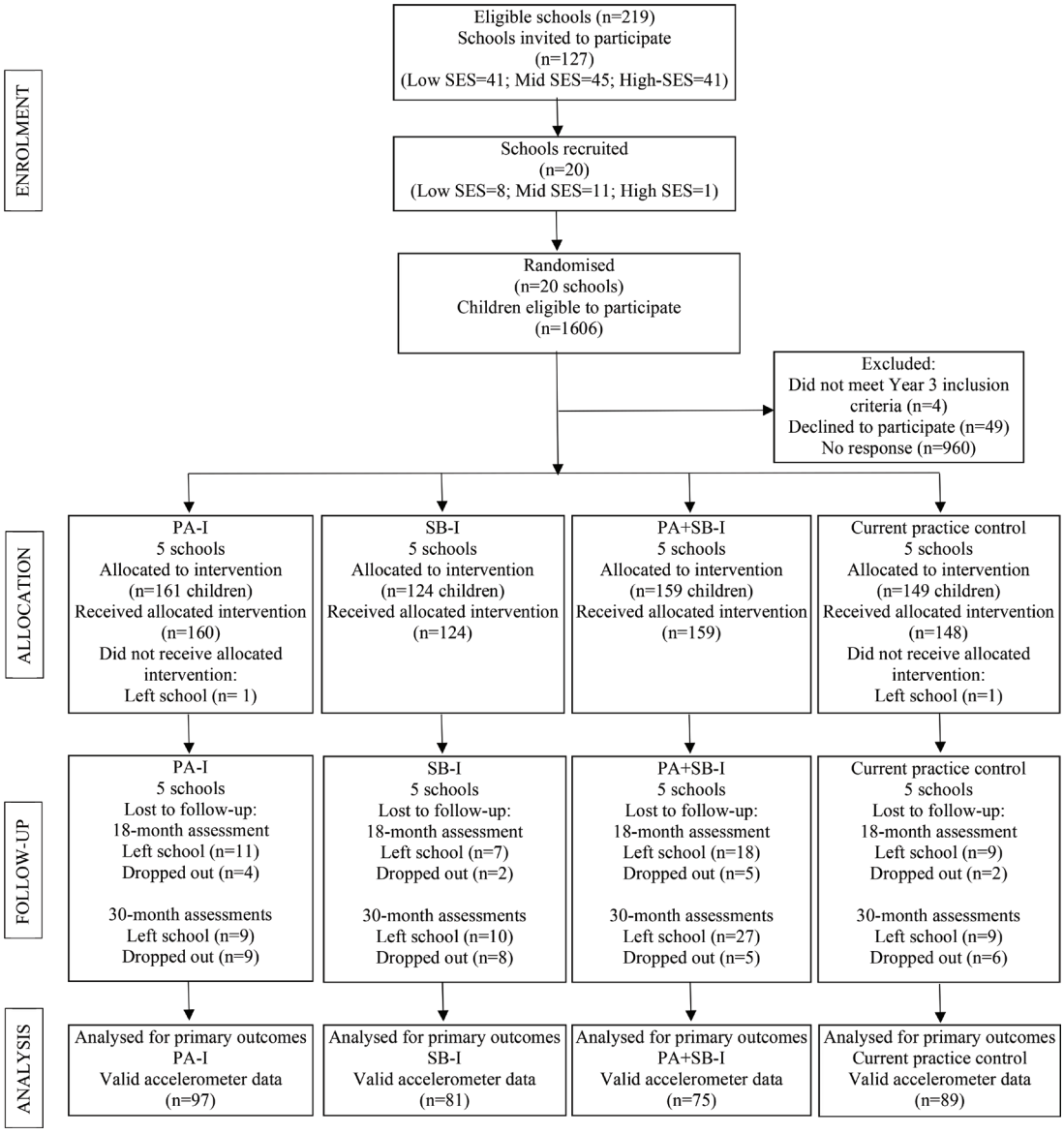

Figure 1 Flowchart showing participant recruitment and drop-out for primary outcomes. SES, socioeconomic status.

data, however, 139 participants were excluded from the analyses as they did not meet the wear time criteria. No significant between-group differences in accelerometer wear time by group were observed at any time point.

