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Psychological interventions for women with non-metastatic breast cancer (Review)

Jassim GA, Doherty S, Whitford DL, Khashan AS

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[Intervention Review]

Psychological interventions for women with non-metastatic breast cancer

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ABSTRACT

Background

Breast cancer is the most common cancer affecting women worldwide. It is a distressing diagnosis and, as a result, considerable research has examined the psychological sequelae of being diagnosed and treated for breast cancer. Breast cancer is associated with increased rates of depression and anxiety and reduced quality of life. As a consequence, multiple studies have explored the impact of psychological interventions on the psychological distress experienced after a diagnosis of breast cancer. This review is an update of a Cochrane Review first published in 2015.

Objectives

To assess the effect of psychological interventions on psychological morbidities and quality of life among women with non-metastatic breast cancer.

Search methods

We searched the Cochrane Breast Cancer Group Specialised Register, CENTRAL, MEDLINE, Embase, CINAHL, PsycINFO, the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) and ClinicalTrials.gov up to 16 March 2021. We also scanned the reference lists of relevant articles.

Selection criteria

Randomised controlled trials that assessed the effectiveness of psychological interventions for women with non-metastatic breast cancer.

Data collection and analysis

Two review authors independently appraised, extracted data from eligible trials, and assessed risk of bias and certainty of the evidence using the GRADE approach. Any disagreement was resolved by discussion. Extracted data included information about participants, methods, the intervention and outcomes.

Main results

We included 60 randomised controlled trials comprising 7998 participants. The most frequent reasons for exclusion were non-randomised trials and the inclusion of women with metastatic disease. The updated review included 7998 randomised women; the original review included 3940 women.

A wide range of interventions was evaluated. Most interventions were cognitive- or mindfulness-based, supportive-expressive, and educational. The interventions were mainly delivered face-to-face (56 studies) and in groups (50 studies) rather than individually (10 studies). Most intervention sessions were delivered on a weekly basis with an average duration of 14 hours. Follow-up time ranged from two weeks to 24 months.

Pooled standardised mean differences (SMD) from baseline indicated that the intervention may reduce depression (SMD -0.27, 95% confidence interval (CI) -0.52 to -0.02; P = 0.04; 27 studies, 3321 participants, I^2 = 91%, low-certainty evidence); anxiety (SMD -0.43, 95% CI -0.68 to -0.17; P = 0.0009; 22 studies, 2702 participants, I^2 = 89%, low-certainty evidence); mood disturbance in the intervention group (SMD -0.18, 95% CI -0.31 to -0.04; P = 0.009; 13 studies, 2276 participants, I^2 = 56%, low-certainty evidence); and stress (SMD -0.34, 95% (CI) -0.55 to -0.12; P = 0.002; 8 studies, 564 participants, I^2 = 31%, low-certainty evidence). The intervention is likely to improve quality of life in the intervention group (SMD 0.78, 95% (CI) 0.32 to 1.24; P = 0.0008; 20 studies, 1747 participants, I^2 = 95%, low-certainty evidence). Adverse events were not reported in any of the included studies.

Authors' conclusions

Based on the available evidence, psychological intervention may have produced favourable effects on psychological outcomes, in particular depression, anxiety, mood disturbance and stress. There was also an improvement in quality of life in the psychological intervention group compared to control group. Overall, there was substantial variation across the studies in the range of psychological interventions used, control conditions, measures of the same outcome and timing of follow-up.

PLAIN LANGUAGE SUMMARY

Use of psychological interventions in women diagnosed and under treatment for non-metastatic breast cancer

Review question

We reviewed the evidence for the effect of psychological interventions on the psychological impact and quality of life among women with non-metastatic breast cancer (that is cancer that has not spread beyond the breast). Cochrane Review authors collected and analysed all relevant studies to answer these questions and found 60 studies.

