The Effectiveness of Cognitive Behaviour Therapy-Based Interventions for Depression in Women with Non-Metastatic Breast Cancer: A Systematic Review and Meta-Analysis

Shagun Chawla

This thesis is submitted in partial fulfillment of the Honours degree of Bachelor of Psychology

School of Psychology

University of Adelaide

October 2018

Word Count: 9000

Table of Contents

List of Tables and Figures

Abstract

Breast cancer is one of the most common types of cancer and the leading cause of cancer-related death in women worldwide. Depressive symptoms, common during non-metastatic breast cancer, can be overlooked and therefore, undertreated. Researchers have previously evaluated the efficacy of Cognitive Behaviour Therapy (CBT) in treating depression in breast cancer patients. However, research investigating the short- and longer-term effectiveness of CBT-based interventions (CBT-BI) in a comprehensive manner is limited, with study quality seldom examined. To address this gap, this meta-analysis searched six electronic databases, identifying six randomised controlled trials (RCT) that examined the effectiveness of CBT-BI for depression in women with non-metastatic breast cancer ($N_{participants} = 710$). Standardised mean differences between intervention and control groups on self-report depression measures were calculated. Results highlighted that short-term CBT-BI (Hedge's $g = $-1.215), particularly individual CBT-BI (Hedge's $g = $-1.999), significantly reduced depression in comparison to control groups, while group CBT-BI demonstrated a medium but non-significant effect (Hedge's $g = $-.578). CBT-BI also decreased depression levels at three-month follow-up, however, this effect was not maintained at six- and 12-month follow-up. Additionally, quality of included studies was explored in terms of risk of bias, study quality, intervention description, and researcher allegiance, and was found to be of moderate quality. A thorough investigation of CBT-BI, such as conducted in the current research, encourages evidence-based practice by allowing clinicians to more accurately gauge the efficacy of such interventions in treating depression amongst this population, thus, facilitating the development of optimal treatment protocols to improve clinical practices.

DECLARATION:

This work contains no material which has been accepted for the award of any other degree or diploma 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.

I give permission for the digital version of my thesis to be made available on the web, via the University's digital research repository, the Library Search and also through web search engines, unless permission has been granted by the School to restrict access for a period of time.

Shagun Chawla

October, 2018

Acknowledgements

First and foremost, I would like to thank Dr Melissa Oxlad. Your on-going support, patience, and guidance throughout was invaluable. You have taught me so much, and I am very lucky to have had you as my honours supervisor. Thank you for everything you have done, you are a true inspiration. Secondly, I owe a big thank you to my family and friends for their incredible support during the year. You pushed me through it all and never let me give up, and for that I am eternally grateful.

Chapter 1: Introduction

1.1 Definition and Incidence of Breast cancer

Cancer, a multifactorial disease instigated by somatic mutations in abnormal cells forming an invasive (or malignant) tumour, can occur in any part of the human body, including the breast (Australian Institute of Health and Welfare [AIHW] & Cancer Australia, 2012). Upon cancer diagnosis, staging of cancer (0, I, II, III, or IV) determines the anatomic extent of the disease (Brierley, Gospodarowicz, & O'Sulivan, 2016). Stages 0-III are considered early-stage or non-metastatic, while Stage IV is termed advanced or metastatic. Metastatic cancer is an invasive tumour that spreads beyond the breast to other parts of the body (Edge, Byrd, Compton, Fritz, Greene, & Trotti, 2010).

In 2015, approximately 2.4 million women globally were diagnosed with breast cancer, making it the most common cancer amongst women (DeSantis et al., 2016; Fitzmaurice et al., 2017) and being identified as the leading cause of cancer-related death among women (Fitzmaurice et al., 2017). In Australia, breast cancer affects one in eight women and one in 37 women will die from it before the age of 85 years (AIHW & Cancer Australia, 2012).

1.2 Impact of Breast Cancer on Physical and Psychological Wellbeing

Due to advances in medical technology, a greater number of women are surviving breast cancer (Ban & Godellas, 2014), although, significant adverse impacts on their physical and psychosocial wellbeing remain (Agarwala & Riba, 2010). The most common physical impacts experienced by women include chemotherapy-related side-effects such as nausea, loss of libido, and hot flushes (Agarwala & Riba, 2010; Fobair et al., 2006; Kim et al., 2018). Whilst these issues are physical in origin, they also often affect a woman's psychological wellbeing. One key psychological consequence of breast cancer is depression, the focus of the current research.

1.2.1   Depression in breast cancer.

1.2.1.1 Classification and diagnosis of depression.

Since the 1960s, depression, characterised by excessive rumination (Nestler et al., 2002), has been diagnosed as "major depression" based on symptomology outlined in the Diagnostic and Statistical Manual of Mental Disorders (DSM; American Psychiatric Association [APA], 2013). According to the DSM-V, individuals need to satisfy a number of criteria to receive a diagnosis of Major Depressive Disorder (MDD). First, from a series of possible symptoms, individuals must experience at least five symptoms nearly every day during the same two-week period, with at least one symptom being depressed mood or loss of interest / pleasure. These symptoms include decrease / increase in appetite or significant weight loss / weight gain; insomnia / hypersomnia; psychomotor agitation / retardation; fatigue / loss of energy; feelings of worthlessness / excessive or inappropriate guilt; and diminished ability to think or concentrate / indecisiveness. Individuals may also experience recurrent thoughts of death, suicidal ideation, or a suicide attempt (APA, 2013).

MDD diagnoses among breast cancer populations may be difficult to make, as the symptoms observed may result from the physical aspects of cancer (Rodin et al., 2007). Furthermore, differences exist between being diagnosed with MDD, and presenting with depressive symptomology which commonly arises due to factors such as cancer-related therapy and side-effects, fear of recurrence, and life stresses (Bower, 2008; Jassim, Whitford, Hickey, & Carter, 2015). Consequently, one may not satisfy all criteria for a diagnosis of MDD but may still experience depressive symptoms, as Bower (2008) noted that 20% to 30% of women with non-metastatic breast cancer experienced increased depressive symptomology, although the prevalence of MDD amongst them was considerably lower. For the purpose of this research, the term depression is investigated broadly with the inclusion of depressive symptoms.

1.2.1.2 Rates of depression in breast cancer.

Breast cancer is highly associated with depressive symptoms and MDD with rates ranging from 20% to 58% and 11% to 13%, respectively (Abad, Bakhtiari, Kashani, & Habibi, 2016; Bower, 2008; Burgess et al., 2005; Fann et al., 2008; Jassim et al., 2015; Torta & Ieraci, 2013; Zabora, Brintzenhofeszoc, Curbow, Hooker, & Piantadosi, 2001). Depression has been commonly ascribed to the debilitating nature of breast cancer, fears surrounding diagnosis and treatment, and likelihood of poor outcomes (Sharpley & Christie, 2007), resulting in lower treatment compliance, reduced quality of life and higher rates of relapse following treatment (Fann et al., 2008; Li et al., 2016; Sharpley & Christie, 2007).

Depression rates amongst women with non-metastatic breast cancer vary depending on time since diagnosis, with rates up to 30% in the initial six months (Akechi, Okuyama, Imoto, Yamawaki, & Uchitomi, 2001; Fallowfield, Hall, Maguire, & Baum, 1990; Hopwood, Howell, & Maguire, 1991), reducing to 25% and 15% in the second year and fifth year, respectively (Burgess et al., 2005). Additionally, evidence proposes that depression prevalence is also influenced by disease stage, with higher rates found in women with metastatic disease (23% to 45%; Hopwood et al., 1991; Hotopf, Chidgey, Addington-Hall, & Lan Ly, 2002; Kissane et al., 2004).

1.3 Cognitive Behaviour Therapy for Depression in Breast Cancer

The current research draws from Aaron Beck's Cognitive Theory of Depression, developed in 1963 (Beck, 1963), in which he explained that those experiencing depression demonstrate automatic, repetitive cognitions pertaining to themes of loss and exhibiting negative views of the self, the world, and the future (cognitive triad). The level of such cognitions and dysfunctional beliefs are associated with depressive schemas being activated in response to certain stressors, and thus, directly related to depression severity (Beck, Rush, Shaw, & Emery, 1979; Haaga, Dyck, & Ernst, 1991; Kovacs & Beck, 1978). Based on

Beck's (1963) theory, CBT was formulated, one of the most widely used psychological interventions for depression and been proven to be effective in reducing depressive symptoms in a range of populations (Butler, Chapman, Forman, & Beck, 2006; Hollon, Stewart, & Strunk, 2006). CBT may include any form of psychotherapy delivered in an individual or group setting (Jassim et al., 2015).

1.3.1 Processes involved in CBT/CBT-BI and impact of CBT-BI on depression in women with breast cancer.

To treat depression, CBT uses a goal-orientated approach to target and modify dysfunctional cognitions and behaviours, and excessive rumination through cognitive restructuring and teaching specific coping skills (Cuijpers, Smit, Bohlmeijer, Hollon, & Andersson, 2010; Hopko et al., 2011; Hundt, Mignogna, Underhill, & Cully, 2013; Jassim et al., 2015). Patients use these skills to change specific (usually negative) cognitions and behaviours (Hundt et al., 2013).

CBT consists of a variety of approaches which can be subdivided into third-wave therapies, such as mindfulness, cognitive behavioural stress management (CBSM), cognitive-existential group therapy (CEGT), and acceptance and commitment therapy (Dahl, Wilson, & Nilsson, 2004; Jassim et al., 2015). Therefore, treatment can include various other components such as progressive cognitive therapy and muscle relaxation, meditation, and systematic desensitisation (Jassim et al., 2015).

CBT-based interventions (CBT-BI) have shown to be effective in addressing depression in women with breast cancer (Brothers, Yang, Strunk, & Andersen, 2011; Carlson, Speca, Patel, & Goodey, 2003; Daniels, 2015; Jassim et al., 2015; Lengacher et al., 2009; Tatrow & Montgomery, 2006). By promoting awareness through psychoeducation, and providing emotional support and cognitive restructuring skills, CBT-BI assists women to

better cope with their disease by targeting the depression-induced cognitive dysfunctions (see

Figure 1), which commonly occur in cancer (Fann et al., 2008; Sandgren & McCaul, 2007).
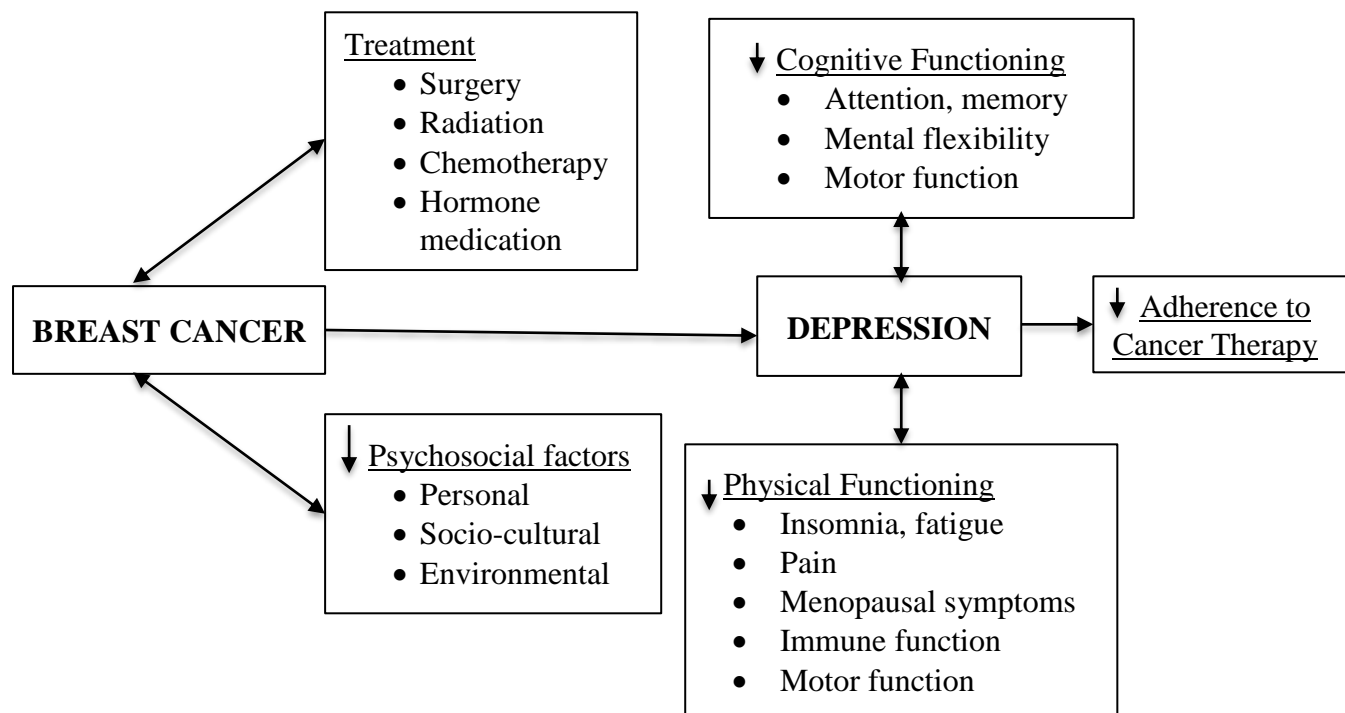
Figure 1. Theoretical model of depression in women with breast cancer. Adapted from "Major depression a fter breast cancer: a review of epidemiology and treatment," by J.R. Fann, A.M. Thomas-Rich, W.J. Katon, D. Cowley, M. Pepping, B.A. McGregor, and J. Gralow, 2008, *General Hospital Psychiatry*, *30*(2), pg. 120. Copyright 2008 by Elsevier Inc.

1.4 Evidence-Based Practice

Over the past few decades, there has been an increased call for evidence-based

practice (EBP) with health care policies incorporating it as a central tenet (McHugh &

Barlow, 2010). EBP is frequently used to treat physical components of breast cancer, but is

also warranted for the associated psychological impacts, including depression (Drake et al.,

2001). Translating research findings into clinical practice is essential and is dependent on

clinicians administering psychological interventions on the basis of published research

findings (McHugh & Barlow, 2010). Despite this, evidence-based psychological practices

across mental health remain under-developed, with research confirming the lack of successful

dissemination and implementation of research findings in clinical practice settings (Goisman, Warshaw, & Keller, 1999; Stewart & Chambless, 2007).

This review recognises that clinicians must employ EBP to best assist women with breast cancer and depression. However, in order for clinicians to make insightful decisions about which interventions to implement in sound EBP, they must have accurate research evidence regarding intervention effectiveness based on gold standard RCTs and meta-analyses (Dragioti, Dimoliatis, & Evangelou, 2015; Meline, 2006).

1.5 Methodological Issues in the Breast Cancer, Depression and Psychological Intervention Literature

CBT-BI have gained extensive recognition in reducing improving depressive symptoms among cancer patients through systematic reviews and meta-analyses (Barsevick, Sweeney, Haney, & Chung, 2002; Bower, 2008; Devine & Westlake, 1995; Meyer & Mark, 1995), however many gaps in knowledge remain with regards to the effectiveness of such treatments. For example, little is known about whether treatment setting, mode of delivery, and length of intervention influence outcomes. Furthermore, the findings of these meta-analyses are limited by methodological concerns, including small sample sizes, highly biased studies, and a paucity of RCTs, which limit the scope of interpretation.

A review of the current literature revealed that some meta-analyses have only searched a small number of databases; Cobeanu & David (2018) searched only two databases, while Haller and colleagues (2017) searched three. Additionally, Haller and colleagues' (2017) meta-analysis included women with both non-metastatic and metastatic breast cancer, which may be problematic due to differing rates of depression across disease stages. Also, depression was not the primary outcome of interest for Haller et al. (2017) and quality assessment of included studies was not undertaken.

Two other meta-analyses in the area also raise methodological concerns; one examined the effectiveness of CBT in people with mixed cancers, including both breast cancer patients and survivors (Piet, Würtzen, & Zachariae, 2012), while another study (Cramer, Lauche, Paul, & Dobos, 2012) failed to report quality assessments. Additionally, two meta-analyses assessed only short-term effects of CBT-BI (Haller et al., 2017; Zhang, Xu, Wang, & Wang, 2016), despite recommendations that long-term benefits of CBT-BI ought to be further explored to enhance clinical practices (Butler et al., 2006; Newell, Sanson-Fisher, & Savolainen, 2002; Qiu et al., 2013).

In light of these findings, the literature and clinical field would benefit from meta-analyses that specifically: (1) examine interventions designed to target depression as the primary outcome in women with non-metastatic breast cancer; (2) use well-validated measures of depression; (3) include RCTs only; (4) conduct an extensive database search over a longer period of time; (5) assess both short- and longer-term effects of CBT-BI; and (6) conduct comprehensive quality assessments.