A total of 342 participants (43% boys; mean±SD, age 8.4±0.7 at baseline) were included in analyses for the primary outcomes (table 1). Two supplementary tables (online supplemental table S1 and S2) are provided which describe the sex and age of the sample as well unadjusted means and SD of the various physical activity and sedentary measures. There were significant interaction effects of the PA and SB interventions on average sedentary time per weekday and frequency of sedentary breaks per weekday at 30 months. Therefore, the intervention effects of each of the three groups (relative to the C group) were reported separately. Children in the SB-I group recorded more than 1 hour less sedentary time per weekday compared with usual practice, while the mean 19 min and 25 min differences in sedentary time were not significant for the PA-I and PA+SBI groups compared with C, respectively. As there was no significant three-way interaction on average weekday sedentary time at 18 months, only the main effects were reported. There was a significant main effect of the PA intervention (PA-I and PA+SBI) of almost 30 min on children's weekday sedentary time at 18 months. Children who received the SB intervention (SB-I and PA+SBI) engaged in significantly more moderate-intensity to vigorous-intensity physical activity on an average day (5 min) at 18 months, and less sedentary time on an average weekday (−63 min) and average day (−33 min) at 30 months compared with those who did not receive the SB intervention.

Secondary outcomes

For the anthropometric outcomes (n=564) and blood pressure (n=537) (table 2), there was a significant interaction between the PA and SB interventions on BMI z-scores at 30 months, with children in the PA-I and SB-I groups recording significantly lower BMI z-scores compared with the usual practice C group, while the effect for the PA+SBI was not significant. There was also a significant interaction effect on systolic and diastolic blood pressure at 18 and 30 months, with only children in the combined PA+SBI group recording significantly lower systolic blood pressure at 18 months compared with C, and children in the PA-I

Table 1 Mean baseline physical activity and sedentary behaviour outcomes (±SD), modelled changes (95% CI) from baseline for each group, interaction p value and the main effects (95% CI) of physical activity and sedentary behaviour at 18 and 30 months

									Main effects (if interaction not significant) or intervention effects (comparison between each experimental group and the control group) if interaction significant		
Outcome	N	Control group	n	PA-I group	N	SB-I group	n	PA+SBI group	PA×SB interaction (P value)	PA intervention	SB intervention	PA+SB intervention
Sedentary time (min/weekday)												
Baseline	89	327±72	97	322±64	81	342±57	75	328±74				
Change at 18 months	38	29.8 (−35.1 to 95.1)	53	−4.1 (−67.7 to 59.5)	43	11.2 (−53.0 to 75.5)	41	−0.5 (−64.7 to 63.6)	p=0.237	**−27.0* (−47.3 to −5.3)**	−5.7 (−27.4 to 15.1)	NA
Change at 30 months	44	49.3 (−15.6 to 114.2)	47	31.3 (−33.1 to 95.6)	33	−13.7 (−77.3 to 50.0)	31	19.0 (−49.1 to 87.0)	**56.4** (15.8 to 96.4)**	−18.9 (−45.6 to 9.2)	**−62.8*** (−92.0 to −33.9)**	−25.4 (−55.5 to 4.7)
Sedentary time (min/average day)												
Baseline	89	334±67	97	339±63	81	351±53	75	344±71				
Change at 18 months	38	22.4 (−35.4 to 80.1)	53	28.7 (−55.6 to 57.1)	43	12.9 (−43.8 to 69.5)	41	5.1 (−51.7 to 69.8)	p=0.132	−16.5 (−33.8 to 0.78)	−2.1 (−18.8 to 14.5)	NA
Change at 30 months	44	51.7 (−5.5 to 109.0)	47	38.8 (−18.0 to 95.5)	33	1.2 (−54.8 to 57.2)	31	22.6 (−34.5 to 80.0)		2.43 (−14.3 to 19.2)	**−33.3*** (−50.6 to −16.0)**	NA
Sedentary breaks (frequency/weekday)												
Baseline	89	313±41	97	311±39	81	318±48	75	318±45				
Change at 18 months	38	40.8 (−0.3 to 81.8)	53	35.5 (−4.6 to 75.6)	43	30.3 (−10.0 to 70.5)	41	32.4 (−8.0 to 72.8)	p=0.530	−2.4 (−14.7 to 9.9)	−6.0 (−17.9 to 5.9)	NA
Change at 30 months	44	20.0 (−21.0 to 60.6)	47	31.6 (−8.8 to 72.1)	33	34.6 (−5.2 to 74.5)	31	17.4 (−23.3 to 58.0)	**−29.09* (−51.36 to −5.40)**	11.8 (−4.34 to 28.0)	14.8 (−2.4 to 32.1)	−2.4 (−20.0 to 15.1)
Sedentary breaks (frequency/average day)												
Baseline	89	313±39	97	310±34	81	315±45	75	316±41				
Change at 18 months	38	37.0* (0.5 to 73.5)	53	40.7* (4.9 to 76.4)	43	32.2 (−3.5 to 67.8)	41	36.7* (0.7 to 72.6)	p=0.094	3.4 (−7.0 to 13.7)	−4.2 (−14.2 to 5.8)	NA
Change at 30 months	44	21.1 (−15.0 to 57.3)	47	32.1 (−3.8 to 67.9)	33	34.9 (−0.4 to 70.1)	31	22.4 (−13.7 to 58.6)		0.6 (−9.4 to 10.6)	2.0 (−8.4 to 12.4)	NA
Moderate-to-vigorous intensity physical activity (min/weekday)												
Baseline	89	69±19	97	64±20	81	67±19	75	66±19				
Change at 18 months	38	−16.9 (−38.2 to 4.4)	53	−18.2 (−39.0 to 2.6)	43	−16.8 (−37.6 to 4.1)	41	−11.7 (−32.7 to 9.2)	p=0.438	1.6 (−4.6 to 7.8)	3.5 (−2.5 to 9.5)	NA
Change at 30 months	44	−18.9 (−40.1 to 2.2)	47	−17.2 (−38.1 to 3.7)	33	−27.8** (−48.4 to 7.2)	31	−17.2 (−38.3 to 3.8)		5.8 (−0.3 to 11.8)	−4.5 (−10.8 to 1.7)	NA
Moderate-to-vigorous intensity physical activity (min/average day)												
Baseline	89	69±27	97	62±20	81	67±19	75	66±19				
Change at 18 months	38	−20.8* (−40.3 to −1.4)	53	−22.4* (−41.4 to −3.3)	43	−15.9 (−34.9 to 3.2)	41	−16.3 (−35.4 to 2.9)	p=0.964	−1.1 (−6.6 to 4.5)	**5.5* (0.1 to 10.8)**	NA
Change at 30 months	44	−23.9* (−43.2 to −4.6)	47	−23.3* (−42.4 to −4.2)	33	−29.0** (−47.8 to −10.1)	31	−26.4** (−45.7 to −7.1)		1.5 (−3.8 to 6.9)	−4.2 (−9.7 to 1.3)	NA