Background

Breast cancer is the most common cancer affecting women worldwide. Being a distressing diagnosis, considerable research has examined the psychological consequences of being diagnosed and treated for breast cancer. Breast cancer diagnosis and treatment can cause depression and anxiety and reduce the quality of life. As a result, various psychological interventions have been used to help address the psychological distress experienced after a diagnosis of breast cancer.

Study characteristics

The evidence was current to March 2021. An intervention could be delivered in a group setting (group intervention), as one-to-one contact between a therapist and a patient (individual intervention), or in the form of couple therapy where the patient and her spouse attend the therapy sessions (couple intervention). The control group could receive educational leaflets or have access to seminars or relaxation classes.

A comprehensive search of the literature was conducted and 60 studies comprising 7998 participants were included. The majority of interventions were based on cognitive behavioural therapy, which involves changing a person's thoughts and behaviour. Generally, the methods for assessing outcomes (such as anxiety, depression, quality of life) after the intervention and the timing of these assessments were not uniform across studies.

Key results

Women who received psychological therapy showed reductions in depression, anxiety, mood disturbance and stress, as well as an improvement in quality of life compared to the control group. The effect of psychological therapy on coping and survival could not be determined because very few studies collected or reported these outcomes.

Adverse events were not reported or studied in any of the included studies.

Further research should aim to provide evidence for people to make informed decisions about whether the effects of these treatments are sustainable after discontinuation of the therapy.

Certainty of the evidence

The evidence for each outcome was low certainty. The interventions varied between studies as did the methods and timing of outcome measures and care received within the control groups.

SUMMARY OF FINDINGS

Summary of findings 1. Cognitive behavioural therapy versus control for women with non-metastatic breast cancer

Cognitive behavioural therapy versus control for women with non-metastatic breast cancer

Patient or population: Women with non-metastatic breast cancer
Settings: Clinics or cancer centres
Intervention: Psychological interventions versus control

Outcomes	Illustrative comparative risks* (95% CI) Corresponding risk Psychological therapy versus control	No of Participants (studies)	Certainty of the evidence (GRADE)	Comments
Depression Hospital Anxiety and Depression Scale (HADS) or Beck Inventory Score (HADS score range from 0 to 21 and Beck Inventory Score range from 0 to 63)[1] Follow-up: 1 to 12 months	The mean depression in the intervention groups was **0.27 standard deviations lower** (0.52 to 0.02 lower)	3321 (27 studies)	⊕⊕⊖⊖ **low**[2,3,4]	SMD (-0.27, 95% confidence interval (CI) -0.52 to -0.02)
Anxiety Hospital Anxiety Scale, STAI **(**State-Trait Anxiety Inventory) Follow-up: 4 to 12 weeks	The mean change in anxiety in the intervention groups was **0.43 standard deviations lower** (0.68 to 0.17 lower)	2702 (22studies)	⊕⊕⊖⊖ **low**[5,6,7]	SMD (-0.43, 95% CI -0.68 to -0.17)
Mood disturbance Profile of mood state (higher score indicates more mood disturbance, score range from 0 to 200) Follow-up: 1 to 12 months	The mean mood disturbance in the intervention groups was **0.18 standard deviations lower** (0.31 to 0.04 lower)	2276 (13 studies)	⊕⊕⊖⊖ **low**[8,9,10]	SMD (-0.18, 95% CI -0.31 to -0.04)
Quality of life Several tools were used e.g. EORTC, FACT B, Medical outcomes, QoL Cancer Survivor Follow-up: 1 to 12 months	The mean quality of life was **0.78 standard deviations higher** (0.32 lower to 1.24 higher)	1747 (20 studies)	⊕⊕⊖⊖ **low**[7, 11, 12,13]	SMD (0.78 (95% CI 0.32 to 1.24)
Stress Follow-up: 6 weeks to 12 months	The mean stress the intervention was **0.34 standard deviations lower** (0.55 to 0.12 lower)	564 (8 studies)	⊕⊕⊖⊖**low**[7,14,15]	SMD -0.34 (95% CI -0.55 to -0.12