1.6 Research Aims of the Current Study

The aforementioned methodological concerns of previous studies impact researchers' and clinicians' abilities to make judgments about the reliability and validity of the effectiveness of CBT-BI for depression in women with breast cancer. In order to address these concerns, this comprehensive systematic review and meta-analysis examines the efficacy of CBT-BI for treating depression in women with non-metastatic breast cancer Specifically, the current research aims to:

1. Examine the short-term effectiveness of CBT-BI for treating depression among women with non-metastatic breast cancer;

2. Examine the longer-term effectiveness of CBT-BI for treating depression among women with non-metastatic breast cancer;

3. Evaluate the quality of studies included in the meta-analysis in terms of risk of bias, study quality, intervention description, and researcher allegiance (RA).

Chapter 2: Method

2.1 Literature Search

A comprehensive search of six databases (CINHL, Embase, PsycINFO, PubMed, Scopus, and Web of Science) was conducted for the period between database commencement and June 2018 to source suitable studies that have examined CBT-BI for depression in women with non-metastatic breast cancer. Search strategies were saved so that regular email updates could be delivered for any new results that matched the search criteria. Search terms were tailored to individual databases and comprised a range of extensive keywords, as listed in Table 1 (refer to Appendix A for detailed search strategies). To ensure accuracy, an expert research librarian assisted with the development of search terms. Additionally, the reference lists of included studies and past meta-analyses in the field were examined to detect any useful research that may have been missed.

Table 1

Search Terms and Boolean (Logical) Operators used in the Database Searches

AND ⟹

Breast Cancer	Depression	Psychological Intervention (CBT)	Study Type
Breast neoplasm*	Depression	Cognitive therapy	Random allocation
Breast carcinoma*	Depressive disorder	Cognitive behavioural therapy	Randomized
Breast tumour*	Depressive	Cognitive behav*	Randomized
Breast tumor*	Depressed	Mindful* based cognitive therap*	Randomized control trial*
Breast malignan*	Distress*	CBSM	Randomised control trial*
Cancer of the breast*	Major depressive disorder*	CBT	RCT*
Neoplasm of the breast*	Major depressive episode*	Cognitive psychotherapy*	Controlled clinical trial*
Non-metastatic breast cancer*	Depressive episode*	Cognitive therap*	Randomised clinical trial*
Non-metastatic breast		Cognitive behav*	Randomized clinical

OR ⬇

neoplasm*	therap*	trial*
Non-metastatic breast carcinoma*		
Lobular carcinoma*		
Ductal carcinoma*		
Breast cancer*		

Note. Search terms includes stated terms and derivatives *(e.g., behaviour and behavioural). Both plural and singular terms searched.

2.2 Eligibility Criteria

To enhance scientific rigour in meta-analyses of clinical or healthcare questions, it is recommended that the research question be formed in terms of Population (P), Intervention (I), Comparison (C) and Outcomes (O), using the PICO framework (Burns & Chung, 2010; Gillam & Siriwardena, 2014; Moher et al., 2009; Morton, Berg, Levit, & Eden, 2011). Thus, study inclusion in the current research was guided by following this framework: Population – breast cancer; Intervention – CBT-BI; Comparison – control group (waitlist control/standard care); and Outcomes - depression.

This meta-analysis included studies if they satisfied the following criteria: (1) evaluated change in depression as a primary outcome of participation in interventions undertaken in a RCT; in (2) women with non-metastatic breast cancer over the age of 18 years diagnosed with depression; who (3) participated in a CBT-BI or control group; where (4) depression was assessed using a validated self-report instrument (e.g., HADS, BDI-II, CES-D); and (5) baseline and post-intervention measures of depression were reported. In addition, studies had to (6) provide parametric data to enable the calculation of an effect size (i.e., means, *SDs*, exact *p* values), and (7) be published in the English language.

Studies examining multiple stages (Stages 0-IV) of breast cancer, where data for individual stages could not be separately extracted, were excluded. Secondly, studies which only included women with metastatic breast cancer were excluded because their survival rates decline dramatically, and their psychosocial concerns differ (e.g., greater importance of

symptomatic relief) compared with women diagnosed at earlier stages (Nápoles et al., 2015; Reich, Lesur, & Perdrizet-Chevallier, 2008). Lastly, breast cancer survivors, defined as those not undergoing active treatment(s) to manage their cancer, were also excluded.

The initial literature search returned 340 articles across the databases (see Figure 2). Removal of duplicates narrowed the pool of studies to 220. The title and abstracts of these articles were subsequently screened against the selection criteria, leaving 59 articles. The full-text versions of these remaining articles were retrieved and re-screened against the inclusion/exclusion criteria, resulting in five eligible studies. An additional article was sourced from other articles' reference lists and upon assessment, was also included in the review. Three authors (Abad et al., 2016; Antoni et al., 2001; Simpson, Carlson, & Trew, 2001) were contacted by the author (SC) to obtain additional information, as the data provided was insufficient to draw conclusions about inclusion/exclusion. Of these, one author (Antoni et al., 2001) provided further data, and as a result, their study was included in the analysis, taking the number of eligible studies to six. Several other relevant papers were identified but were study protocols only, thus were excluded. Where possible, the first author (SC) contacted lead authors to check whether any published data was available. Of the three authors contacted, one (Low et al., 2016) replied indicating that their study was unpublished and under review. All these follow-ups resulted in a final sample of six studies.

Reliability of this article selection process was checked by a second reviewer (thesis supervisor, MO), who screened titles and abstracts of 10% of potentially eligible studies, randomly chosen by the primary reviewer (SC). Inter-rater reliability was high, with agreement among raters achieved on 97% of occasions ($K = .94$, $p < .05$) (McHugh, 2012). Any discrepancies were discussed and resolved by consensus.

Identification

Records identified through database searching:
Pubmed (34), PsycINFO (10), Embase (111),
Web of Science (67), CINAHL (42), Scopus (76)
Total = 340

Additional records identified through other sources
($n = 1$)

Screening

Duplicates excluded
($n = 120$)

Titles and Abstracts screened
($n = 220$)

Excluded - Irrelevant/off-topic ($n = 161$)

Eligibility

Full-text articles assessed for eligibility
($n = 59$)

Exclusion reasons ($n = 54$):

Could not retrieve full article ($n = 11$)

Breast cancer survivors ($n = 5$)

Not a RCT ($n = 7$)

Depression not measured ($n = 2$)

Not breast cancer/range of cancers ($n = 5$)

Stage 4 cancer ($n = 5$)

Insufficient data ($n = 3$)

Not CBT ($n = 5$)

Depression not a primary outcome measure ($n = 6$)

Advanced/metastatic cancer ($n = 1$)

Not a validated depression scale ($n = 4$)

Included

Studies included in final synthesis
($n = 6$)

Figure 2. PRISMA flowchart of study selection process. Adapted from "Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement," by D. Moher, A. Liberati, J. Tetzlaff, D. G. Altman, The PRISMA Group, 2009, PLoS Medicine, 6(7): e1000097.

2.3 Data Collection and Preparation

In accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Moher et al., 2009), and evidence-based recommendations for the reporting of systematic and meta-analytic reviews (Moher, Liberati, Tetzlaff, & Altman, 2010), key information for each study was summarised using a data extraction sheet (see Appendix B). This included information relating to: (1) sample characteristics and demographics (e.g., sample size, recruitment source, age range and mean, gender, cancer stage); (2) study characteristics (e.g., study design, standardised outcome measures); (3) effect size estimates (e.g., means, standard deviations, *p* values); and (4) treatment characteristics (e.g., therapy format and modality, frequency, and duration).

2.4 Statistical Analysis

Both short-term (i.e., change in depression score from baseline to first assessment reported post-intervention) and longer-term treatment effects (i.e., change in depression score from baseline to three, six and 12-month follow-up) were calculated using Hedges *g* effect size (Borenstein, Hedges, Higgins, & Rothstein, 2009). Longer-term was defined as pre-intervention to follow-up assessments, rather than post-intervention to follow-up assessments because three studies (Arving et al., 2007; Kissane et al., 2003; Marchioro et al., 1996) did not conduct an immediate post-intervention assessment of depression. One study (Desautels, Savard, Ivers, Savard, & Caplette-Gingras, 2018) was excluded from longer-term analysis as participants as participants initially in the control condition were later reassigned to receive CBT-BI and thus, if included, this study may have potentially contaminated any possible effect.

Effect size data was entered into Comprehensive Meta-Analysis (CMA) Software Version 3 (Borenstein, Hedges, Higgins, & Rothstein, 2014). As recommended by Cumming (2012), a random-effects model of meta-analysis was utilised. This model assumes that

variation between observed effect sizes is due to subject-level sampling error and differences within individual study designs (Lipsey & Wilson, 2001).

Effect sizes were computed using means and standard deviations (SD). The depression outcome measure scores were entered as continuous data, with the effect size calculated being the standardised mean difference (SMD) between CBT-BI and control groups, with 95% confidence intervals (CI) indicating the difference in means between groups, divided by the pooled SD. If studies examined multiple intervention groups (Arving et al., 2007; Desautels et al., 2018), only the relevant intervention data on CBT-BI and depression was used. One study (Desautels et al., 2018) used multiple self-report measures and a clinician measure of depression. For this, only the self-report measure was used, with an average effect size calculated and used in subsequent pooled analyses to ensure consistencies between effect size analyses. Rosenthal's (1993) recommendation of using a conservative estimate ($r = .7$) in cases, where correlations between the pre- and post-treatment measures were unavailable in within-group designs, was employed. To calculate the mean effect size for a group of studies, individual effect sizes were pooled using a random-effects model rather than a fixed-effect model as the included studies were not identical in design.

While Cohen's *d* is one SMD estimate that is often used, it has been noted to have a positive bias, tending to overestimate the absolute value of effect size in small samples (Borenstein et al., 2009). This bias can be removed by instead using Hedge's *g* (Borenstein et al., 2009). In this meta-analysis, the small number of included studies and discrepancies in samples sizes between these (sample size of smallest group = 11 and sample size of largest group = 154), made Hedges *g* the optimal effect size measure to use as it is useful for great diversity in samples (Borenstein et al., 2009; Ellis, 2010; Higgins & Green, 2011). The direction of the effect size estimate was standardised for ease of data interpretation, such that

a negative Hedge's *g* indicated improvement in depression symptoms amongst individuals who received CBT-BI compared to the control group. Effect sizes were interpreted using Cohen's guidelines (0.2 = small, 0.5 = medium, and 0.8 = large effect) (Cohen, 1988).

To ascertain the accuracy of individual and weighted effect sizes, exact *p* values and 95% CIs were calculated. CIs reflect the range of values within which the true mean value lies. At the 95% level, there is only a 5% chance that the actual effect size will lie beyond the range of values specified by the CI (Stratford, 2010). Effect sizes were considered to be statistically significant when the CI did not include the value of zero.

In addition, where possible, Orwin's fail-safe Ns (N_{fs}) (Orwin, 1983) were calculated for effect size subsets to address possible publication bias which is a potential threat to the validity of this meta-analysis (Rosenthal & DiMatteo, 2001). Meta-analytic techniques may overestimate treatment effects as they can be subject to the "file drawer problem" – or a bias towards studies that report significant results (Orwin, 1983). This problem arises when the results of published and unpublished studies are systematically different, and reviews like the current one, rely on data from published studies only (Orwin, 1983).

The N_{fs} reflects the number of unpublished or unidentified studies reporting no effect (i.e., no relationship) that would need to exist to produce a small effect size, defined in this review as an effect size of 0.20, as suggested by Orwin (1983).

We calculated N_{fs} using Orwin (1983) fail-safe N formula (Eq. (11)):

$$N_{fs} = \frac{N\,(d - d_c)}{d_c}$$

where N = the number of studies in the meta-analysis, d = the average effect size for the studies synthesized, and d_c = the criterion value selected that d would equal when some knowable number of hypothetical studies (N_{fs}) were added to the meta-analysis. The value for d_c was set at 0.2 (small effect). Generally, the higher the N_{fs} value the more confidence can be held in the result as it is more unlikely that there are unpublished studies that would

contradict the findings (Ellis, 2010). This meta-analysis employed a conservative approach whereby, findings were considered robust when the N_{fs} value exceeded the number of studies contributing to an effect size estimate (i.e., $N_{fs} > N_{studies}$). This differs from other N_{fs} formula, which rely on the total number of studies undergoing a meta-analysis (Zakzanis, 2001).

Finally, heterogeneity among studies in each group was systematically assessed. Heterogeneity tests the variation in study outcomes between studies (Borenstein et al., 2009). This study used the I^2 statistic and the chi-squared statistic (Cochrane's Q; Borenstein et al., 2009; Haidich, 2010) to both evaluate the degree of consistency in pooled effect size estimates (Higgins & Green, 2011), and to test if there was a significant difference in the effect sizes between individual and group CBT-BI compared to control groups, respectively. The value of I^2 denotes the percentage of observed between-studies variance that can be credited to real differences in effect sizes (heterogeneity) instead of chance (Higgins & Thompson, 2002; Higgins, Thompson, Deeks, & Altman, 2003). I^2 values of 2% are considered low; 50% considered moderate; and greater than 50% (i.e., 75%) indicate considerable heterogeneity across individual effect size estimates (Brewin, Andrews, & Valentine, 2000; Higgins et al., 2003). Because I^2 measures the proportion of heterogeneity to the total observed dispersion, it is not influenced by low statistical power and is not contingent on the number of studies included in the meta-analysis (Littell, Corcoran, & Pillai, 2008).

In combination, these statistics were used to assess the effectiveness of CBT-BI in reducing depression among women with non-metastatic breast cancer. Specifically, CBT-BI was deemed to have an important effect on depression in women with breast cancer if it was: (1) associated with a medium (Hedge's $g \geq .50$) to large (Hedge's $g \geq .80$); (2) that was statistically significant (i.e., 95% CIs $\neq 0$; $p < .05$); and (3) had a Nfs greater than the number

of studies which contributed to the pooled effect size. The interpretation of these results was considered in the context of study heterogeneity.

2.5 Quality Assessments

Four forms of quality assessment, risk of bias, study quality, intervention description, and RA, were undertaken.

2.5.1 Risk of bias assessment.

Risk of bias assessment to evaluate methodological quality of included studies was conducted (see Appendix C) following Cochrane guidelines (Higgins et al., 2011). Studies were rated on critical aspects pertinent to clinical research (Pannucci & Wilkins, 2010), namely: internal validity (i.e., extent to which a study minimises systematic error by reducing biases in measurement and data collection), and external validity (i.e., extent to which the study findings can be generalised to the broader breast cancer and depression population).

2.5.2 Quality assessment of included studies.

Quality of included research studies was evaluated using the Quality Index (QI) developed by Downs & Black (1998). This 27-item scale examines three key areas that routinely contribute to methodological bias in health intervention research: external validity, internal validity, and study power. Each item is critically appraised and scored as either 1 or 0, with additional points awarded if the study details potential confounders in the selection of study participants in addition to meeting the criteria for study power (i.e., statistically significant group difference of $p < .05$, with power at 80% for this review; Cohen, 1992). Item scores are summed to obtain an overall score between 0 and 32 which can be categorised as follows: excellent (26-32); good (20-25); fair (15-19); and poor (≤14) (Hooper, Jutai, Strong, & Russell-Minda, 2008).

The QI has demonstrated good psychometric properties, including test-retest

reliability ($r = 0.88$) and inter-rater reliability ($r = 0.75$; Downs & Black, 1998). Quality

ratings were independently conducted by the author (SC) and second reviewer (MO). The

results were compared and discrepancies were resolved by consensus. Correlations between

total QI ratings revealed sound agreement between the two evaluators (Kendall's Tau =

0.600, $p = .091$) (Stemler, 2004). Kendall's Tau is more robust than Spearman's rho, and is a

proxy for Pearson's product-moment correlation in research where sample sizes are small,

making it the preferable estimator from both perspectives (Croux & Dehon, 2010; Field,

2009; Walker, 2016). Given the small number of studies and that Kendall's Tau is based on

the sample, and thus, highly affected by the sample size, it is predicted that the current results

were non-significant for these reasons.

2.5.3 Quality assessment of CBT-BI descriptions in included studies.

An assessment of intervention descriptions was also undertaken because without

complete published descriptions of interventions, researchers cannot replicate or add to

research findings and clinicians cannot reliably implement effective interventions (Hoffmann

et al., 2014). The Template for Intervention Description and Replication (TIDieR), was

developed in response to the very poor quality of intervention descriptions in the literature

(Hoffmann et al., 2014). Hence, this meta-analysis used TIDieR to evaluate the quality of

intervention descriptions used in included studies. This 12-item checklist allows examination

of the following areas that make it easier to understand and replicate effective interventions,

especially in trials: brief name, why (rationale), what (materials), what (procedure), who

provided, how, where, when and how much, tailoring, modifications, how well (planned),

and how well (actual).