Significant intervention effects bolded. All estimates of group-specific changes from baseline and intervention effects are adjusted for school socioeconomic status, child's age and sex, number of valid days of accelerometry data, average daily minutes of wear time, baseline outcome value and season in which the assessment was conducted (spring, summer, autumn and winter). Intervention effects estimated according to intention-to-treat whereby all participants with valid baseline outcome data were included in the analyses. Only main effects of PA and SB are reported because the interaction effect of PA and SB interventions was not significant. These represent the adjusted average difference in change from baseline between participants receiving the PA or SB intervention and those not receiving the interventions. If the interaction of PA and SB interventions was significant, then main effects were not reported. *p<0.05; **p<0.01; ***p<0.001.
moderate-to-vigorous intensity physical activity, corresponding to 4-6 METs; n, number of observations at specific time points; NA, not applicable; ns interact, interaction effect of PA and SB interventions not significant at a specific time point (p value of interaction term); PA-I, physical activity (PA) promotion group; PA+SB-I, combination of PA-I and SB-I; SB-I, reducing sedentary behaviour (SB) group; Sedentary breaks, frequency of occasions exceeding 100 cpm; Sedentary time, <100 counts per min (cpm).

Table 2 Mean baseline anthropometric and blood pressure outcomes (±SD), modelled changes (95% CI) from baseline for each group, interaction p value and the main effects (95% CI) at 18 and 30 months