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

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

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[1] A higher score on either tool indicated higher depression
[2] No allocation concealment in one study, in 19/27 studies allocation concealment was not reported
[3] Several scales were used to measure the outcome
[4] Unexplained heterogeneity was introduced by three studies
[5] Allocation concealment was not reported in 16/22 studies
[6] Several tools and several subscales were used to measure the outcome
[7] In two studies, the high percentage of losses to follow up could not be explained
[8] Allocation concealment was not done in 7/13 studies
[9] Different forms of the POMS tool was used to measure mood disturbance (i.e. total score versus sub-scale score)
[10] The high percentage of losses to follow up could not be explained
[11] allocation concealment was not reported in 15/20 studies
[12] Several tools were used to measure QoL
[12] In one study allocation concealment was not done
[13] Several tools were used to measure QoL
[14] Allocation concealment was not reported in 4/8 studies
[15] The sample size was too small in one study
The quality of evidence was downgraded in all outcomes by two levels because of serious imprecision because the confidence interval for the pooled estimate is wide and crosses or nearly crosses unity.

BACKGROUND

Description of the condition

Breast cancer remains the most common cancer in women of all ages with an estimated two million new cancer cases diagnosed in 2018 (23% of all cancers), and ranks second overall (10.9% of all cancers) (Zaidi 2019). In 2018, it is estimated that 627,000 women died from breast cancer, that is approximately 15% of all cancer deaths among women (WHO 2021). Improved prevention and detection methods, as well as advances in medical treatment, have resulted in recognising breast cancer as a chronic condition rather than a life-threatening illness (Bodai 2015). The survival gains achieved in breast cancer have led to a greater emphasis on rehabilitation and management of long-term sequelae of the constellation of therapeutic modalities (Bodai 2015). Despite the growing recognition of the need to address the psychological requirements of patients with cancer, current practice has lagged in targeting the psychological elements of living with cancer resulting in disparity in comprehensive cancer care (Greer 2013).

Breast cancer is still a distressing diagnosis and, as a result, considerable research has examined the psychological sequelae of being diagnosed and treated for breast cancer (Jassim 2015). In line with the increasing adoption of a bio-psychosocial model of health care, one focus of interest has been to determine whether a diagnosis of breast cancer is associated with specific psychological disorders, and what course these take in patients (Malik 2013). Psychological morbidities such as anxiety, depression, stress, distress, difficulty in adjustment and decreased social interactions are common responses to the diagnosis and treatment of breast cancer (Malik 2013). Such responses may arise from pain, fear of recurrence, treatment side-effects, life stresses and lymphoedema (Koch 2013). Many women consider chemotherapy as the most distressing aspect of treatment as it is usually associated with unpleasant symptoms such as nausea, emesis, fatigue, pain and alopecia (partial or complete loss of hair) (Hellerstedt-Börjesson 2016). The debilitating effects are more profound in younger women who also experience consequences of menopause, including loss of fertility and physiological symptoms such as night sweats, hot flashes, vaginal dryness, and weight gain (Trogdon 2016; Rosenberg 2013).

The considerable data available suggest that many people with breast cancer experience fatigue, depression, and/or anxiety months to years after their breast cancer diagnosis, with these symptoms being associated with greater disability and a poorer quality of life (Tsaras 2018; Syrowatka 2017). The prevalence of depression in breast cancer survivors varies greatly from as low as 1% to as high as 56% depending on how it is defined (Zainal 2013). Reviewing 72 studies in 30 countries, the global prevalence of depression among breast cancer patients was found to be 32.2% with the highest rates observed in the Eastern Mediterranean region and twice as high in middle-income countries as compared to developed countries (Pilevarzadeh 2019). This wide variation in rates of psychological disorders may be attributed to methodological differences across studies, different characteristics of the groups studied heterogeneous tumour stage and the stage at which assessment took place in relation to diagnosis or treatment. Further, the use of different diagnostic criteria for depression and anxiety may have contributed to the different rates reported in the above studies (Zainal 2013; Pilevarzadeh 2019).