2.5.4 Researcher allegiance (RA).

The RA effect is very important in studies evaluating psychotherapeutic intervention

effectiveness because researchers may portray allegiances which influence their actions or

reporting of their results (Dragioti et al., 2015). Given that psychotherapeutic research is

prone to RA as an influential factor, it has been recently suggested that RA should be

routinely examined in meta-analyses (Dragioti et al., 2015). To address this issue, a RA

checklist (Wampold et al., 2011) was used, whereby, a study was defined as showing RA

when the author(s) had: (1) developed the intervention; (2) developed both the therapy and

trained the therapists; (3) developed both the intervention and supervised the therapists; (4)

supervised and/or trained the therapists alone; or (5) advocated the therapy. Studies are coded

using a 6 category system (0 = No apparent advocacy of one treatment over another - 5 =

Authors created intervention and supervised/trained therapist), with higher scores indicating

higher RA (Wampold et al., 2011).

Chapter 3: Results

3.1 Study Characteristics

Six RCTs were included in this meta-analysis (see Table 2), published in peer-reviewed journals between 1996 and 2018. Data originated from diverse areas around the world, with single studies from The United States of America, Australia, Canada, Sweden, Iran, and The United Kingdom. Sample sizes ranged from a small quasi-experimental study (Mohabbat-Bahar, Maleki-Rizi, Akbari, & Moradi-Joo, 2015) of 30 participants, to two RCTs (Desautels et al., 2018; Marchioro et al., 1996) of 62 and 36 participants, respectively. Two multi-center studies (Antoni et al., 2001; Kissane et al., 2003) contributed 403 participants, with one study from Sweden (Arving et al., 2007) contributing an additional 179 participants.

A total of four depression measures were utilised across the six studies. The majority of studies relied on self-report measures ($N_{studies} = 6$), with one study (Desautels et al., 2018) also including clinician rating of depression. The Beck Depression Inventory (BDI, BDI-II; (Beck, Steer, & Brown, 1996) and the Hospital Anxiety and Depression Scale (HADS; (Zigmond & Snaith, 1983) were the most commonly used measures. One study (Antoni et al., 2001) utilised the Center for Epidemiologic Studies Depression Scale (CES-D; Radloff, 1977), while another (Desautels et al., 2018) used a clinician-assessed depression measure, the Hamilton Depression Rating Scale (HDRS; Hamilton, 1960) in addition to the HADS and the BDI-II. Given that only one study used a clinician measure, the clinician data was not used in the analyses to prevent any potential confounding effects (Mohr, Boudewyn, Goodkin, Bostrom, & Epstein, 2001). The majority of studies ($N_{studies} = 4$) relied on a single source for participant recruitment (e.g., single oncology unit), with participants approached directly by researchers or hospital staff for two studies (Arving et al., 2007; Mohabbat-Bahar et al., 2015) which can help maximise the representativeness of a sample. Two studies

(Antoni et al., 2001; Desautels et al., 2018) used the broad recruitment strategy of

Oncologists or Physicians sending a letter of invitation to potential participants.

Table 2

Descriptive Characteristics of Included Studies ($N_{studies}$ = 6)

Lead author	Sample		Method					CBT-BI treatment				Control condition(s)
	$N_{participants}$		Country	Recruitment source	Study design	Pre-post measures	Attrition rate	Treating discipline	Therapy format	Therapy modality	Session frequency, duration and model	
	T	C										
Antoni (2001)	47	53	United States	Physician letter	RCT	POMS; CES-D	8.1% (short-term); 6.6% (3-month); 11.8% (9-month)	Psychology	Group	Face-to-face	Weekly in 1-2 (usually 2 hour) hour session time slots, for 10 weeks; Cognitive Behaviour Stress Management.	1-day seminar; face-to-face.
Arving (2007)	60, 60	59	Sweden	Hospital Inpatient	RCT	HADS	24% (6-month)	Psychology & Oncology (Nurse)	Individual	Telephone + face-to-face	Every session was scheduled to last for 45 to 60 minutes; number of sessions varied; Cognitive Behaviour Therapy.	Standard care; face-to-face.
Desautels *(2018)	25 (CT), 26 (BLT)	11	Canada	Oncologist letter	RCT	BDI-II; HADS; HDRS	12.9%	Psychology	Individual	Face-to-face	8 weekly sessions of approximately 60 minutes; Cognitive Therapy.	Waiting-list control; telephone.
Kissane (2003)	154	149	Australia	Hospital Inpatient	RCT	HADS; ABS	14%	Psychiatry, psychology, social work, occupational therapy and oncology nursing	Group	Face-to-face	20 weekly sessions, each lasting 90min; Cognitive-existential group therapy	Control group receiving 3 relaxation classes; face-to-face.
Marchioro (1996)	18	18	United Kingdom	Hospital Inpatient	RCT	BDI-II	0%	Psychology	Individual	Face-to-face	Weekly 50 minute sessions; Cognitive Psychotherapy.	Standard follow-up; face-to-face
Mohabbat-Bahar (2015)	15	15	Iran	Hospital Inpatient	RCT	BDI	0%	Not reported	Group	Face-to-face	90 minutes over 4 consecutive weeks; Acceptance and Commitment Therapy.	Control group.

Note. Measure Abbreviations: ABS, Affect Balance Scale; BDI, Beck Depression Inventory; BDI-II, Beck Depression Inventory-II; CES-D, Centre for Epidemiologic Studies Depression Scale; HADS, Hospital Anxiety and Depression Scale; HDRS, Hamilton Depression Rating Scale; POMS, Profile of Mood States.

*Study had two intervention groups, with one intervention group not included in the analysis (Bright light therapy; *n* = 26), as it was not relevant to this study.

3.2 Participant Characteristics

The total pooled sample included 710 individuals with non-metastatic breast cancer (see Table 3). All participants were female and the mean age of individuals was approximately 51.2 years, with one study (Marchioro et al., 1996) reporting a range of 35-65 years. The majority of women had been diagnosed with Stage II breast cancer; Stage 0 was the least common diagnosis, although this data was inconsistently reported. All studies reported marital status with most participants being partnered or married (74.9%). Only one study (Antoni et al., 2001) reported the participant ethnicity, with the majority being Non-Hispanic White (10.4%). Half of the studies (Desautels et al., 2018; Kissane et al., 2003; Marchioro et al., 1996) reported level of education; among those with reported data, the majority ($n_{participants} = 241$) described their highest educational achievement as high-school or lower, with another 160 participants reporting tertiary/university education. Finally, two thirds of the total studies (Antoni et al., 2001; Desautels et al., 2018; Kissane et al., 2003; Marchioro et al., 1996) reported employment status, with 26.2% employed and 30% unemployed out of the total sample reporting this data ($n_{participants} = 501$).

Critical sample characteristics (e.g., age, gender) were provided by more than 80% of the studies; one study (Marchioro et al., 1996) did not provide specific data. Missing data was at least partially explained by all studies (e.g., by providing $N_{incomplete}$ data, with reasons), thereby diminishing the risk of attrition bias.

Table 3

Sociodemographic Characteristics and Medical History for Individuals With Breast Cancer for Included Studies ($N_{studies}$ = 6)

Variable	$N_{studies}$[a]	$N_{participants}$[a] (%) [b]	M (SD)	Range
Sample size	6	710 (100)	118.3 (105.7)	30-303
Age at study recruitment (years)	5	674 (94.9)	51.2 (6.03)	23-87
Gender				
Male	0	0 (0)		
Female	6	710 (100)		
Marital status				
Partnered/married	6	532 (74.9)		
	6	176 (24.8)		
Single/widowed/divorced				
Stage of Breast Cancer				
Stage 0	2	10 (1.4)		
Stage 1	2	97 (13.7)		
Stage 2	2	295 (41.6)		
Stage 3	2	0 (0)		
Ethnicity				
Non-Hispanic White	1	74 (10.4)		
Hispanic	1	16 (2.3)		
African	1	6 (0.9)		
Other	1	4 (0.6)		
Education	3			
≤High-school	3	241 (3.9)		
	3	160 (22.5)		
College/University/Tertiary				
Employment	4			
Employed	4	186 (26.2)		
Not Employed	4	213 (30)		

Note. $N_{studies}$ = number of studies providing data; $N_{participants}$ = number of participants in which the data was provided.

[a] Number varies within columns because not all studies reported this information. [b] Percentage (%) of participants that fulfill that category in relation to the total sample size of the studies that reported the data

3.3 Effect Size Estimates

Five sub-analyses of CBT-BI were conducted in this meta-analysis. Of these, only three were considered clinically significant in accordance with the criteria adopted for this review (i.e., Hedge's $g \geq .50$; $N_{fs} > N$; CIs $\neq 0$) for both short- and longer-term effects. This included sub-analyses of: pre-post treatment; individual versus group therapy; pre-treatment to three-, six-, 12-month follow-up. Effect size estimates varied considerably in their magnitude, as discussed below.

3.3.1 Short-term findings.

3.3.1.1 Overall short-term findings – pre-treatment to post-treatment.

All six studies investigated the short-term effect of CBT-BI on depression. Effect size estimates (see Figure 3) suggested that overall, CBT-BI is highly effective in reducing depression in the short-term, in comparison to controls ($N_{studies} = 6$, Hedge's $g = -1.215$, 95% CIs [-1.931, -.295]; $Nfs > N_{studies;}$ $p = .002$). However, substantial heterogeneity was noted ($I^2 = 96\%$). The Nfs of 30 suggests this finding is somewhat robust, indicating that a substantial number of unpublished studies with non-significant results would need to exist to call this finding into question.

Hedge's *g* and 95% CI

Lead author of study	Depression measure	$N_{studies}$	$N_{participants}$	Hedge's *g*	*Standard error* (σ_M)	95% CI Lower	95% CI Upper	*p*
Antoni (2001)	CES-D	1	100	-.179	.199	-.570	.211	.368
Arving (2007)	HADS	1	179	-.364	.130	-.619	-.109	.005
Desautels (2018)b	BDI HADS	1	62	-5.681	.538	-6.735	-4.627	.000
Kissane (2003)	HADS	1	303	-.136	.115	-.361	.089	.237
Marchioro (1996)	BDI	1	36	-.439	.330	-1.086	.207	.183
Mohabbat-Bahar (2015)	BDI	1	30	-1.497	.404	-2.289	-.704	.000
Overall (all studies)		**6**	**710**	**-1.215**	**.398**	**-1.931**	**-.295**	**.002**
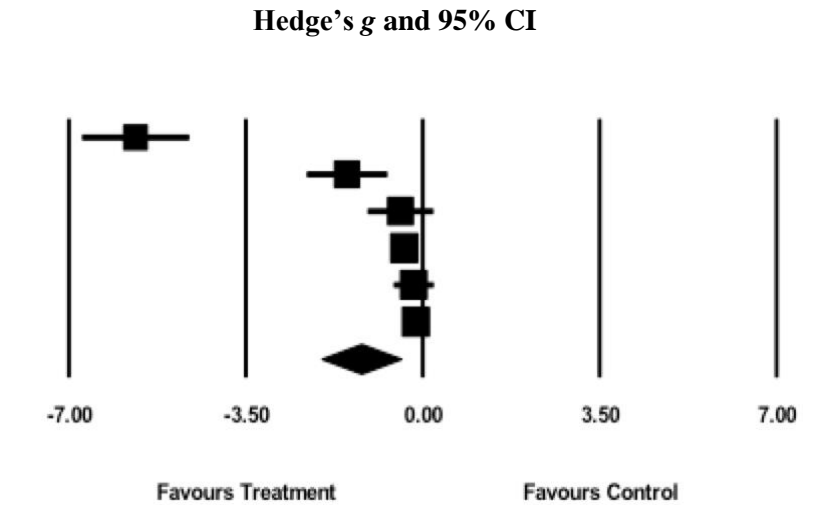
Figure 3. Depression by CBT-BI for all studies from pre-treatment to first measurement post-treatment (short-term effect). A negative effect indicates that individuals in the intervention group experienced reduced depression scores as compared with the control group. CI = confidence interval. bAveraged scores of self-report depression measures used in the analysis. CI = confidence interval; bAveraged scores of self-report depression measures used in the analysis.

Lead author of study	Therapy type/setting	Depression measure	$N_{studies}$	$N_{participants}$	Hedge's g	Standard error (σ_M)	95% CI Lower	95% CI Upper	p
Antoni (2001)	Group	CES-D	1	100	-.179	.199	-.570	.211	.368
Kissane (2003)	Group	HADS	1	303	-.136	.115	-.361	.089	.237
Mohabbat-Bahar (2015)	Group	BDI	1	30	-1.497	.404	-2.289	-.704	.000
Overall Group			**3**	**433**	**-.578**	**.709**	**-1.968**	**.812**	**.415**
Arving (2007)[a]	Individual	HADS	1	179	-.364	.130	-.619	-.109	.005
Desautels (2018)[b]	Individual	BDI HADS	1	62	-5.681	.538	-6.735	-4.627	.000
Marchioro (1996)	Individual	BDI	1	36	-.439	.330	-1.086	.207	.183
Overall Individual			**3**	**277**	**-1.999**	**.723**	**-3.417**	**-.518**	**.006**
Overall (all studies)			**6**	**710**	**-1.274**	**.506**	**-2.267**	**-.282**	**.012**

Hedge's *g* and 95% CI

Favours Treatment — Favours Control
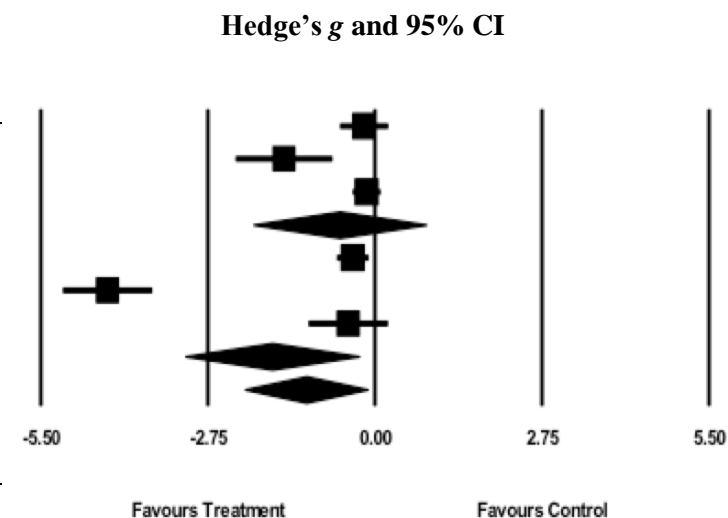
Figure 4. Depression by CBT-BI comparing individual to group CBT-BI for all studies from pre-treatment to post-treatment. A negative effect indicates that individuals in the intervention group experienced reduced depression scores as compared with the control group. CI = confidence interval. [a] Averaged scores of depression measure for two interventions (INS and IPS) and a control, used in the analysis; [b] Averaged scores of self-report depression measures used in the analysis.

3.3.1.2 *Individual versus group CBT-BI.*

All studies were divided into sub-groups of either individual or group CBT-BI, and examined (see Figure 4). Findings demonstrate that CBT-BI delivered in an individual format showed a significant positive effect on depression compared to controls ($n_{studies}$ = 6, Hedge's g = -1.999, 95% CIs [-3.417, -.518]; $N_{fs} > N_{studies}$; p = .006). In contrast, group CBT-BI exhibited a medium, but non-significant effect on depression as compared to controls ($N_{studies}$ = 6, Hedge's g = -.578, 95% CIs [-1.968, .812]; $N_{fs} > N_{studies}$; p = .415). Despite differences in effect size significance between the two formats, there was no evidence that CBT-BI delivered individually conferred more statistically significant benefits compared to that delivered in group format (Q = 1.176, df = 1, p = .278). However, substantial heterogeneity was noted (I^2 = 96%). The N_{fs} was found to be 16 and 5 for individual and group CBT-BI, respectively, suggesting that this finding for individual CBT-BI is robust, while the results for group CBT-BI may be less robust.

3.3.2 Longer-term findings.

3.3.2.1 *Pre-treatment to three-month follow-up.*

Two studies examined the longer-term effect of CBT-BI on depression at three-month follow-up (see Figure 5). The overall effect size estimate was medium and highly significant, suggesting that women who had undertaken CBT-BI had less depression compared to controls at three-month follow-up ($n_{studies}$ = 2, Hedge's g = -.490, 95% CIs [-.730, -.250]; $N_{fs} < N_{studies}$; p < .001). However, N_{fs} was less than the number of studies included in the analysis, suggesting that this finding may not be robust and may be influenced by publication bias. Out of the two studies, Arving et al. (2007) was assigned the bulk of the weighting (86.06%). Statistical homogeneity (I^2 = 0.00) was found, which could be credited to similarities in intervention procedures, including patients being assessed one-, three-, six-

months post-intervention ($n_{studies} = 2$) in the individual studies (Arving et al., 2007; Marchioro et al., 1996).