									Main effects (if interaction not significant) or intervention effects (comparison between each experimental group and the control group) if interaction significant		
Outcome	N	Control group	n	PA-I group	n	SB-I group	n	PA+SB I group	PA×SB interaction (P value)	PA intervention	SB intervention	PA+SB intervention
Body mass index z-score												
Baseline	141	0.44±1.06	153	0.32±1.03	120	0.32±0.89	150	0.41±0.94				
Change at 18 months	126	0.01 (−0.06 to 0.08)	135	−0.02 (−0.09 to 0.05)	112	−0.05 (−0.13 to 0.03)	130	0.04 (−0.04 to 0.11)	p=0.128	0.03 (−0.05 to 0.10)	−0.001 (−0.08 to 0.07)	NA
Change at 30 months	114	0.01 (−0.06 to 0.09)	118	−0.12** (−0.20 to −0.05)	94	−0.13** (−0.22 to −0.05)	98	−0.04 (−0.12 to 0.04)	**0.22** (0.08 to 0.38)**	**−0.13* (−0.24 to −0.03)**	**−0.14* (−0.26 to −0.03)**	−0.05 (−0.16 to 0.06)
Waist circumference (cm)												
Baseline	141	59.9±7.9	153	59.7±7.4	120	59.6±6.0	150	60.5±7.0				
Change at 18 months	128	3.76*** (2.80 to 4.72)	135	3.32*** (2.54 to 4.10)	112	2.29[c] (1.26 to 3.32)	130	2.61*** (1.64 to 3.54)	p=0.519	−0.09 (−1.03 to 0.84)	**−1.04* (−1.97 to −0.10)**	NA
Change at 30 months	115	5.95*** (4.94 to 6.95)	118	5.06*** (4.08 to 6.05)	94	3.71*** (2.65 to 4.76)	98	3.94*** (2.94 to 4.94)		−0.35 (−1.36 to 0.66)	**−1.65** (−2.66 to −0.65)**	NA
Systolic blood pressure (mm Hg)												
Baseline	132	102.5±9.0	149	100.3±8.8	116	100.0±7.7	140	103.6±9.2				
Change at 18 months	121	3.49*** (1.57 to 5.41)	134	4.79*** (3.11 to 6.48)	108	4.95*** (2.89 to 7.01)	121	0.04 (−1.88 to 1.96)	**−6.21** (−9.91 to −2.40)**	1.30 (−1.25 to 3.85)	1.46 (−1.36 to 4.27)	**−3.45* (−6.16 to −0.73)**
Change at 30 months	108	−0.44 (−2.42 to 1.55)	115	1.80 (−0.14 to 3.74)	90	−0.58 (−2.71 to 1.56)	91	−2.96** (−2.89 to −0.94)	**−4.62* (−8.58 to −0.61)**	2.24 (−0.54 to 5.01)	−0.14 (−3.06 to 2.77)	−2.52 (−5.35 to 0.31)
Diastolic blood pressure (mm Hg)												
Baseline	132	61.8±9.3	149	58.8±8.0	116	59.2±7.9	140	61.9±8.1				
Change at 18 months	121	0.60 (−1.41 to 2.60)	134	4.24*** (2.58 to 5.90)	108	3.11** (0.97 to 5.24)	121	−2.19* (−4.19 to −0.20)	**−8.94*** (−12.77 to −5.01)**	**3.64** (1.04 to 2.25)**	2.51 (−4.42 to 5.44)	−2.79 (−5.62 to 0.04)
Change at 30 months	108	−1.56 (−3.63 to 0.52)	115	0.96 (−1.05 to 2.97)	90	−1.12 (−3.33 to 1.08)	91	−4.23* (−6.28 to −2.17)	**−5.62** (−9.70 to −1.46)**	2.52 (−0.37 to 5.40)	0.43 (−2.59 to 3.46)	−2.67 (−5.59 to 0.25)

Significant intervention effects bolded. All estimates of group-specific changes from baseline and intervention effects are adjusted for school socioeconomic status, child's age and sex, and baseline outcome value. If the interaction of PA and SB interventions was not significant, only main effects are reported. These represent the adjusted average difference in change from baseline between participants receiving the PA or SB intervention and those not receiving the interventions. If the interaction of PA and SB interventions was significant, intervention effects reported in this table represent the adjusted average difference in change from baseline between participants in a particular intervention group (PA-I, SB-I or PA+SB-I) and the control group. Only main effects of PA and SB are reported because the interaction effect of PA and SB interventions was not significant. *p<.05; **p<.01; ***p<.001.
PA+SB I, combination of PA-I and SB-I.; n, number of observations at specific time points; NA, not applicable; PA-I, physical activity (PA) promotion group; SB-I, reducing sedentary behaviour (SB) group.

but not PA+SBI group recording higher diastolic blood pressure at 18 months compared with C. There was a significant main effect on waist circumference, with children who received the SB intervention recording a lower waist circumference at 18 months (−1.0 cm) and 30 months (−1.7 cm) compared with those in C.