Psychological morbidities also include distress and mood disturbance which are often used interchangeably. The National Comprehensive Cancer Network (NCCN) has recognised distress as an important sequela of cancer diagnosis and treatment (NCCN 2019). Up to one-quarter of studied women with breast cancer maintained clinically significant levels of distress over a 12-month period (Millar 2005). Distress intensified when women expected symptoms to disappear but symptoms persisted instead (Rosedale 2010). Further, it increased particularly in younger women when they faced fertility concerns as well as associated menopausal issues (Rosenberg 2013). The recent literature also suggests that fear of recurrence is one of the most prevalent and prominent concerns for patients for which they seek professional help (Alfano 2019). People with existing psychological disorders, such as anxiety or depression, may be at higher risk for severe levels of fear of recurrence suggesting that it is a unique and significant mental health issue (Alfano 2019).

Predictors of psychological morbidity following breast cancer diagnosis and treatment were primarily related to the patient (namely marital status and presence of children rather than to the disease or treatment; Schlegel 2012). It was also demonstrated that these effects may last as long as one year post-treatment (if not more) (Schlegel 2012). A recent review reported that predictors associated with distress among breast cancer patients were: younger age, non-Caucasian ethnicity, being unmarried, lower socioeconomic status, lower education, and lower income. Breast cancer characteristics and treatments predictive of distress were more advanced cancer at diagnosis, treatment with chemotherapy, longer primary treatment duration and breast cancer recurrence (Syrowatka 2017).

In addition to specific psychological disorders such as anxiety and depression, over the last two decades, quality of life (QoL) outcomes have been increasingly used as a crucial and meaningful endpoint, particularly in oncology (Marta 2017). Arm problems, comorbidity, age, surgery, and, to a lesser extent, marital, educational and employment status were significantly associated with the quality of life of breast cancer patients (Engel 2003). As a consequence of the effects of breast cancer on depression, anxiety and QoL, various psychological interventions have been utilised to help address the psychological distress experienced after a diagnosis of breast cancer.

Description of the intervention

Psychological intervention includes a wide range of therapeutic techniques and is poorly defined in the literature.

Cognitive behavioural therapy (CBT) is a psychotherapeutic approach that aims to solve problems concerning dysfunctional cognition, emotions and behaviours through a goal-oriented systematic procedure. CBT includes a variety of approaches and therapeutic systems; some of the most well known include cognitive therapy, rational emotive behaviour therapy and multimodal therapy. CBT focuses on changing specific thoughts or behaviours or on learning specific coping skills (Hopko 2008), such as progressive muscle relaxation training, meditation, hypnotherapy, systematic desensitisation, biofeedback, behaviour modification or reinforcement and cognitive therapy. In the past decade, research has supported mindfulness-based therapies such as meditation for a number of medical and psychological conditions accompanying breast cancer diagnosis and treatment

(Carlson 2003; Lengacher 2009). In recent years, CBT therapists have witnessed a shift towards focused therapies such as acceptance and commitment therapy (ACT) (Dahl 2004).

Psychotherapy, or personal counselling with a psychotherapist, is an intentional interpersonal relationship used by trained psychotherapists to aid a client or patient in problems of living. It includes non-directive, psychodynamic, existential, supportive, general or crisis intervention; no specific behavioural or coping skills are taught (Barsevick 2002).

A psycho-educational intervention is the education offered to people who live with a psychological disturbance. Frequently, psycho-educational training involves patient training courses in the context of treating a physical illness (Bäuml 2008). Family members are also included in the education. Patients and their relatives are empowered to understand and accept the illness and cope with it in a successful manner (Bäuml 2008). The goal is for the patient to understand and deal with the presenting illness. Also, the patients' own strengths, resources and coping skills are reinforced in order to avoid relapse and for them to contribute to their own health and wellness on a long-term basis. The theory considers that the better knowledge the patient has of her illness, the better the patient can live with her condition.