3.3.2.2 Pre-treatment to six-month follow-up.

The overall effect size from the four studies which examined the effect of CBT-BI from pre-treatment to six-month follow-up was small in strength and, despite being close to obtaining statistical significance, was non-significant (see Figure 6). Thus, depression levels at six-month follow-up did not differ between the CBT-BI and control groups ($n_{studies} = 4$, Hedge's $g = -.193$, 95% [-.391, .004]; $N_{fs} < N_{studies}$; $p = .055$). Given the small N_{fs} statistic, this finding must be interpreted with caution as the results may be influenced by publication bias.

Hedge's *g* and 95% CI

Lead author of study	Depression measure	$N_{studies}$	$N_{participants}$	Hedge's *g*	Standard error (σ_M)	95% CI		*p*
						Lower	Upper	
Arving (2007)[a]	HADS	1	179	-.520	.132	-.779	-.261	.000
Marchioro (1996)	BDI	1	36	-.306	.328	-.949	.336	.350
Overall (selected studies)		**2**	**215**	**-.490**	**.122**	**-.730**	**-.250**	**.000**

-1.50 -0.75 0.00 0.75 1.50

Favours Treatment   Favours Control

Figure 5. Depression by CBT-BI for selected studies from pre-treatment to three-month follow-up (longer-term effect). A negative effect indicates that individuals in the intervention group experienced reduced depression scores as compared with the control group. CI = confidence interval; [a] Averaged scores of depression measure for two interventions (INS and IPS) and a control, used in the analysis.

Hedge's *g* and 95% CI

Lead author of study	Depression measure	$N_{studies}$	$N_{participants}$	Hedge's *g*	Standard error (σ_M)	95% CI		*p*
						Lower	Upper	
Antoni (2001)	CES-D	1	100	-.072	.199	-.462	.317	.716
Arving (2007)[a]	HADS	1	179	-.366	.131	-.623	-.109	.005
Kissane (2003)	HADS	1	303	-.045	.115	-.270	.179	.693
Marchioro (1996)	BDI	1	36	-.467	.331	-1.115	.181	.158
Overall (selected studies)		**4**	**618**	**-.193**	**.101**	**-.391**	**.004**	**.055**

-1.50 -0.75 0.00 0.75 1.50
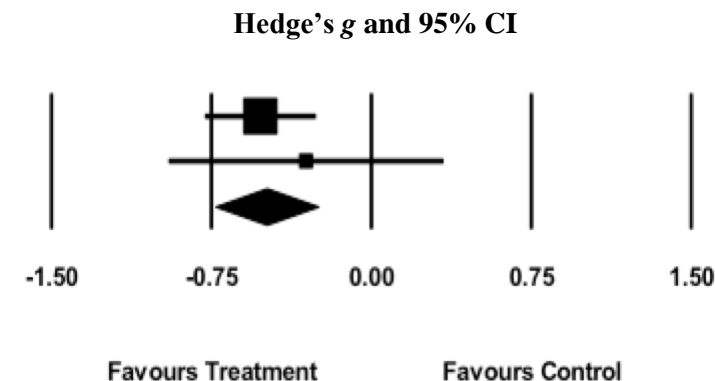
Favours Treatment   Favours Control

Figure 6. Depression by CBT-BI for selected studies from pre-treatment to six-month follow-up (longer-term effect). A negative effect indicates that individuals in the intervention group experienced reduced depression scores as compared with the control group. CI = confidence interval; [a] Averaged scores of depression measure for two interventions (INS and IPS) and a control, used in the analysis.

Hedge's *g* and 95% CI

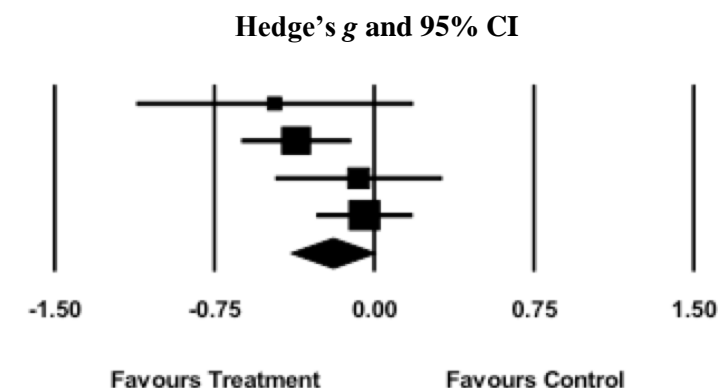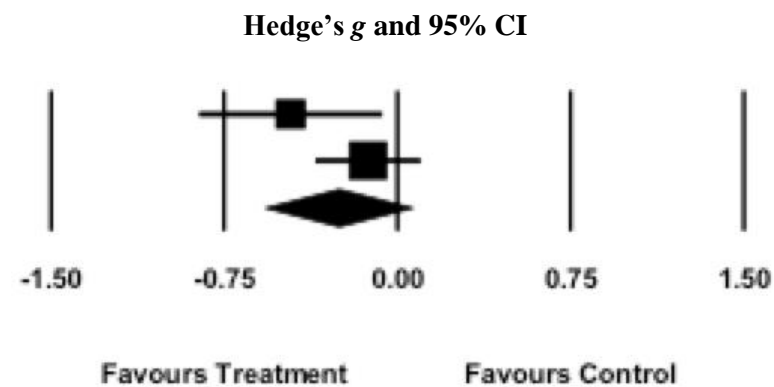| Lead author of study	Depression measure	$N_{studies}$	$N_{participants}$	Hedge's *g*	*Standard error* (σ_M)	95% CI Lower	95% CI Upper	*p*
Antoni (2001)	CES-D	1	100	-.462	.201	-.857	-.067	.022
Kissane (2003)	HADS	1	303	-.127	.115	-.352	.098	.268
Overall (selected studies)		**4**	**618**	**-.253**	**.162**	**-.571**	**.064**	**.118**

Figure 7. Depression by CBT-BI for selected studies from pre-treatment to 12-month follow-up (longer-term effect). A negative effect indicates that individuals in the intervention group experienced reduced depression scores as compared with the control group. CI = confidence interval.

3.3.2.3 Pre-treatment to 12-month follow-up.

Two studies examined the longer-term effect of CBT-BI on depression at 12-month follow-up (see Figure 7). The overall effect size was small and non-significant ($n_{studies} = 2$, Hedge's g = -.253, 95% CIs [-.571, .064]; $N_{fs} < N_{studies}$; p = .118). Specifically, Antoni et al. (2001) reported a medium and significant effect (Hedges g = -.462, p = .022), however, Kissane et al. (2003) reported a small and non-significant effect (Hedges g = -.127, p = .268). The strength and lack of significance of the overall effect could be attributed to the latter study being assigned the bulk of the weighting (62.25%). A moderate level of between-studies heterogeneity (I^2 = 52%) was also noted, potentially reflecting Antoni et al's (2001) focus on CBSM, with participants receiving a lower number of intervention sessions (10 weekly sessions), as opposed to Kissane et al's (2003) focus on CEGT and double the number of intervention sessions. The N_{fs} was less than the number of studies included in the analysis, suggesting that these findings may be influenced by publication bias.

3.4 Quality Findings

3.4.1 Risk of bias assessment.

All studies were assessed on their risk of bias, with results highlighting that all incorporated random sampling methods (e.g., computer generated sampling, random blocks or tables of numbers) for recruitment, making them all low-risk for selection bias (see Table 4). Although, selection bias was unclear due to insufficient data reported on blinding of participants and outcomes in the studies. Five out of the six (83%) studies (Arving et al., 2007; Desautels et al., 2018; Kissane et al., 2003; Marchioro et al., 1996; Mohabbat-Bahar et al., 2015) reported low rates of incomplete intervention outcome data for CBT-BI and half of the studies (Kissane et al., 2003; Marchioro et al., 1996; Mohabbat-Bahar et al., 2015) reported low rates of incomplete control outcome data, with reasons. Therefore, important bias would not be expected and overall, the majority of the studies were classified as low risk

for attrition bias. Finally, no studies selectively reported data, reducing reporting bias in this

meta-analysis.

Table 4

Risk of Bias Assessment for Included Studies (N$_{studies}$ = 6)

Studies	Random Sequence Generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete intervention outcome data (attrition bias)	Incomplete control outcome data (attrition bias)	Selective outcome reporting (reporting bias)
Antoni et al. (2001)	+	?	?	+	?	?	+
Arving et al. (2007) [a]	+	?	?	?	− +	−	+
Desautels et al. (2018)	+	?	+	+	+	−	+
Kissane et al. (2003)	+	?	?	−	+	+	+
Machioro et al. (1996)*[a, b]	+	?	?	?	+	+	+
Mohabbat-Bahar et al. (2015)*[a, b]	+	?	?	?	+	+	+

Key
+ Low risk of bias
− High risk of bias
? Unclear risk of bias

Note: Adapted from "The Cochrane Collaboration's tool for assessing risk of bias in randomised trials," by J. P. Higgins et al., (2011).
* Studies with no reports of missing data for both intervention and control groups were considered to be low risk on both.
[a] Studies with three intervention groups (2 intervention/treatment groups and 1 control group). [b] Studies for which only 1 of the 2 intervention groups was relevant and the risk of bias for which is reported on the table.

3.4.2 Quality assessment of the included studies.

Study quality was examined using the QI (see Appendix D). Results revealed study

quality scores ranging from 15 to 24 (M = 19.5, SD = 3.15), indicating both low- and higher-

quality study designs (see Table 5).

The level of reporting in the studies was sound, with only one study's (Arving et al., 2007) losses to follow-up being unable to be determined, and just one study (Mohabbat-Bahar et al., 2015) not reporting exact *p*-values. Additionally, Item 8 on the QI was unclear as it was not reported.

Conversely, external validity or generalisability of the data was somewhat compromised. While most studies at least partially reported data on source population and characteristics, only one study double-blinded personnel and participants (Desautels et al., 2018). Furthermore, intervention compliance was only reported by one third of the studies (Desautels et al., 2018; Kissane et al., 2003). Nonetheless, all studies presented good external validity on the latter QI Items (16-20), which included using valid and accurate measures of depression (e.g., HADS, BDI-II), and appropriate statistical testing. Lastly, inclusion and exclusion criteria were routinely reported, with potential participants with pre-existing mental conditions (e.g., anxiety) excluded to enhance generalisability of the findings. Positively, external validity was heightened due to participants hailing from various countries.

Thirdly, internal validity was moderately well-reported across studies. Random allocation of participants to group assignment was done in all studies using comparable groups, while recruitment time was reported at least partially by all studies, except one (Antoni et al., 2001). As is typical in psychotherapy research (Schnurr, 2007) participants and assessors were generally informed of group assignment, with only Desautels et al. (2018) incorporating blinded intervention group allocation. Importantly, all studies reported the number of participants lost to follow up. Intent-to-treat analyses, implying the assessment of all participants who were initially randomised including dropouts were utilised by half of the studies (Antoni et al., 2001; Arving et al., 2007; Desautels et al., 2018).

Lastly, 50% of the studies (Antoni et al., 2001; Arving et al., 2007; Kissane et al., 2003) obtained good power by meeting the minimum sample size to achieve a large and statistically significant effect met the minimum sample size to achieve a large and statistically significant effect (i.e., $N_{participants}$ = 26, power at .80, α = .05; Cohen, 1992).

Table 5

Evaluation of Included Studies (N_studies = 6) Using the Quality Index

Studies	Reporting										External Validity										Internal Validity						Power	Total Quality Index score
	1. Hypotheses/Aims/Objectives	2. Outcomes	3. Sample	4. Intervention	5. Confounders	6. Main findings	7. Variability (e.g., SD, IQR etc.)	8. Adverse effects	9. Loss to follow-up (characteristics)	10. Exact *p* values	11. Source population representative	12. Sample representative	13. Setting representative	14. Blinding of group assignment	15. Blinding of assessors	16. Planned analyses	17. Assessment interval	18. Statistical tests	19. Intervention compliance	20. Outcome measures standardised	21. Comparable groups	22. Recruitment time	23. Randomisation	24. Blinded randomisation	25. Intent-to-treat analyses	26. Loss to follow-up (numbers)	27. Power	
Antoni et al. (2001)	●	●	●	●	●	●	●	○	●	●	○	⏜	○	○	●	●	●	●	○	●	●	○	●	⏜	●	●	●	20/27
Arving et al. (2007)	●	●	●	●	●	●	●	○	○	●	●	⏜	○	○	○	●	●	●	○	●	●	●	●	○	●	●	●	20/27
Desautels et al. (2018)	●	●	●	●	●	●	●	○	●	●	●	⏜	○	●	●	●	●	●	●	●	●	●	●	●	●	●	○	24/27
Kissane et al. (2003)	●	●	●	●	●	●	●	○	●	●	○	⏜	○	●	○	●	●	●	●	●	●	●	●	○	○	●	●	21/27
Machioro et al. (1996)	●	●	●	●	●	●	●	○	●	●	●	⏜	○	○	○	●	●	●	○	●	●	⏜	●	○	○	●	○	17/27
Mohabbat-Bahar et al. (2015)	●	●	●	●	●	●	●	○	●	○	⏜	○	○	○	○	●	●	●	○	●	●	⏜	●	○	○	●	○	15/27

Note. ● present (score of 1, or 2 for item 5); ⏜ present, with some limitations (score of 0); ○ not present or unable to determine (score of 0). Item 27: Necessary *N* for power of 0.80, α = 0.05, to detect a large difference between two independent means = 26 (Reference: Cohen, J. (1992). A power primer. *Psychological Bulletin, 112,* p.158).

3.4.3 Quality assessment of intervention descriptions.

Intervention descriptions were assessed using *TIDieR Checklist* (see Appendix E). Results demonstrate that the number of fulfilled criteria ranged from five to 10 (see Table 6). Four studies (Antoni et al., 2001; Arving et al., 2007; Desautels et al., 2018; Kissane et al., 2003) described interventions in sufficient detail to allow replication, reporting on at least eight of the 12 items, with no studies modifying interventions, rendering Item 10 not applicable. In the majority of the studies, all participants within treatment and control groups were given the same intervention, except one study (Arving et al., 2007) that tailored its intervention to the participants. Therefore, Items nine and 10 were not applicable to most studies. Information on intervention characteristics (i.e., brief name, rationale, procedure, modes of delivery, when and how much) were consistently reported by all studies at least partially. Half of the studies (Antoni et al., 2001; Arving et al., 2007; Desautels et al., 2018) planned to assess adherence or fidelity and all reported data to support their findings.

Table 6

Evaluation of Included Studies (N$_{studies}$ = 6) Using the TIDieR Checklist

Studies	TIDieR Checklist											
	1. Brief Name (describes intervention)	2. Why (rationale, theory or goal)	3. What – Materials (participants, delivery, training of providers)	4. What - Procedure (procedures, activities)	5. Intervention Provider	6. Modes of Delivery	7. Location	8. When and How Much	9. Tailoring	10. Modifications	11. How Well – Planned	12. How Well – Actual
Antoni et al. (2001)	●	●	●	●	●	●	●	●	○	○	●	●
Arving et al. (2007)	●	●	●	●	●	●	○	●	●	○	●	●
Desautels et al. (2018)	●	●	●	●	●	●	○	●	○	○	●	●
Kissane et al. (2003)	●	●	●	●	●	●	○	●	○	○	○	○
Machioro et al. (1996)	●	●	○	◗	●	●	○	●	○	○	○	○
Mohabbat-Bahar et al. (2015)	●	●	○	●	○	●	○	●	○	○	○	○

Note. ● present; ◗ present, with some limitations; ○ not present or unable to determine

3.4.4 Quality assessment of researcher allegiance.

RA was assessed using the RA checklist (see Appendix F). Results exhibit that all studies were allegiant RCTs and evidence of author's allegiance was provided in the publications (see Table 7). The majority of the studies (Antoni et al., 2001; Arving et al., 2007; Desautels et al., 2018; Kissane et al., 2003) were moderately weak allegiant studies (allegiance = code 3), indicating that authors advocated for treatment and trained the therapist. Two studies (Marchioro et al., 1996; Mohabbat-Bahar et al., 2015) were weak allegiant studies (allegiance = code 1) as they explained the intervention in the introduction or method, however there was insufficient data to determine if they qualified for a higher allegiance code.