Online supplemental table S3 shows intervention effects on biomarkers at 18 months (sample ranged from n=206 to n=218). There was a significant interaction effect between the PA and SB interventions on IL-6 and IL-2. Greater increases in IL-6 among the three intervention groups compared with C were observed, with the PA+SBI group showing a smaller effect than the sum of the single PA and SB interventions. Greater increases in IL-2 were observed among children in the PA-I, but not PA+SBI, arm compared with C. There were significant main effects among children who received the PA intervention with greater increases in CRP and TNF-α, compared with those who did not receive the PA intervention. Increased CRP, IL-6, IL-2 and TNF-α are indicative of increased cardiometabolic risk. Among children who received the SB intervention, there was a significant positive main effect on vitamin D, and a lower proportional change in BDNF and PAI-1 compared with C. For the remaining 13 inflammatory biomarkers there were no significant intervention effects.

DISCUSSION

Transform-Us! had stronger effects on children's sedentary behaviour than physical activity in both the PA and SB interventions, and there were beneficial effects on children's adiposity for both intervention approaches. Overall, *Transform-Us!* had more positive behavioural effects at 30 months than 18 months, highlighting the need for longer time frames to demonstrate programme benefits. No clear conclusions could be drawn regarding which intervention (PA or SB) had the strongest or more consistent effects on children's health outcomes. Previous research highlights that the majority of children's time is spent in sedentary behaviour (approximately 70% during school hours[8]) and approximately 11% of waking hours are spent in moderate-intensity to vigorous-intensity physical activity.[44] Therefore, our findings suggest that targeting reductions in children's sedentary behaviour is feasible, and may also be beneficial to aspects of children's adiposity.

While there is substantial evidence that regular physical activity from a young age is beneficial for children's cardiometabolic health,[1] the present study contributes much needed intervention evidence of the potential impact of reducing accumulated sedentary time over a prolonged period on some aspects of children's cardiometabolic health. The Intervention Centered on Adolescents' Physical activity and Sedentary behaviour study delivered to French schoolchildren over a 4-year period with a 2.5-year follow-up also reported sustained beneficial effects on children's BMI and self-reported physical activity and screen time.[45] Findings of the present study on cardiometabolic outcomes were mixed, however, children who received the SB intervention seemed to have more favourable health outcomes overall (lower BMI, waist circumference, vitamin D, BNDF, PAI-1; elevated IL-6) than children who received the PA intervention (lower BMI; elevated CRP, TNF-α, IL-2 and diastolic blood pressure). TNF-α, IL-2 and IL-6 are pro-inflammatory cytokines which play a role in systemic inflammation and can be related to childhood obesity.[46] However, a systematic review found that although physical activity was related to lower levels of CRP among children with obesity, there was no relationship between activity levels and TNF-α or IL-6.[47] Given the PA intervention had minimal effects on physical activity but a significant effect on sedentary time at 18 months, there is a need to better understand relationships between sedentary time and inflammatory markers in children.

The small difference of 5.5 min/day in moderate-to-vigorous physical activity among children who received the SB intervention in the current study compared with those who did not, is consistent with a meta-analysis of 30 school-based interventions that used device-based measures of children's physical activity and also found a small positive effect of approximately 5 min/day.[12] However, most studies in that review were short-term interventions (up to 48 weeks), so it is encouraging that the current intervention had a small but positive effect after 18 months, although this was not sustained at 30 months. Further research is needed to identify strategies that have a greater effect on children's physical activity and metabolic indices other than adiposity.

With larger differences in sedentary time compared with differences in moderate-to-vigorous physical activity, it is possible that there were also intervention effects on light-intensity physical activity. Recent compositional analyses of the *Transform-Us!* accelerometry data patterns (accumulated time and bouts in sedentary, light-intensity, moderate-intensity and vigorous-intensity physical activity) with a subsample of children (n=267) at 18 months found that the changes in activity patterns were mainly explained by changes in moderate-intensity and vigorous-intensity physical activity.[48] This may explain why children who received the SB intervention increased their physical activity at 18 months. The analysis also showed that only groups that received the SB intervention reduced their time in sedentary bouts relative to the overall compositional mean change, suggesting that the intervention was implemented as intended.