These interventions can be delivered individually or in a group. Group therapy, is a form of psychotherapy in which one or more therapists treat a small group of clients (Montgomery 2002). The term refers to any form of psychotherapy when delivered to a group, including CBT, interpersonal therapy and psychodynamic group therapies; the group process explicitly using mechanisms of change by developing, exploring and examining interpersonal relationships within the group.

How the intervention might work

The purpose of psychological support programmes in breast cancer is to promote awareness and education, provide emotional support, and assist women with problem-solving so that they can go through the processes and cope better with cancer (Sandgren 2000). It has been suggested that understanding the uncertainty that is experienced plays a key role in positively influencing future behaviours (Montgomery 2010). Based on Garssen 2010, the most important mechanisms that can be identified through which these interventions might work include: (1) increasing knowledge on cancer (psycho-education or social support groups), (2) enhancing coping skills (psychotherapy or cognitive behavioural interventions), or (3) expressing emotions (psychotherapy or social support groups).

Why it is important to do this review

An update is warranted given the availability of new trial data showing conflicting results. The previously published review on the same topic (Jassim 2015) yielded that psychological intervention, particularly cognitive behavioural therapy, has a general benefit in reducing the severity of psychological symptoms and improving quality of life, but the effect was uncertain for survival. Since the publication of this review, there has been a growing body of evidence evaluating different forms of psychological interventions on breast cancer patients. Several items pertaining to the intervention remained unsolved in the previous review for instance duration, dose, type, and the optimal time to start therapy. Further, the amount of heterogeneity between studies in the previous review has been substantial. Hence, we conducted this updated systematic review to explore the uncertainty arising from conflicting results in a number of recent studies in this area.

OBJECTIVES

To assess the effect of psychological interventions on psychological morbidities and quality of life among women with non-metastatic breast cancer.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials which compare any form of psychological or behavioural intervention with a placebo, waiting list control or an alternative form of psychological intervention.

Types of participants

Women with a histologically confirmed diagnosis of breast carcinoma of an early non-metastatic stage (Grade I-III) as defined by the American Joint Committee on Cancer (AJCC) TNM (tumour, lymph nodes, metastasis) staging system (American Joint Committee on Cancer 2009).

We excluded:

- studies including women with distant metastasis (Grade IV) unless there were subgroup analyses;
- studies including patients with other types of cancer unless there were subgroup analyses of breast cancer groups;
- studies about psychological intervention in caregivers of women with breast cancer as they represent a different entity.
- studies evaluating psychological intervention in women with genetic predisposition for breast cancer.

Types of interventions

A range of psychological interventions to treat psychological distress were eligible for inclusion:

- cognitive behavioural techniques;
- psychotherapy or counselling; and
- psycho-educational interventions.

We compared these interventions with an inactive control intervention; that is placebo, standard care or waiting list control: 'a group that is assigned to a waiting list to receive an intervention after the active treatment group does', or with an active control intervention (for example, another form of psychological intervention). Studies with multi-interventions were excluded unless data were extractable.

Types of outcome measures

Primary outcomes

- Depression: depression score measured using any validated disease specific tool at the end of the study

- Anxiety: anxiety score measured using any validated disease specific tool at the end of the study
- Stress: stress score measured using any validated disease specific tool at the end of the study
- Mood disturbance: mood disturbance score measured using any validated disease specific tool at the end of the study

Secondary outcomes

- Quality of life (QoL): QoL score measured using any validated questionnaire at the end of the study
- Coping: coping score measured using any validated disease specific tool at the end of the study
- Adjustment: adjustment score measured using any validated disease specific tool at the end of the study
- Fear of cancer recurrence: score measured using any validated disease specific tool at the end of the study
- Survival: all-cause patient survival at the latest study time point

Search methods for identification of studies

See: Breast Cancer Group methods used in reviews.