Table 7

Evaluation of Eligible Included Studies (N_{studies} = 6) Using the RA Checklist

Studies	RA Checklist					
	0. No apparent advocacy of one treatment over another	1. Treatment explanation occurred in introduction/methods	2. Authors advocated for treatment but did not	3. Authors advocated for treatment and they	4. Authors created intervention but did not supervise/train	5. Authors created intervention and supervised/trained therapist
Antoni et al. (2001)	○	○	○	●	○	○
Arving et al. (2007)	○	○	○	●	○	○
Desautels et al. (2018)	○	○	○	●	○	○
Kissane et al. (2003)	○	○	○	●	○	○
Machioro et al. (1996)	○	●	○	○	○	○
Mohabbat-Bahar et al. (2015)	○	●	○	○	○	○

Note. ● present; ○ not present or unable to determine

Chapter 4: Discussion

4.1 Key Findings

This meta-analysis examined the effectiveness of CBT-BI on depression in women with non-metastatic breast cancer. Analyses of short- and longer-term effects, and study quality were assessed for six studies involving 710 participants. The results of this study highlighted that CBT-BI was significant in reducing depression in some contexts: overall short-term, short-term individual CBT-BI, and at three-month follow-up. However, these results were not maintained at six- and 12-month follow-up. Lastly, the included studies were of moderate quality. In combination, these findings suggest that CBT-BI are efficacious in reducing depression in women with non-metastatic breast cancer, albeit differences in efficacy are noted depending on time since intervention.

4.1.1 Short-term findings.

4.1.1.1 Overall short-term findings.

Results of this review exhibit that CBT-BI is highly effective in the short-term, concurring with existing evidence (Qiu et al., 2013; Tatrow & Montgomery, 2006). Of these, Tatrow & Montgomery (2006) found a smaller effect size ($d = 0.31$) compared to the current study, which, although speculative, may be credited to intervention variations in both studies. Nonetheless, previous research has concluded that short-term psychological interventions, involving psychoeducation and directed at specific behaviour change and cognitive restructuring, confer positive effects on emotional adjustment in breast cancer patients (Barsevick et al., 2002; Cohen & Fried, 2007; Meyer & Mark, 1995; Osborn, Demoncada, & Feuerstein, 2006).

Notably, the current findings were characterised by substantial sample heterogeneity, although common in RCTs among such populations and is usually driven by variability in participants and interventions between studies Corbett, Devane, Walsh, Groarke, & McGuire,

2015; Haidich, 2010), no firm conclusions can be drawn. Considering the small sample of

studies included, over- or under-estimation of heterogeneity is common, however, this was

accounted for by utlising a random-effects meta-analysis model (DerSimonian & Laird,

1986; Von Hippel, 2015). Furthermore, heterogeneous samples strengthen applicability of

CBT-BI across a range of ages and diverse cancer types and stages (Carlson & Garland,

2005).

4.1.1.2 Individual versus group CBT-BI.

Individual CBT-BI was significantly associated with reduced depression compared to

controls. This finding coincides with previous research showing significantly large effects for

individual CBT-BI compared to patients in control groups (Tatrow & Montgomery, 2006;

Xiao et al., 2017). Secondly, the current finding of no significant difference in depression

levels between group CBT-BI and control groups, juxtapose previous findings suggesting

benefits of group processes (e.g., reassurance, instilling hope) (Cohen & Fried, 2007; Qiu et

al., 2013; Simpson et al., 2001; Spiegel, Bloom, & Yalom, 1981). This discrepancy in results

could be attributed to a range of factors including presence of outliers, group characteristics,

therapist approach, or differing intervention designs (Cohen & Fried, 2007; Tatrow &

Montgomery, 2006). Additionally, the present study demonstrated a lack of evidence for the

superiority of one method of CBT-BI delivery over the other. Again, these findings juxtapose

previous literature which often states that either individual CBT-BI is more efficacious than

group CBT-BI (Greer et al., 1992; Tatrow & Montgomery, 2006) due to tailored treatment

and rapport building, or that the latter is more effective than the former, due to group

processes (Spiegel et al., 1981). However, in comparison with the current study, Spiegel and

colleagues' (1981) research was specific to metastatic rather than non-metastatic breast

cancer, which could contribute to these discrepant findings. Larger scale studies comparing

individual and group therapy formats in non-metastatic breast cancer populations are required to definitively determine if one is more effective than the other.

4.1.2 Longer-term findings.

Researchers often wonder if CBT-BI sustain their effects over time. The current research results display that for three-month follow-up, there was a moderate and significant effect of CBT-BI on depression, compared to controls. Previous literature assessing CBT-BI's longer-term effects in breast cancer populations is scarce, however, the current results are consistent with one study (Greer et al., 1992) which suggested that CBT-BI reduced depression at four-month follow-up.

The persistence of CBT-BI effects at six-month follow-up was also analysed. Overall, results revealed that while initially, depression dropped significantly following CBT-BI, changes were not maintained at six-month follow-up. These results correspond with conclusions from previous literature (Hollon, Thase, & Markowitz, 2002), suggesting that effects of CBT-BI substantially weaken, if not disappear entirely, once the intervention discontinues. While some have suggested that CBT-BI is associated with general long-term effectiveness and relapse prevention (Simons, Levine, Lustman, & Murphy, 1984), others have stated that CBT-BI is not effectual at all in the long-term (Haller et al., 2017). These divergent results could be linked to intervention differences, duration of treatment in the studies (10-28 weeks), differences in therapists' skills, varying outcomes measures and follow-up assessment time-points, as well as depression severity (Butler et al., 2006; Cohen & Fried, 2007; Dobson, 1989). Additionally, previous analyses of CBT-BI and depression have revealed that personal factors (e.g., age, number of previous depressive episodes, baseline depression levels, remaining depressive symptoms at treatment completion) and social contexts may affect responses to CBT-BI, and thus, may account for variance present in the current findings (Kovacs, Rush, Beck, & Hollon, 1981; Mitchell et al., 2011; Simons,

Murphy, Levine, & Wetzel, 1986; Yang et al., 2014). However, these arguments are tautological and require further empirical testing via longitudinal studies (Kovacs et al., 1981).

Similar to the six-month follow-up results, CBT-BI gains were not maintained at 12-month follow-up, in contrast to previous literature (Stagl et al., 2015). Kovacs et al. (1981) suggest that such CBT-BI relapse, as observed in this meta-analysis, could be attributed to insufficient intervention potency. The studies included in this sub-analysis (Antoni et al., 2001; Kissane et al., 2003) had a stronger focus on behavioural components (e.g., stress monitoring skills, emotional support) rather than cognitive restructuring, which may have resulted in similarities in depression between intervention and control groups at 12-month follow-up. Similar to three-month follow-up, there was a limited number of studies in this sub-group analysis, underlining the need for additional primary research exploring CBT-BI's longer-term effects for depression in women with non-metastatic breast cancer.

4.1.3 Quality findings.

The current results should be interpreted in the context of study quality, which was assessed using risk of bias, study quality, intervention descriptions and RA. Firstly, this study's risk of bias assessments demonstrated low attrition bias, no selection and reporting biases, indicating that included studies had sufficient data despite dropouts, random sequence of allocation of intervention to participants, and no direct evidence for selective outcome reporting, which were strengths of the studies. These findings juxtapose Haller et al's (2017) findings of high attrition bias and Cramer et al's (2012) high reporting bias. Differences in included study designs and interventions may have caused these discrepant findings.

Second, study quality found that studies reported adequately on sample data, intervention and outcomes. Internal and external validity were moderately well-reported, with all studies using standardised outcome measures and participant randomisation, although

blinding methods were inconsistently described. However, double-blinding is not always practical or possible in psychotherapy research, but, quality can still be shown as long as alternative research designs are well-justified, with confounders well- understood, documented and measured (Bonell et al., 2009; Dragioti et al., 2015), points which were consistently covered by all included studies. Studies used intent-to-treat analyses, which is often suggested to decrease Type I error (Lachin, 2000), and thus, recommended for psychotherapy research (Schnurr, 2007). Overall, these quality results contradicted the majority of low quality studies found by two previous meta-analyses (David, Cotet, Matu, Mogoase, & Stefan, 2018; Xiao et al., 2017; Zhang et al., 2016), where the eight criteria by Cuijpers et al. (2010) and the Jadad Scale (Jadad et al., 1996) were used to assess quality, respectively. Due to the lack of prior evidence on quality assessments using the QI, direct quality comparisons cannot be made.

Additionally, studies' intervention descriptions were assessed using the TIDieR Checklist (Hoffmann et al., 2014). The findings established that the included studies consistently reported on treatment descriptions, however, intervention locations were seldom reported. Finally, findings from the RA checklist (Wampold et al., 2011) highlighted that overall, studies were weakly or moderately allegiant, indicating lack of reporting bias. However, for both TIDieR intervention descriptions and RA, definitive conclusions cannot be drawn due to insufficient data provided in some studies, which is warranted, given the evolving nature of reporting criteria and expectations that have occurred over time. Most of the included studies were published prior to such expectations. Given that RA is a recent development, when paired with a lack of strict reporting policy, it is unlikely to be reported in meta-analyses and RCTs (Dragioti et al., 2015). However, in current times, psychotherapeutic research ought to report on these essential aspects.

4.2 Clinical Implications and Future Research

Findings from this comprehensive analysis of CBT-BI have implications for management of depression in women with non-metastatic breast cancer and highlight promising avenues for clinical practice and research. First and foremost, these results enhance understandings of the efficacy of CBT-BI in reducing depression in women with non-metastatic breast cancer, and are feasible to be delivered as an evidence-based therapy for depression in oncology settings (Sturmey, 2009). Furthermore, the quality assessments conducted in the current study allow clinicians to assess research evidence, better able to confidently plan their evidence-based approach by considering factors such as length of time delivered and setting of delivery.

Many remaining moderator analyses (e.g., comparisons of specific CBT-BI techniques; moderators of age, social context, quality of life, biological therapy used) (Dobson, 1989; Reich et al., 2008; Trudel-Fitzgerald, Savard, & Ivers, 2013) beyond the scope of the present research, could be undertaken. Additionally, evidence suggests that certain stages in the disease trajectory result in differing levels of patient vulnerability, who may need more or less psychological support (Trudel-Fitzgerald et al., 2013), are avenues for future research to analyse treatment engagement and compliance. As the literature grows, it is hoped that such areas will be pursued to confidently establish moderating effects.

Finally, while this meta-analysis analysed longer-term effects of CBT-BI on depression among women with non-metastatic breast cancer, there is a need for primary research, particularly RCTs, to examine these effects. Fuelling a greater evidence base will allow for the establishment of a highly effective form of therapy before researchers can begin to address the question of possible beneficiaries of CBT-BI (Dobson, 1989).

4.3 Study Limitations and Strengths

Findings must be considered in light of the study limitations. Firstly, due to the small number of studies included, analyses should be viewed with caution, particularly the individual versus group CBT-BI, and three- and six-month follow-up sub-analyses, which were underpowered due to not meeting suggested minimal requirements of having four studies (Borenstein et al., 2009). Nonetheless, low-powered analyses can still provide useful insights by revealing deficiencies in the CBT-BI, depression and breast cancer literature that deserve further exploration (Greco, Zangrillo, Biondi-Zoccai, & Landoni, 2013). Overall, the small number of studies is attributable to this study's rigorous inclusion criteria. While only six studies were included, there is no universally accepted minimum number of studies, but Fu et al. (2011) states that a minimum of 6 studies has been accepted by Cochrane as sufficient for meta-analyses, suggesting it was appropriate to proceed with the current meta-analysis. Nonetheless, the present study should be viewed as both a commentary on the fact that this area of study is under-researched, as well as a catalyst for future, well-designed investigations. Also, despite the small number of included studies, this review contained data from variety of countries, therefore, making it cross-culturally applicable and extending the external validity of the study.

Secondly, the included studies reported ambiguous or incomplete data on aspects of the intervention (e.g., length of intervention, professional delivering intervention). However, Dobson (1989) found that CBT-BI gains were not significantly related to length of intervention. Also, intervention characteristics varied across the studies, suggesting possible heterogeneity. Although psychotherapy research contains some inherent heterogeneity, the included studies used treatment manuals with prescribed goals and techniques to minimise variability between therapists.

It could also be suggested that broader inclusion criteria may have expanded the

number of eligible studies. However, strict criteria provides the current study with an

advantage from previous meta-analyses (i.e., Cramer et al., 2012; Haller et al., 2017; Xiao et

al., 2017) due to its focus on breast cancer patients only, thereby reducing heterogeneity

associated with including a broad range of cancers with variable participant diagnoses

(Tatrow & Montgomery, 2006). Additionally, the rigorous inclusion criteria also allowed

outcomes to be applicable to specific breast cancer patients, which, as lack of evidence

suggests, is an underresearched area (Greco et al., 2013). Moreover, multiple search terms

and synonyms, and different combinations of these, improved effectiveness and sensitivity of

the literature search by preventing potentially relevant articles from being missed (Bown &

Sutton, 2010; Singh, 2017). To further address the problem of eligible studies being missed in

database searches, N_{fs} was calculated, albeit, this statistic does not fully alleviate the 'file

drawer problem' (Lipsey & Wilson, 2001).

Although limitations are acknowledged, this meta-analysis also encompasses many

strengths. Presently, it is the first formal meta-analysis that comprehensively investigated

CBT-BI in non-metastatic breast cancer populations, and doing so by using RCTs only.

Additionally, the extensive quality assessments conducted in this research, including TIDieR

and RA, added to this study's strengths. This, paired with the stringent inclusion criteria and

extensive database searches, highlighted the sound design of this meta-analysis.

4.4 Conclusions

This systematic review and meta-analysis, in conjunction with other published CBT-

BI literature for depression in breast cancer populations, revealed that CBT-BI present

significant promise in reducing depression in the short-term, especially when delivered in an

individualised setting. The findings have significant implications for the development of

psychological intervention strategies and future research. Notably, results of this meta-

analysis provide support for further application of CBT-BI, however, several aspects of CBT-BI are still underresearched or misunderstood. Thus, further large-scale primary, and longitudinal research examining moderating variables in the treatment process that influence CBT-BI gains in breast cancer populations, is warranted. Consequently, this data can be used to guide recommendations on EBP standards and promote the creation of optimal and tailored CBT-BI protocols for patients, to better contribute to depression reduction.

References

References marked with an asterick (*) indicate studies included in the meta-analysis.

Abad, A. N. ., Bakhtiari, M., Kashani, F. L., & Habibi, M. (2016). The comparison of

    effectiveness of treatment based on acceptance and commitment with cognitive-

    behavioral therapy in reduction of stress and anxiety in cancer patients. *Journal of*

    Cancer Research and Prevention, *9*(3), 229.

Agarwala, P., & Riba, M. B. (2010). Tailoring depression treatment for women with breast

    cancer: factors unique to these patients help determine treatment strategies. *Current*

    Psychiatry, *9*(11), 39–45.

Akechi, T., Okuyama, T., Imoto, S., Yamawaki, S., & Uchitomi, Y. (2001). Biomedical and

    psychosocial determinants of psychiatric morbidity among postoperative ambulatory

    breast cancer patients. *Breast Cancer Research and Treatment*.

    http://doi.org/10.1023/A:1010661530585

American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental*

    disorders : DSM-5. American Psychiatric Association. *DSM*.

    http://doi.org/10.1176/appi.books.9780890425596.744053

Antoni, M. H., Lehman, J. M., Kilbourn, K. M., Boyers, a E., Culver, J. L., Alferi, S. M., …

    Carver, C. S. (2001). Cognitive-behavioral stress management intervention decreases the

    prevalence of depression and enhances benefit finding among women under treatment

    for early-stage breast cancer. *Health Psychology*. http://doi.org/10.1037/0278-

    6133.20.6.458a

Arving, C., Sjödén, P. O., Bergh, J., Hellbom, M., Johansson, B., Glimelius, B., &

    Brandberg, Y. (2007). Individual psychosocial support for breast cancer patients: A

    randomized study of nurse versus psychologist interventions and standard care. *Cancer*

    Nursing. http://doi.org/10.1097/01.NCC.0000270709.64790.05

Australian Institute of Health and Welfare & Cancer Australia. (2012). *Cancer in Australia: an overview, 2012. Cancer Series no.74*. http://doi.org/CAN 70

Ban, K. A., & Godellas, C. V. (2014). Epidemiology of breast cancer. *Surgical Oncology Clinics of North America*, *23*(3), 409–422.

Barsevick, A. M., Sweeney, C., Haney, E., & Chung, E. (2002). A Systematic Qualitative Analysis of Psychoeducational Interventions for Depression in Patients With Cancer. *Oncology Nursing Forum*. http://doi.org/10.1188/02.ONF.73-87

Beck, A. T. (1963). Thinking and Depression: I. Idiosyncratic Content and Cognitive Distortions. *Archives of General Psychiatry*, *9*, 324–333. http://doi.org/10.1001/archpsyc.1963.01720160014002

Beck, A. T., Rush, A. J., Shaw, B. F., & Emery, G. (1979). *Cognitive therapy of depression. Cognitive Therapy of Depression*.