A recent process evaluation of the trial found that at 18 months, responding teachers (50% response rate) delivered 70% of the nine key learning messages, and almost one in five teachers provided children with active homework once a week.[49] One-third of the teachers delivered an active lesson and 56% delivered an active break every day, and almost all teachers provided access to the physical activity/sports equipment during recess and lunch breaks as well as during class lessons. The use of active pedagogy increased over time as did the use of line markings in the playground for lesson delivery. This was particularly so for teachers in the PA-I group, which may explain the unexpected effects on sedentary time among this group. The teachers also identified that support of school leaders, the programme being a priority, and commitment to delivery as being key to successful implementation. This is consistent with previous research on implementation of a physical activity initiative in a school setting.[50]

A major strength of this study was the factorial design, which enabled the testing of interactive effects of the SB and PA interventions, and the length of the intervention (2.5 years) and the real-life setting. Children had up to three different class teachers over this time period, which suggests good translatability and diffusion of the programme within the school and that the findings are not dependent on a particular teacher. The length of the trial was also important for testing the impact of long-term intervention exposure on children's cardiometabolic health, as evidenced by the effects on adiposity being strongest at 2.5 years. Further strengths include the use of objective behavioural and health outcome measures, all of which are implicated in cardiometabolic related health and disease in adulthood.[18] While there were few changes in biomarkers overall and some changes were in an unexpected direction (eg, CRP, IL-6, IL-2 and TNF-α),

it may be that the cohort of children was within a healthy range to begin with, therefore, improvements were unlikely.

Limitations include the 37% response rate from parents for their child to participate in the assessments, and participant attrition after 18 months (10%) and 30 months (12%). Lack of compliance with wearing the accelerometer also resulted in a loss of 139 participants from the analyses. However, the intention-to-treat analysis meant the full sample was retained from baseline which helped address loss of power at subsequent time points. Data collection occurred over two school terms in the first half of the year at baseline and this was contracted to one school term at the end of each year after that, which may have impacted the results. Analyses adjusted for seasonality to account for these different data collection points. A further limitation of the accelerometer is the device cannot distinguish sitting from standing still, so sedentary time is an approximation of sitting, not a direct measure.[34] BMI and waist circumference were assessed as indicators of children's adiposity, neither of which provide information about the fat or lean mass of participants. However, both anthropometric indices have been shown to be related to cardiometabolic indicators in children and adolescents.[51] For children in the PA+SBI group the lack of intervention effect on BMI may have been due to the null effects on sedentary time and physical activity for that group. Although there were inconsistent findings for systolic (favourable for PS+SBI group) and diastolic (unfavourable for PA-I group) BP outcomes at 18 months, children's mean blood pressure levels were consistent with reference values at the 50th percentile for this age group.[52] This suggests these differences may not be clinically meaningful.

CONCLUSION

Based on findings from this study, government education departments and schools should consider adopting and implementing whole-of-school programmes to promote children's physical activity and reduce sitting through active pedagogy and supportive social and physical environments at school and home to benefit children's sedentary time and some markers of cardiometabolic health. However, increasing children's physical activity beyond 5 min a day remains a challenge.[12] Assessing cost-effectiveness and effectiveness and implementation 'at scale' are the next phases in this research.

Author affiliations
[1]School of Exercise and Nutrition Sciences, Deakin University Institute for Physical Activity and Nutrition, Geelong, Victoria, Australia
[2]Institute for Health and Ageing, Australian Catholic University Faculty of Health Sciences, Melbourne, Victoria, Australia
[3]Allied Health and Human Performance, University of South Australia, Adelaide, South Australia, Australia
[4]Baker IDI Heart and Diabetes Institute, Melbourne, Victoria, Australia
[5]School of Exercise and Nutrition Sciences, Deakin University Centre for Sport Research, Geelong, Victoria, Australia
[6]School of Exercise and Nutrition Sciences, Deakin University, Geelong, Victoria, Australia
[7]Department of Public and Occupational Health, Vrije Universiteit Amsterdam, Amsterdam, The Netherlands
[8]Institute for Health Transformation, Deakin University Faculty of Health, Burwood, Victoria, Australia
[9]Deakin Health Economics, Deakin University, Geelong, Victoria, Australia
[10]School of Public Health, The University of Adelaide, Adelaide, South Australia, Australia

Twitter Jo Salmon @profjsalmon and Vicki Brown @Vicki_BBB

Contributors All authors made substantial contributions to either the conception of the work, the acquisition, analysis and interpretation of data, and helped draft, revise and approve the final version. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. JS is the guarantor and accepts full responsibility for the work and conduct of the study, had access to the data and controlled the decision to publish.

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ORCID iDs
Jo Salmon http://orcid.org/0000-0002-4734-6354
Vicki Brown http://orcid.org/0000-0003-2891-9476

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