There were no language limits. We included articles in any language and translated relevant articles.

Electronic searches

We searched the following databases up to 16 March 2021:

1. The Cochrane Breast Cancer Group's (CBCG) Specialised Register was maintained by the Cochrane Breast Cancer Group. Details of the search strategies used by the CBCG for the identification of studies and the procedure used to code references are outlined in their module (http://onlinelibrary.wiley.com/o/cochrane/clabout/articles/BREASTCA/frame.html). Trials with the keywords 'psychological intervention', 'early breast cancer', 'cognitive-behavioral technique', 'cognitive behavioral therapy, 'psychotherapy', 'psycho-educational therapy', 'psychotherapeutic', 'CBT' and 'acceptance and commitment therapy' were extracted for consideration.
2. The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2021, Issue 4). See Appendix 1.
3. MEDLINE (via OvidSP) (July 2008 to 3 May 2021). See Appendix 2.
4. Embase (via OvidSP) (2013 to 3 May 2021) See Appendix 3. Previous searches were conducted in Embase via Embase.com (2008 to 2013). See Appendix 4.
5. PsycINFO (via OvidSP) (1960 to 3 May 2021). See Appendix 4.
6. CINAHL (via EBSCO) (1982 to 3 May 2021). See Appendix 5.
7. The World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) search portal (http://apps.who.int/trialsearch/Default.aspx) for all prospectively registered and ongoing trials. See Appendix 6.
8. Clinicaltrials.gov (http://clinicaltrials.gov/ct2/search). See Appendix 7.

In the original version of the review, we searched additional databases including CancerLit, PsyLit, Iranmedex, Indmed (July 2008 to May 2013). See Appendix 8; Appendix 9; Appendix 10; Appendix 11.

Keywords used were: breast cancer, breast neoplasm, quality of life, well-being, depression, anxiety, stress, distress, adjustment, coping, mental health, health-related quality of life, psychological intervention, psychological morbidity, psychiatric morbidity, cognitive behavioral therapy, group psychotherapy, relaxation, supportive therapy, visual imagery and psychosocial intervention.

Searching other resources

We conducted the following searches.

Bibliography searching

The bibliographies of all included studies and review papers were searched in order to identify other potentially suitable studies. Articles cited by relevant studies were reviewed. Language restrictions were not imposed. We conducted full translations of all non-English language papers using local resources.

Unpublished literature

Experts in this field were contacted. Letters were sent to all authors of included studies requesting information on unpublished data or ongoing studies.

Hand searching of journals

A list of journals currently being hand-searched by The Cochrane Collaboration is available on the US Cochrane Center Handsearch master list page (http://apps1.jhsph.edu/cochrane/masterlist.asp).

Data collection and analysis

Selection of studies

Two review authors (GJ and SD) independently assessed the titles and abstracts of each identified trial for inclusion into the review. After the initial assessment, we obtained full versions of all potentially relevant articles. A third author (DW) was approached to resolve any discrepancies regarding eligibility. We used Covidence 2021 to enter and screen abstracts.

If the results of a randomised controlled trial (RCT) were unpublished but available, and three review authors (GJ, SD, and DW) were satisfied with the quality of the data, data were included (where possible) and disclosed in the discussion section.

Data extraction and management

Data from all relevant studies were extracted and entered into the 'Characteristics of included studies' table in RevMan Web (Review Manager 2020). All studies were appraised independently by two review authors (GJ, SD). Any disagreement was resolved by discussion. Extracted data included the following.

(a) Participants: country of origin, sample size, setting, diagnostic criteria, age, ethnicity, date of study and data on baseline psychological morbidity for assessment of effect modifiers.
(b) Methods: study design, methods of allocation, allocation sequence concealment, blinding, exclusion of participants after randomisation, proportion and reasons for loss at follow-up.
(c) Interventions: type, dose, length and frequency of intervention (for each intervention and comparison group).
(d) Outcomes: primary and secondary outcomes using validated instruments were extracted.