Beck, A. T., Steer, R. A., & Brown, G. K. (1996). Manual for the Beck depression inventory-II. *San Antonio, TX: Psychological Corporation*.

Bonell, C. P., Hargreaves, J., Cousens, S., Ross, D., Hayes, R., Petticrew, M., & Kirkwood, B. R. (2009). Alternatives to randomisation in the evaluation of public health interventions: Design challenges and solutions. *Journal of Epidemiology and Community Health*, *65*(7), 582–587. http://doi.org/10.1136/jech.2008.082602

Borenstein, M., Hedges, L. ., Higgins, J. P. ., & Rothstein, H. . (2009). Introduction to Meta-Analysis. *Psychotherapy Research Journal of the Society for Psychotherapy Research*. http://doi.org/10.1002/9780470743386

Borenstein, M., Hedges, L., Higgins, J., & Rothstein, H. (2014). *Comprehensive Meta Analysis, Version 3*. Englewood, NJ: Biostat.

Bower, J. E. (2008). Behavioral symptoms in patients with breast cancer and survivors. *Journal of Clinical Oncology : Official Journal of the American Society of Clinical*

Oncology. http://doi.org/10.1200/JCO.2007.14.3248

Bown, M. J., & Sutton, A. J. (2010). Quality control in systematic reviews and meta-
analyses. *European Journal of Vascular and Endovascular Surgery*.
http://doi.org/10.1016/j.ejvs.2010.07.011

Brewin, C. R., Andrews, B., & Valentine, J. D. (2000). Meta-analysis of risk factors for
posttraumatic stress disorder in trauma-exposed adults. *Journal of Consulting and
Clinical Psychology*. http://doi.org/10.1037/0022-006X.68.5.748

Brierley, J., Gospodarowicz, M., & O'Sulivan, B. (2016). The principles of cancer staging.
Ecancermedicalscience. http://doi.org/10.3332/ecancer.2016.ed61

Brothers, B. M., Yang, H. C., Strunk, D. R., & Andersen, B. L. (2011). Cancer patients with
major depressive disorder: testing a biobehavioral/cognitive behavior intervention.
Journal of Consulting and Clinical Psychology, 79(2), 253–260.

Burgess, C., Cornelius, V., Love, S., Graham, J., Richards, M., & Ramirez, A. (2005).
Depression and anxiety in women with early breast cancer: Five year observational
cohort study. *British Medical Journal*. http://doi.org/10.1136/bmj.38343.670868.D3

Burns, P. B., & Chung, K. C. (2010). Developing Good Clinical Questions and Finding the
Best Evidence to Answer Those Questions. *Plastic and Reconstructive Surgery*.
http://doi.org/10.1097/PRS.0b013e3181de24a7

Butler, A. C., Chapman, J. E., Forman, E. M., & Beck, A. T. (2006). The empirical status of
cognitive-behavioral therapy: A review of meta-analyses. *Clinical Psychology Review*.
http://doi.org/10.1016/j.cpr.2005.07.003

Carlson, L. E., & Garland, S. N. (2005). Impact of Mindfulness-Based Stress Reduction
(MBSR) on sleep, mood, stress and fatigue symptoms in cancer outpatients.
International Journal of Behavioral Medicine.
http://doi.org/10.1207/s15327558ijbm1204_9

Carlson, L. E., Speca, M., Patel, K. D., & Goodey, E. (2003). Mindfulness-based stress reduction in relation to quality of life, mood, symptoms of stress, and immune parameters in breast and prostate cancer outpatients. *Psychosomatic Medicine*. http://doi.org/10.1097/01.PSY.0000074003.35911.41

Cobeanu, O., & David, D. (2018). Alleviation of side effects and distress in breast cancer patients by cognitive-behavioral interventions: A systematic review and meta-analysis. *Journal of Clinical Psychology in Medical Settings*, 1–21. http://doi.org/10.1007/s10880-017-9526-7

Cohen, J. (1988). *Statistical Power Analysis for the Behavioral Sciences (2nd ed.). Statistical Power Analysis for the Behavioral Sciences*. http://doi.org/10.1234/12345678

Cohen, J. (1992). A power primer. *Psychological Bulletin*. http://doi.org/10.1037/0033-2909.112.1.155

Cohen, M., & Fried, G. (2007). Comparing relaxation training and cognitive-behavioral group therapy for women with breast cancer. *Research on Social Work Practice*. http://doi.org/10.1177/1049731506293741

Corbett, T., Devane, D., Walsh, J. C., Groarke, A., & McGuire, B. E. (2015). Protocol for a systematic review of psychological interventions for cancer-related fatigue in post-treatment cancer survivors. *Systematic Reviews*, *4*(1), 174.

Cramer, H., Lauche, R., Paul, A., & Dobos, G. (2012). Mindfulness-based stress reduction for breast cancer— a systematic review and meta-analysis. *Current Oncology*, *19*(5), e343. http://doi.org/10.3747/co.19.1016

Croux, C., & Dehon, C. (2010). Influence functions of the Spearman and Kendall correlation measures. *Statistical Methods and Applications*. http://doi.org/10.1007/s10260-010-0142-z

Cuijpers, P., Smit, F., Bohlmeijer, E., Hollon, S. D., & Andersson, G. (2010). Efficacy of

cognitive-behavioural therapy and other psychological treatments for adult depression:

Meta-analytic study of publication bias. *British Journal of Psychiatry*.

http://doi.org/10.1192/bjp.bp.109.066001

Cumming, G. (2012). *Understanding the new statistics: Effect sizes, confidence intervals,

and meta-analysis. Understanding the new statistics: Effect sizes, confidence intervals,

and meta-analysis.* http://doi.org/10.1037/a0028079

Dahl, J., Wilson, K. G., & Nilsson, A. (2004). Acceptance and commitment therapy and the

treatment of persons at risk for long-term disability resulting from stress and pain

symptoms: A preliminary randomized trial. *Behavior Therapy*.

http://doi.org/10.1016/S0005-7894(04)80020-0

Daniels, S. (2015). Cognitive behavior therapy for patients with cancer. *Advanced

Practitioner in Oncology, 6*(1), 54–56.

David, D., Cotet, C., Matu, S., Mogoase, C., & Stefan, S. (2018). 50 years of rational-

emotive and cognitive-behavioral therapy: A systematic review and meta-analysis.

Journal of Clinical Psychology. http://doi.org/10.1002/jclp.22514

DerSimonian, R., & Laird, N. (1986). Meta-analysis in clinical trials. *Controlled Clinical

Trials*. http://doi.org/10.1016/0197-2456(86)90046-2

DeSantis, C. E., Fedewa, S. A., Goding Sauer, A., Kramer, J. L., Smith, R. A., & Jemal, A.

(2016). Breast cancer statistics, 2015: Convergence of incidence rates between black and

white women. *CA: A Cancer Journal for Clinicians*, *66*(1), 31–42.

http://doi.org/10.3322/caac.21320

Desautels, C., Savard, J., Ivers, H., Savard, M.-H., & Caplette-Gingras, A. (2018). Treatment

of depressive symptoms in patients with breast cancer: A randomized controlled trial

comparing cognitive therapy and bright light therapy. *Health Psychology*.

http://doi.org/10.1037/hea0000539

Devine, E. C., & Westlake, S. K. (1995). The effects of psychoeducational care provided to

    adults with cancer: meta-analysis of 116 studies. *Oncology Nursing Forum*.

Dobson, K. S. (1989). A meta-analysis of the efficacy of cognitive therapy for depression.

    Journal of Consulting and Clinical Psychology. http://doi.org/10.1037/0022-

    006X.57.3.414

Downs, S. H., & Black, N. (1998). The feasibility of creating a checklist for the assessment

    of the methodological quality both of randomised and non-randomised studies of health

    care interventions. *Journal of Epidemiology and Community Health*.

    http://doi.org/10.1136/jech.52.6.377

Dragioti, E., Dimoliatis, I., & Evangelou, E. (2015). Disclosure of researcher allegiance in

    meta-analyses and randomized controlled trials of psychotherapy: A systematic

    appraisal. *BMJ Open*. http://doi.org/10.1136/bmjopen-2014-007206

Drake, R. E., Goldman, H. H., Leff, H. S., Lehman, a F., Dixon, L., Mueser, K. T., &

    Torrey, W. C. (2001). Implementing Evidence-Based Practices in Routine Mental

    Health Service Settings. *Psychiatric Services (Washington, D.C.)*, *52*(2), 179–182.

    http://doi.org/10.1176/appi.ps.52.2.179

Edge, S. B., & Compton, C. C. (2010). The american joint committee on cancer: The 7th

    edition of the AJCC cancer staging manual and the future of TNM. *Annals of Surgical

    Oncology*. http://doi.org/10.1245/s10434-010-0985-4

Ellis, P. D. (2010). The Essential Guide to Effect Sizes : An Introduction to Statistical Power

    , Meta-Analysis and the Interpretation of Research Results. *Power*.

Fallowfield, L. J., Hall, A., Maguire, G. P., & Baum, M. (1990). Psychological outcomes of

    different treatment policies in women with early breast cancer outside a clinical trial.

    BMJ. http://doi.org/10.1136/bmj.301.6752.575

Fann, J. R., Thomas-Rich, A. M., Katon, W. J., Cowley, D., Pepping, M., McGregor, B. A.,

& Gralow, J. (2008). Major depression after breast cancer: a review of epidemiology

and treatment. *General Hospital Psychiatry*.

http://doi.org/10.1016/j.genhosppsych.2007.10.008

Field, A. (2009). *Discovering Statistics Using SPSS (3rd Ed.). Sage Publication.*

http://doi.org/10.1234/12345678

Fitzmaurice, C., Allen, C., Barber, R. M., Barregard, L., Bhutta, Z. A., Brenner, H., …

Naghavi, M. (2017). Global, Regional, and National Cancer Incidence, Mortality, Years

of Life Lost, Years Lived With Disability, and Disability-Adjusted Life-years for 32

Cancer Groups, 1990 to 2015. *JAMA Oncology*.

http://doi.org/10.1001/jamaoncol.2016.5688

Fobair, P., Stewart, S. L., Chang, S., D'Onofrio, C., Banks, P. J., & Bloom, J. R. (2006).

Body image and sexual problems in young women with breast cancer. *Psycho-

Oncology*. http://doi.org/10.1002/pon.991

Fu, R., Gartlehner, G., Grant, M., Shamliyan, T., Sedrakyan, A., Wilt, T. J., … Trikalinos, T.

A. (2011). Conducting quantitative synthesis when comparing medical interventions:

AHRQ and the Effective Health Care Program. *Journal of Clinical Epidemiology*.

http://doi.org/10.1016/j.jclinepi.2010.08.010

Gillam, S., & Siriwardena, A. N. (2014). Evidence-based healthcare and quality

improvement. *Quality in Primary Care*.

Goisman, R. M., Warshaw, M. G., & Keller, M. B. (1999). Psychosocial Treatment

Prescriptions for Generalized Anxiety Disorder, Panic Disorder, and Social Phobia,

1991–1996. *Am J Psychiatry*.

Greco, T., Zangrillo, A., Biondi-Zoccai, G., & Landoni, G. (2013). Meta-analysis: Pitfalls

and hints. *Heart, Lung and Vessels*.

Greer, S., Moorey, S., Baruch, J. D., Watson, M., Robertson, B. M., Mason, a., … Bliss, J.

M. (1992). Adjuvant psychological therapy for patients with cancer: a prospective

randomised trial. *BMJ (Clinical Research Ed.)*. http://doi.org/10.1136/bmj.304.6828.675

Haaga, D. a, Dyck, M. J., & Ernst, D. (1991). Empirical status of cognitive theory of

depression. *Psychological Bulletin*. http://doi.org/10.1037/0033-2909.110.2.215

Haidich, A. B. (2010). Meta-analysis in medical research. *Hippokratia*.

http://doi.org/10.5005/jp/books/10519

Haller, H., Winkler, M. M., Klose, P., Dobos, G., Kümmel, S., & Cramer, H. (2017).

Mindfulness-based interventions for women with breast cancer: an updated systematic

review and meta-analysis. *Acta Oncologica*.

http://doi.org/10.1080/0284186X.2017.1342862

Hamilton, M. (1960). A rating scale for depression. *Journal of Neurology, Neurosurgery, and

Psychiatry*. http://doi.org/10.1136/jnnp.23.1.56

Higgins, J. P. T., Altman, D. G., Gøtzsche, P. C., Jüni, P., Moher, D., Oxman, A. D., …

Sterne, J. A. C. (2011). The Cochrane Collaboration's tool for assessing risk of bias in

randomised trials. *British Medical Journal*. http://doi.org/doi: 10.1136/bmj.d5928

Higgins, J. P. T., & Green, S. (2011). Cochrane Handbook for Systematic Reviews of

Interventions Version 5.1.0 [updated March 2011]. In *The Cochrane Collaboration*.

Higgins, J. P. T., & Thompson, S. G. (2002). Quantifying heterogeneity in a meta-analysis.

Statistics in Medicine. http://doi.org/10.1002/sim.1186

Higgins, J. P. T., Thompson, S. G., Deeks, J. J., & Altman, D. G. (2003). Measuring

inconsistency in meta-analyses. *BMJ : British Medical Journal*.

http://doi.org/10.1136/bmj.327.7414.557

Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., … Michie, S.

(2014). Better reporting of interventions: Template for intervention description and

replication (TIDieR) checklist and guide. *BMJ (Online)*.

http://doi.org/10.1136/bmj.g1687

Hollon, S. D., Stewart, M. O., & Strunk, D. (2006). Enduring Effects for Cognitive Behavior

Therapy in the Treatment of Depression and Anxiety. *Annual Review of Psychology*.

http://doi.org/10.1146/annurev.psych.57.102904.190044

Hollon, S. D., Thase, M. E., & Markowitz, J. C. (2002). Treatment and Prevention of

Depression. *Psychological Science in the Public Interest*. http://doi.org/10.1111/1529-

1006.00008

Hooper, P., Jutai, J. W., Strong, G., & Russell-Minda, E. (2008). Age-related macular

degeneration and low-vision rehabilitation: a systematic review. *Canadian Journal of*

Ophthalmology / Journal Canadien d'Ophtalmologie. http://doi.org/10.3129/i08-001

Hopko, D. R., Armento, M. E. A., Robertson, S. M. C., Ryba, M. M., Carvalho, J. P.,

Colman, L. K., … Lejuez, C. W. (2011). Brief behavioral activation and problem-

solving therapy for depressed breast cancer patients: Randomized trial. *Journal of*

Consulting and Clinical Psychology. http://doi.org/10.1037/a0025450

Hopwood, P., Howell, A., & Maguire, P. (1991). Screening for psychiatric morbidity in

patients with advanced breast cancer: Validation of two self-report questionnaires.

British Journal of Cancer. http://doi.org/10.1038/bjc.1991.305

Hotopf, M., Chidgey, J., Addington-Hall, J., & Lan Ly, K. (2002). Depression in advanced

disease: A systematic review part 1. Prevalence and case finding. *Palliative Medicine*.

http://doi.org/10.1191/02169216302pm507oa

Hundt, N. E., Mignogna, J., Underhill, C., & Cully, J. A. (2013). The Relationship Between

Use of CBT Skills and Depression Treatment Outcome: A Theoretical and

Methodological Review of the Literature. *Behavior Therapy*.

http://doi.org/10.1016/j.beth.2012.10.001

Jadad, A. R., Moore, R. A., Carroll, D., Jenkinson, C., Reynolds, D. J. M., Gavaghan, D. J.,

& McQuay, H. J. (1996). Assessing the quality of reports of randomized clinical trials: Is blinding necessary? *Controlled Clinical Trials*. http://doi.org/10.1016/0197-2456(95)00134-4

Jassim, G. A., Whitford, D. L., Hickey, A., & Carter, B. (2015). Psychological interventions for women with non-metastatic breast cancer. *Cochrane Database of Systematic Reviews*. http://doi.org/10.1002/14651858.CD008729.pub2

Kim, Y. H., Choi, K. S., Han, K., & Kim, H. W. (2018). A psychological intervention programme for patients with breast cancer under chemotherapy and at a high risk of depression: A randomised clinical trial. *Journal of Clinical Nursing*. http://doi.org/10.1111/jocn.13910

Kissane, D. W., Bloch, S., Smith, G. C., Miach, P., Clarke, D. M., Ikin, J., … McKenzie, D. (2003). Cognitive-existential group psychotherapy for women with primary breast cancer: a randomised controlled trial. *Psycho-Oncology*. http://doi.org/10.1002/pon.683

Kissane, D. W., Grabsch, B., Love, A., Clarke, D. M., Bloch, S., & Smith, G. C. (2004). Psychiatric disorder in women with early stage and advanced breast cancer: a comparative analysis. *The Australian and New Zealand Journal of Psychiatry*. http://doi.org/10.1111/j.1440-1614.2004.01358.x

Kovacs, M., & Beck, A. T. (1978). Maladaptive cognitive structures in depression. *American Journal of Psychiatry*. http://doi.org/10.1176/ajp.135.5.525

Kovacs, M., Rush, A. J., Beck, A. T., & Hollon, S. D. (1981). Depressed Outpatients Treated with Cognitive Therapy or Pharmacotherapy: A One-Year Follow-up. *Archives of General Psychiatry*. http://doi.org/10.1001/archpsyc.1981.01780260035003

Lachin, J. M. (2000). Statistical considerations in the intent-to-treat principle. *Controlled Clinical Trials*. http://doi.org/10.1016/S0197-2456(00)00046-5

Lengacher, C. A., Johnson-Mallard, V., Post-White, J., Moscoso, M. S., Jacobsen, P. B.,

Klein, T. W., … Kip, K. E. (2009). Randomized controlled trial of mindfulness-based stress reduction (MBSR) for survivors of breast cancer. *Psycho-Oncology*. http://doi.org/10.1002/pon.1529

Li, M., Kennedy, E. B., Byrne, N., G´erin-Lajoie, C., Katz, M. R., Keshavarz, H., … Green, E. (2016). Management of depression in patients with cancer: a clinical practice guideline. *Journal of Oncology Practice*, *12*(8), 747–756. http://doi.org/https://doi.org/10.1200/jop.2016.011072.

Lipsey, M. W., & Wilson, D. B. (2001). Practical meta-analysis. *Applied Social Research Methods Series*. http://doi.org/10.1016/j.autneu.2007.06.087

Littell, J., Corcoran, J., & Pillai, V. (2008). *Systematic Reviews and Meta-Analysis*. New York: Oxford University Press, Inc.

Low, J., Serfaty, M., Davis, S., Vickerstaff, V., Gola, A., Omar, R. Z., … Jones, L. (2016). Acceptance and commitment therapy for adults with advanced cancer (CanACT): study protocol for a feasibility randomised controlled trial. *Trials*. http://doi.org/10.1186/s13063-016-1169-8

Marchioro, G., Azzarello, G., Checchin, F., Perale, M., Segati, R., Sampognaro, E., … Vinante, O. (1996). The impact of a psychological intervention on quality of life in non-metastatic breast cancer. *European Journal of Cancer (Oxford, England : 1990)*. http://doi.org/10.1016/0959-8049(96)00134-7

McHugh, M. L. (2012). Interrater reliability: the kappa statistic. *Biochemia Medica*. http://doi.org/10.11613/BM.2012.031

McHugh, R. K., & Barlow, D. H. (2010). The dissemination and implementation of evidence-based psychological treatments. A review of current efforts. *The American Psychologist*. http://doi.org/10.1037/a0018121

Meline, T. (2006). Selecting Studies for Systematic Review: Inclusion and Exclusion

Criteria. *Contemporary Issues in Communication Science and Disorders*.

http://doi.org/1092-5171/06/3301-0021

Meyer, T. J., & Mark, M. M. (1995). Effects of Psychosocial Interventions With Adult

Cancer Patients: A Meta-Analysis of Randomized Experiments. *Health Psychology*.

http://doi.org/10.1037//0278-6133.14.2.101

Mitchell, A. J., Chan, M., Bhatti, H., Halton, M., Grassi, L., Johansen, C., & Meader, N.

(2011). Prevalence of depression, anxiety, and adjustment disorder in oncological,

haematological, and palliative-care settings: A meta-analysis of 94 interview-based

studies. *The Lancet Oncology*. http://doi.org/10.1016/S1470-2045(11)70002-X

Mohabbat-Bahar, S., Maleki-Rizi, F., Akbari, M. E., & Moradi-Joo, M. (2015). Effectiveness

of group training based on acceptance and commitment therapy on anxiety and

depression of women with breast cancer. *Iranian Journal of Cancer Prevention*.

Moher, D., Liberati, A., Tetzlaff, J., & Altman, D. G. (2010). Preferred reporting items for

systematic reviews and meta-analyses: The PRISMA statement. *International Journal of*

Surgery. http://doi.org/10.1016/j.ijsu.2010.02.007

Moher, D., Liberati, A., Tetzlaff, J., Altman, D. G., Altman, D., Antes, G., … Tugwell, P.

(2009). Preferred reporting items for systematic reviews and meta-analyses: The

PRISMA statement. *PLoS Medicine*. http://doi.org/10.1371/journal.pmed.1000097

Mohr, D. C., Boudewyn, A. C., Goodkin, D. E., Bostrom, A., & Epstein, L. (2001).

Comparative outcomes for individual cognitive-behavior therapy, supportive-expressive

group psychotherapy, and sertraline for the treatment of depression in multiple sclerosis.

Journal of Consulting and Clinical Psychology. http://doi.org/10.1037//0022-

006x.69.6.942

Morton, S., Berg, A., Levit, L., & Eden, J. (Eds.). (2011). *Finding what works in health care:*

standards for systematic reviews. Washington, D.C.: National Academies Press.

Nápoles, A. M., Ortíz, C., Santoyo-Olsson, J., Stewart, A. L., Gregorich, S., Lee, H. E., …

    Luce, J. (2015). Nuevo amanecer: Results of a randomized controlled trial of a

    community-based, peer-delivered stress management intervention to improve quality of

    life in Latinas with breast cancer. *American Journal of Public Health*.

    http://doi.org/10.2105/AJPH.2015.302598

Nestler, E. J., Barrot, M., DiLeone, R. J., Eisch, A. J., Gold, S. J., & Monteggia, L. M.

    (2002). Neurobiology of depression. *Neuron*. http://doi.org/10.1016/S0896-

    6273(02)00653-0

Newell, S. A., Sanson-Fisher, R. W., & Savolainen, N. J. (2002). Systematic Review of

    Psychological Therapies for Cancer Patients: Overview and Recommendations for

    Future Research. *Journal of the National Cancer Institute*.

    http://doi.org/10.1093/jnci/94.8.558

Orwin, R. G. (1983). A Fail-Safe N for Effect Size in Meta-Analysis. *Journal of Educational

    Statistics*. http://doi.org/10.2307/1164923

Osborn, R. L., Demoncada, A. C., & Feuerstein, M. (2006). Psychosocial interventions for

    depression, anxiety, and quality of life in cancer survivors: meta-analyses. *International

    Journal of Psychiatry in Medicine*. http://doi.org/10.2190/eufn-rv1k-y3tr-fk0l

Pannucci, C. J., & Wilkins, E. G. (2010). Identifying and avoiding bias in research. *Plastic

    and Reconstructive Surgery*. http://doi.org/10.1097/PRS.0b013e3181de24bc

Piet, J., Würtzen, H., & Zachariae, R. (2012). The effect of mindfulness-based therapy on

    symptoms of anxiety and depression in adult cancer patients and survivors: A systematic

    review and meta-analysis. *Journal of Consulting and Clinical Psychology*.

    http://doi.org/10.1037/a0028329

Qiu, J., Chen, W., Gao, X., Xu, Y., Tong, H., Yang, M., … Yang, M. (2013). A randomized

    controlled trial of group cognitive behavioral therapy for Chinese breast cancer patients

with major depression. *Journal of Psychosomatic Obstetrics & Gynecology*.

http://doi.org/10.3109/0167482X.2013.766791

Radloff, L. S. (1977). The CES-D Scale: A Self-Report Depression Scale for Research in the

General Population. *Applied Psychological Measurement*.

http://doi.org/10.1177/014662167700100306

Reich, M., Lesur, A., & Perdrizet-Chevallier, C. (2008). Depression, quality of life and breast

cancer: A review of the literature. *Breast Cancer Research and Treatment*.

http://doi.org/10.1007/s10549-007-9706-5

Rodin, G., Lloyd, N., Katz, M., Green, E., Mackay, J. a, & Wong, R. K. S. (2007). The

treatment of depression in cancer patients: a systematic review. *Supportive Care in*

Cancer : Official Journal of the Multinational Association of Supportive Care in

Cancer. http://doi.org/10.1007/s00520-006-0145-3

Rosenthal, R. (1993). *Meta-analytic procedures for social research.* Newbury Park, CA:

Sage Publications.

Rosenthal, R., & DiMatteo, M. R. (2001). Meta-Analysis: Recent Developments in

Quantitative Methods for Literature Reviews. *Annual Review of Psychology*.

http://doi.org/10.1146/annurev.psych.52.1.59

Sandgren, A. K., & McCaul, K. D. (2007). Long-term telephone therapy outcomes for breast

cancer patients. *Psycho-Oncology*. http://doi.org/10.1002/pon.1038

Schnurr, P. P. (2007). The rocks and hard places in psychotherapy outcome research. In

Journal of Traumatic Stress. http://doi.org/10.1002/jts.20292

Sharpley, C. F., & Christie, D. R. H. (2007). An analysis of the psychometric profile and

frequency of anxiety and depression in Australian men with prostate cancer. *Psycho-*

Oncology. http://doi.org/10.1002/pon.1118

Simons, A. D., Levine, J. L., Lustman, P. J., & Murphy, G. E. (1984). Patient attrition in a

comparative outcome study of depression. A follow-up report. *Journal of Affective Disorders*. http://doi.org/10.1016/0165-0327(84)90021-1

Simons, A. D., Murphy, G. E., Levine, J. L., & Wetzel, R. D. (1986). Cognitive Therapy and Pharmacotherapy for Depression: Sustained Improvement Over One Year. *Archives of General Psychiatry*. http://doi.org/10.1001/archpsyc.1986.01800010045006

Simpson, J. S. A., Carlson, L. E., & Trew, M. E. (2001). Effect of Group Therapy for Breast Cancer on Healthcare Utilization. *Cancer Practice*. http://doi.org/10.1046/j.1523-5394.2001.91005.x

Spiegel, D., Bloom, J. R., & Yalom, I. (1981). Group support for patients with metastatic cancer. A randomized outcome study. *Archives of General Psychiatry*. http://doi.org/doi:10.1001/archpsyc.1980.01780300039004

Stagl, J. M., Lechner, S. C., Carver, C. S., Bouchard, L. C., Gudenkauf, L. M., Jutagir, D. R., … Antoni, M. H. (2015). A randomized controlled trial of cognitive-behavioral stress management in breast cancer: survival and recurrence at 11-year follow-up. *Breast Cancer Research and Treatment*. http://doi.org/10.1007/s10549-015-3626-6

Stewart, R. E., & Chambless, D. L. (2007). Does psychotherapy research inform treatment decisions in private practice? *Journal of Clinical Psychology*. http://doi.org/10.1002/jclp.20347

Stratford, P. W. (2010). The Added Value of Confidence Intervals. *Physical Therapy*, *90*(3), 333–335. http://doi.org/https://doi.org/10.2522/ptj.2010.90.3.333

Sturmey, P. (2009). Behavioral activation is an evidence-based treatment for depression. *Behavior Modification*, *33*(6), 818–829. http://doi.org/10.1177/0145445509350094

Tatrow, K., & Montgomery, G. H. (2006). Cognitive behavioral therapy techniques for distress and pain in breast cancer patients: A meta-analysis. *Journal of Behavioral Medicine*. http://doi.org/10.1007/s10865-005-9036-1

Torta, R. G. V., & Ieraci, V. (2013). Pharmacological Management of Depression in Patients with Cancer: Practical Considerations. *Drugs*. http://doi.org/10.1007/s40265-013-0090-7

Trudel-Fitzgerald, C., Savard, J., & Ivers, H. (2013). Evolution of cancer-related symptoms over an 18-Month period. *Journal of Pain and Symptom Management*. http://doi.org/10.1016/j.jpainsymman.2012.06.009

Von Hippel, P. T. (2015). The heterogeneity statistic I^2 can be biased in small meta-analyses. *BMC Medical Research Methodology*. http://doi.org/10.1186/s12874-015-0024-z

Walker, D. A. (2016). JMASM38: Confidence Intervals for Kendall's Tau with Small Samples (SPSS). *Journal of Modern Applied Statistical Methods*, *15*(1), 45. http://doi.org/https://doi.org/10.22237/jmasm/1462077840

Wampold, B. E., Budge, S. L., Laska, K. M., del Re, A. C., Baardseth, T. P., Fluckiger, C., … Gunn, W. (2011). Evidence-based treatments for depression and anxiety versus treatment-as-usual: A meta-analysis of direct comparisons. *Clinical Psychology Review*. http://doi.org/10.1016/j.cpr.2011.07.012

Xiao, F., Song, X., Chen, Q., Dai, Y., Xu, R., Qiu, C., & Guo, Q. (2017). Effectiveness of psychological interventions on depression in patients after breast cancer surgery: a meta-analysis of randomized controlled trials. *Clinical Breast Cancer*, *17*(3), 171–179. http://doi.org/https://doi.org/10.1016/j.clbc.2016.11.003

Yang, Y.-L., Sui, G.-Y., Liu, G.-C., Huang, D.-S., Wang, S.-M., & Wang, L. (2014). The effects of psychological interventions on depression and anxiety among Chinese adults with cancer: a meta-analysis of randomized controlled studies. *BMC Cancer*. http://doi.org/10.1186/1471-2407-14-956

Zabora, J., Brintzenhofeszoc, K., Curbow, B., Hooker, C., & Piantadosi, S. (2001). The prevalence of psychological distress by cancer site. *Psycho-Oncology*. http://doi.org/10.1002/1099-1611(200101/02)10:1<19::AID-PON501>3.0.CO;2-6

Zakzanis, K. K. (2001). Statistics to tell the truth, the whole truth, and nothing but the truth. Formulae, illustrative numerical examples, and heuristic interpretation of effect size analyses for neuropsychological researchers. *Archives of Clinical Neuropsychology*. http://doi.org/10.1016/S0887-6177(00)00076-7

Zhang, J., Xu, R., Wang, B., & Wang, J. (2016). Effects of mindfulness-based therapy for patients with breast cancer: A systematic review and meta-analysis. *Complementary Therapies in Medicine*, *26*, 1–10. http://doi.org/10.1016/j.ctim.2016.02.012

Zigmond, A. S., & Snaith, R. P. (1983). The Hospital Anxiety and Depression Scale. *Acta Psychiatrica Scandinavica*. http://doi.org/10.1111/j.1600-0447.1983.tb09716.x

Appendices

Appendix A
Final Search Terms

PubMed

Breast Cancer	Depression	CBT	Study Type
"breast neoplasms"[mh] OR "breast carcinoma*"[tw] OR breast neoplas*[tw] breast cancer*[tw] OR breast tumour*[tw] OR breast tumor*[tw] OR breast malignan*[tw] OR breast carcinoma*[tw] OR ductal carcinoma*[tw] OR lobular carcinoma*[tw] OR cancer of the breast*[tw] OR carcinoma of the breast*[tw] OR neoplasm of the breast*[tw] OR non-metastatic breast cancer* [tw] OR non-metastatic breast neoplasm*[tw] OR non-metastatic breast carcinoma*[tw]	"depression"[mh] OR "depressive disorder"[mh] OR depression[tw] OR depressive[tw] OR depressed[tw] OR distress*[tw] OR major depressive disorder*[tw] OR major depressive episode*[tw] OR depressive disorder*[tw] OR depressive episode*[tw]	"cognitive therapy"[mh] OR cognitive therap*[tw] OR cognitive behav*[tw] OR mindful* based cognitive therap*[tw] OR cognitive behav* stress management[tw] OR CBSM[tw] OR CBT[tw] OR cognitive psychotherap*[tw]	"random allocation"[mh] OR randomized[tw] OR randomised[tw] OR randomised control trial*[tw] OR randomized control trial*[tw] OR RCT*[tw] OR controlled clinical trial*[tw] OR randomised clinical trial*[tw] OR randomized clinical trial*[tw]

PsycINFO

Breast Cancer	Depression	CBT	Study Type
(breast neoplasm*).sh OR breast cancer*.tw OR breast tumour*.tw OR breast tumor*.tw OR breast malignan*.tw OR breast carcinoma*.tw OR ductal carcinoma*.tw OR lobular carcinoma*.tw OR cancer* of the breast*.tw OR carcinoma of the breast*.tw OR neoplasm of the breast*.tw OR non-metastatic breast cancer*.tw OR non-metastatic breast neoplasm*.tw OR non-metastatic breast carcinoma*.tw	(depression or depressive disorder).sh OR depress*.tw OR depress* symptom*.tw OR depress* mood*.tw OR distress*.tw OR feelings of distress.tw OR emotional* distress*.tw OR major depress* disorder*.tw OR major depress*.tw OR depress* episode*.tw	(cognitive therap*).sh OR (cognitive behav* therap*).sh OR cognitive therap*.tw OR cognitive behav* therap*.tw OR cognitive behav* stress management.tw OR CBSM.tw OR CBT.tw OR cognitive psychotherap*.tw	random* allocation*.tw OR random* control trial*.tw OR RCT*.tw OR controlled clinical trial*.tw OR random* clinical trial*.tw

Web of Science

Breast Cancer	Depression	CBT	Study Type
TS=("breast neoplas*" OR "breast cancer*" OR "breast tumour*" OR "breast tumor*" OR "breast malignan*" OR "breast carcinoma*" OR "ductal carcinoma*" OR "lobular carcinoma*" OR "cancer of the breast*" OR "carcinoma of the breast*" OR "neoplasm of the breast*" OR "non-metastatic breast cancer*" OR "non-metastatic breast neoplasm*" OR "non-metastatic breast carcinoma*")	TS=(depression OR "depressive disorder" OR depressive OR depressed OR distress* OR "major depressive disorder*" OR "major depressive episode*" OR "depressive disorder*" OR "depressive episode*")	TS=("cognitive therap*" OR "cognitive behav* therap*" OR "cognitive behav*" OR "mindful* based cognitive therap*" OR "cognitive behav* stress management" OR TI CBSM OR TI CBT OR TI "cognitive psychotherap*")	TS=("randomised allocation*" OR "randomized allocation*" OR "random* control trial*" OR "random* allocation*" OR RCT* OR "controlled clinical trial*" OR "random* clinical trial*" OR "random* clinical trial*")

CINAHL

Breast Cancer	Depression	CBT	Study Type
MH "breast neoplasm*" OR MH "breast carcinoma*" OR TI "breast neoplas*" OR AB "breast neoplas*" OR TI "breast cancer*" OR AB "breast cancer*" TI "breast tumo#r*" OR AB "breast tumo#r*" OR TI "breast malignan*" OR AB "breast malignan*"OR TI "breast carcinoma*" OR AB "breast carcinoma*" OR TI "ductal carcinoma*" OR AB "ductal carcinoma*" OR TI "lobular carcinoma*" OR AB "lobular carcinoma*" OR TI "cancer of the breast*" OR AB "cancer of the breast*" OR TI "carcinoma of the breast*" OR AB "carcinoma of the breast*" OR TI "neoplasm of the breast*" OR AB "neoplasm of the breast*" OR TI "non-metastatic breast cancer" OR AB "non-	MH depression OR TI depression OR AB depression OR TI "depressive disorder" OR AB "depressive disorder" OR TI depressive OR AB depressive OR TI depressed OR AB depressed OR TI distress* OR AB distress* OR TI "major depressive disorder*" OR AB "major depressive disorder*" OR TI "major depressive episode*" OR AB "major depressive episode*" OR TI "depressive disorder*" OR AB "depressive disorder*" OR TI	MH "cognitive therapy" OR TI "cognitive therap*" OR AB "cognitive therap*" OR TI "cognitive behav* therap*" OR AB "cognitive behav* therap*" OR TI "cognitive behav*" OR AB "cognitive behav*" OR TI "mindful* based cognitive therap*" OR AB "mindful* based cognitive therap*" OR TI "cognitive behav* stress management" OR AB "cognitive behav* stress management" OR TI CBSM OR AB CBSM OR TI CBT OR AB CBT OR TI	MH "random assignment" OR MH "random* control trial*" OR MH "clinical trial*" OR TI "random* assignment" OR AB "random* assignment" OR TI "clinical trial*" OR AB "clinical trial*" OR TI "random* allocation" OR AB "random* allocation" OR TI "random* control trial*" OR AB "random* control trial*"OR TI random* OR AB random* OR TI "random* control trial*" OR AB "random* control trial*" OR TI RCT* OR AB RCT*OR TI "controlled clinical

metastatic breast cancer*" OR TI "non-metastatic breast neoplasm*" OR AB "non-metastatic breast neoplasm*" OR TI "non-metastatic breast carcinoma*" OR AB "non-metastatic breast carcinoma*"	"depressive episode*" OR AB "depressive episode*"	"cognitive psychotherap*" OR AB "cognitive psychotherap*"	trial*" OR AB "controlled clinical trial*" OR TI "random* clinical trial*" OR AB "random* clinical trial*"

Scopus

Breast Cancer	Depression	CBT	Study Type
TITLE-ABS-KEY ("breast neoplasm*" OR "breast cancer*" OR "breast tumour*" OR "breast malignan*" OR "breast carcinoma*" OR "ductal carcinoma*" OR "lobular carcinoma*" OR "cancer* of the breast" OR "carcinoma of the breast*" OR "neoplasm of the breast*" OR "non-metastatic breast cancer*" OR "non-metastatic breast neoplasm*" OR "non-metastatic breast carcinoma*")	TITLE-ABS-KEY ("depressive disorder" OR "depress* symptoms" OR "depress* mood" OR "feelings of distress" OR "emotional distress" OR "major depress*" OR "depress* episode" OR "major depress* disorder" OR depress* OR distress*)	TITLE-ABS-KEY ("cognitive therap*" OR "cognitive behav*" OR "cognitive behav* therap*" OR "cognitive psychotherap*" OR CBSM OR CBT)	TITLE-ABS-KEY ("randomised allocation*" OR "random* control trial*" OR "random* allocation*" OR RCT* OR "controlled clinical trial*" OR "random* clinical trial*")

Embase

Breast Cancer	Depression	CBT	Study Type
'breast cancer'/exp OR 'breast carcinoma'/exp OR 'breast carcinoma*':ti,ab OR 'breast neoplasm*':ti,ab OR 'breast cancer*':ti,ab OR 'breast tumo$r*':ti,ab OR 'breast malignancy':ti,ab OR 'breast carcinoma*':ti,ab OR 'ductal carcinoma*':ti,ab OR 'lobular carcinoma*':ti,ab OR 'non-metastatic breast cancer*':ti,ab OR 'non-metastatic breast neoplasm*':ti,ab OR 'non-metastatic breast carcinoma*':ti,ab	'depression'/exp OR 'major depression'/exp OR 'depressive disorder':ti,ab OR 'major depression':ti,ab OR 'depress* symptoms':ti,ab OR 'depress* mood':ti,ab OR 'feelings of distress':ti,ab OR 'emotional distress':ti,ab OR 'major depress*':ti,ab OR 'depress* episode':ti,ab OR 'major depress* disorder':ti,ab OR 'depress*':ti,ab OR 'distress*':ti,ab	'cognitive behavioral therapy'/exp OR 'cognitive therap*':ti,ab OR 'cognitive behav* therap*':ti,ab OR 'mindful* based cognitive therap*':ti,ab OR 'cognitive behav* stress management':ti,ab OR 'CBSM':ti,ab OR 'CBT':ti,ab OR 'cognitive psychotherap*':ti,ab	'randomized controlled trial'/exp OR 'controlled clinical trial'/exp OR 'random* control trial':ti,ab OR 'random* allocation':ti,ab OR 'RCT*':ti,ab OR 'controlled clinical trial*':ti,ab OR 'random* clinical trial*':ti,ab

Appendix B
Data Extraction Sheet

Person extracting data:	Date of date extraction:	Year of study publication:

Title:

Author:

Reference:

Other publications from same study (additional reports of the same study should be grouped under the same study identifier see "Organising studies and references", p 35 RevMan User Guide)**:**

Study design

Type of study design (e.g., parallel; cluster; cross-over trial)

Study Country:

Total sample size: Experimental intervention: Total number randomised: n= Control/Comparison intervention: Total number randomised: n= Specify Treatment Group: **Gender (% or n)** Males: Females: **Age:** *At time of assessment* Range: Mean: SD: **Ethnicity (% or n)** European/Caucasian: Asian: African: Other:	**Type of Treatment:** Pharmacological drugs: Psychological Treatment: **Subtype of Drug Treatment:** SSRI: Antidepressant: Other: **Dosage of Drug Treatment:** State: **Time receiving intervention:** Range: Mean: SD: **Subtype of Psychological Treatment:** CBT: Psychotherapy: Other: **Setting of CBT treatment:** Individual: Group:	Specify Control Group – if different from treatment population **Age:** *At time of assessment* Mean: Range: SD: **Placebo medication length:** **Data collection:** [✓] From subject [ ] Medical records [ ] Other Random Selection [✓] Yes [ ] No Eligibility Criteria Specified [✓] Yes [ ] No [ ] Partially General Population [ ] Yes [✓] No

Nature of breast cancer (% or n) Stage 0: Stage 1: Stage 2: Stage 3: Stage 4:	**Number of CBT sessions:** Range: Mean: SD: **Time receiving intervention:** Range: Mean: SD:	Specify: Missing Data explained [✓] Yes [ ] No [ ] Partially Sample recruitment [✓] Not specified [ ] Hospital Inpatient [ ] Database [ ] Rehab Clinic [ ] Medical centre/GP Other: _____

Effect size data:
Outcome measure:

Method of administration: self-report [ ]   clinical interview [ ]   DASS [ ]   BDI-II [ ]   HADS [ ]   other [☐☐]

Cut-off score (if applicable):

Appendix C
Risk of Bias Assessment

Domain	Risk of bias			Support for judgement *(include direct quotes where available with explanatory comments)*	Location in text or source *(pg & ¶/fig/table/other)*
	Low	High	Unclear		
Random sequence generation *(selection bias)*	☐	☐	☐		
Allocation concealment *(selection bias)*	☐	☐	☐		
Blinding of participants and personnel *(performance bias)*	☐	☐	☐	Outcome group: All/	
(if separate judgement by outcome(s) required)	☐	☐	☐	Outcome group:	
Blinding of outcome assessment *(detection bias)*	☐	☐	☐	Outcome group: All/	
(if separate judgement by outcome(s) required)	☐	☐	☐	Outcome group:	
Incomplete outcome data *(attrition bias)*	☐	☐	☐	Outcome group: All/	
(if separate judgement by outcome(s) required)	☐	☐	☐	Outcome group:	
Selective outcome reporting? *(reporting bias)*	☐	☐	☐		
Other bias	☐	☐	☐		
Notes:					

Appendix D
Downs and Black QI

Eligible Studies (*n* =)				
Lead Author of Study:				**Notes/Justification**
Reporting	**0 (= No)**	**1 (= Yes)**	**0 (= Unable to determine)**	
1. *Is the hypothesis/aim/objective of the study clearly described?*				
2. *Are the main outcomes to be measured clearly described in the Introduction or Methods section?* If the main outcomes are first mentioned in the Results section, the question should be answered no.				
3. *Are the characteristics of the patients included in the study clearly described ?* In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case-control studies, a case-definition and the source for controls				
4. *Are the interventions of interest clearly described?* Treatments and placebo (where relevant) that are to be compared should be clearly described.				
5. *Are the distributions of principal confounders in each group of subjects to be compared clearly described?* A list of principal confounders is provided.				
6. *Are the main findings of the study clearly described?* Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions.				

(This question does not cover statistical tests which are considered below).				
7. *Does the study provide estimates of the random variability in the data for the main outcomes?* In non normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes.				
8. *Have all important adverse events that may be a consequence of the intervention been reported?* This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events. (A list of possible adverse events is provided).				
9. *Have the characteristics of patients lost to follow-up been described?* This should be answered yes where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered no where a study does not report the number of patients lost to follow-up.				
10. *Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?*				
External Validity All the following criteria attempt to address the representativeness of the findings of the study and whether they may be generalised to the population				

from which the study subjects were derived.⸗SEP				
11. *Were the subjects asked to participate in the study representative of the entire population from which they were recruited?* The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant population exists. Where a study does not report the proportion of the source population from which the patients are derived, the question should be answered as unable to determine.				
12. *Were those subjects who were prepared to participate representative of the entire population from which they were recruited?*⸗SEP The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.				
13. *Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?*⸗SEP For the question to be answered yes the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered no if, for example, the intervention was undertaken in a specialist centre unrepresentative of the hospitals most of the source population would attend.				
Internal validity – bias				

14. *Was an attempt made to blind study subjects to the intervention they have received?* For studies where the patients would have no way of knowing which intervention they received, this should be answered yes.				
15. *Was an attempt made to blind those measuring the main outcomes of the intervention?*				
16. *If any of the results of the study were based on "data dredging", was this made clear?* Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then answer yes.				
17. *In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?* Where follow-up was the same for all study patients the answer should yes. If different lengths of follow-up were adjusted for by, for example, survival analysis the answer should be yes. Studies where differences in follow-up are ignored should be answered no.				
18. *Were the statistical tests used to assess the main outcomes appropriate?* The statistical techniques used must be appropriate to the data. For example nonparametric methods should be used for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question should be answered yes. If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were appropriate and the question should be answered yes.				
19. *Was compliance with the intervention/s reliable?* Where there was non compliance with the allocated treatment or where there was contamination of one group, the question should be answered no. For studies where the				

effect of any misclassification was likely to bias any association to the null, the question should be answered yes.				
20. *Were the main outcome measures used accurate (valid and reliable)?* For studies where the outcome measures are clearly described, the question should be answered yes. For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered as yes.				
Internal validity - confounding (selection bias)				
21. *Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?* For example, patients for all comparison groups should be selected from the same hospital. The question should be answered unable to determine for cohort and casecontrol studies where there is no information concerning the source of patients included in the study.				
22. *Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?* For a study which does not specify the time period over which patients were recruited, the question should be answered as unable to determine.				
23. *Were study subjects randomised to intervention groups?* Studies which state that subjects were randomized should be answered yes except where method of randomisation would not ensure random allocation. For example alternate allocation would score no because it is predictable.				
24. *Was the randomised intervention assignment concealed from*				

both patients and health care staff until recruitment was complete and irrevocable? All non-randomised studies should be answered no. If assignment was concealed from patients but not from staff, it should be answered no.				
25. *Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?* This question should be answered no for trials if: the main conclusions of the study were based on analyses of treatment rather than intention to treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In nonrandomized studies if the effect of the main confounders was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered as no.				
26. *Were losses of patients to follow-up taken into account?* If the numbers of patients lost to follow-up are not reported, the question should be answered as unable to determine. If the proportion lost to follow- up was too small to affect the main findings, the question should be answered yes.				
Power				
27. *Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?* Sample sizes have been calculated to detect a difference of x% and y%.				
Total score: /27				

Note. ● present (score of 1, or 2 for item 5); ◐ present, with some limitations (score of 0); ○ not present or unable to determine (score of 0).

Appendix E
TIDieR Checklist

Item number	Lead author of study:	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	_____	_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	_____	_____
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	_____	_____ _____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention,	_____	

including any enabling or support activities.

WHO PROVIDED

5. For each category of intervention provider (e.g. psychologist, nursing assistant), describe their _____ _____

   expertise, background and any specific training given.

6. Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or _____ _____

   telephone) of the intervention and whether it was provided individually or in a group.

WHERE

7. Describe the type(s) of location(s) where the intervention occurred, including any necessary _____ _____

   infrastructure or relevant features.

WHEN and HOW MUCH

8. Describe the number of times the intervention was delivered and over what period of time including _____ _____

   the number of sessions, their schedule, and their duration, intensity or dose.

TAILORING

9. If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, _____ _____

   and how.

MODIFICATIONS

10.[‡]   If the intervention was modified during the course of the study, describe the changes (what, why,   _____   _____

when, and how).

HOW WELL

11.   Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any   _____   _____

strategies were used to maintain or improve fidelity, describe them.

12.[‡]   Actual: If intervention adherence or fidelity was assessed, describe the extent to which the   _____   _____

intervention was delivered as planned.

Note. ● present (score of 1); ◐ present, with some limitations (score of 0); ○ not present or unable to determine (score of 0).

Authors - use N/A if an item is not applicable for the intervention being described. Reviewers – use '?' if information about the element is not reported/not sufficiently reported.

Appendix F
Researcher Allegiance Assessment Sheet

Lead Author of Study:				
Criteria	0 (= No); 1 (= Yes)	Support for judgement *(include direct quotes where available with explanatory comments)*	Location in text or source *(pg & ¶/fig/table/other)*	Allegiance code given (author)
0. No apparent advocacy of one treatment over another				
1. Treatment explanation occurred in introduction/methods				
2. Authors advocated for treatment but did not supervise/train therapist				
3. Authors advocated for treatment and they supervised/trained therapist				
4. Authors created intervention but did not supervise/train therapist				
5. Authors created intervention and supervised/trained therapist				
Notes:				

Note. ● present; ◖ present, with some limitations; ○ not present or unable to determine.
Author - use N/A if an item is not applicable for the intervention being described.