If mentioned, sources of funding were recorded in the Characteristics of included studies table.

Assessment of risk of bias in included studies

Two review authors (GJ and SD) graded and assessed each selected trial using a simple contingency form, addressing the seven specific domains discussed in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). The evaluations given by all review authors were compared and any inconsistencies and disagreements were resolved by discussion. Each domain was assigned a judgement related to the risk of bias in that domain. Judgements used were: 'low risk of bias', 'high risk of bias', and 'unclear', which indicated unclear or an unknown risk of bias. The domains were:

1. sequence generation;
2. allocation concealment;
3. blinding of participants and personnel;
4. blinding of outcome assessors;
5. incomplete outcome data;
6. selective outcome reporting; and
7. other sources of bias.

Assessment of these domains for each trial are reported in the Risk of bias in included studies. We also categorised and reported the overall risk of bias of each of the included studies according to the following:

- low risk of bias (bias is unlikely to seriously alter the results) if all criteria were met;
- unclear risk of bias (bias raises some doubt about the results) if one or more criteria were assessed as unclear; and
- high risk of bias (bias seriously weakens confidence in the results) if one or more criteria were not met.

Measures of treatment effect

The data could have been presented as continuous (for example changes in depression scales), dichotomous (for example either depressed or not depressed), ordinal (for example categories on a QoL scale such as mild, moderate and severe), or time-to-event data (for example survival data). Decisions regarding if and how to combine these outcomes were made depending on how the data were collected by each trial. These decisions were guided by section 9.2 'Types of data and effect measures' in the *Cochrane Handbook for Systematic Reviews of Interventions* 5.0.0 (Higgins 2011).

For continuous data, we presented the change from baseline as the standardised mean difference (SMD) due to the same outcome being measured in a variety of ways using different scales. For future updates, the mean and standard deviation (SD) will be reported if possible (that is when the outcome measurements in all studies are made on the same scale).

We interpreted the SMD estimates based on the Cohen method as follows: SMD < 0.4 corresponded to a small effect, 0.4 to 0.7 corresponded to a moderate effect and > 0.7 corresponded to a large effect (Chapter 15.5.3.1; Higgins 2022).

Dichotomous data were not used in this version of the review. In future updates of the review, if presented with dichotomous data and the authors have specified a cut-off point for determining clinical effectiveness, we will use this where appropriate. Otherwise, cut-off points on rating scales will be identified and participants will be divided on the basis of whether they were clinically improved or not. For dichotomous outcomes in future updates, a Mantel-Haenszel odds ratio with (OR) its associated 95% confidence interval (CI) will be estimated.

In the case of time-to-event data (overall all-cause survival and progression-free survival), intervention effects were expressed as hazard ratios. (HRs)

All measures of effect included 95% CIs, P values, and for pooled measures the I^2statistic.

Unit of analysis issues

No studies were identified that experienced unit of analysis issues and it is unlikely that studies of this type will be identified in future updates. If these complications are found in updates, guidance will be taken from *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) and changes between the protocol and the updated review will be highlighted.

If the study included three arms, only two arms will be compared, the standard professional-led psychological intervention and the control arm.

Dealing with missing data

If data were missing from trials less than 10 years old, we tried wherever possible to contact the investigators or sponsors of these studies.

We re-analysed data according to the intention-to-treat (ITT) principle whenever possible. If authors had conducted a per protocol analysis instead of an ITT analysis these results were included.

Where baseline and follow-up data only were summarised, the change from baseline scores have been estimated assuming a common correlation of structure of 0.8 (section 16.1.3.2 in the *Cochrane Handbook for Systematic Reviews of Interventions)* (Higgins 2011). In cases where variability data were summarised at baseline but not at follow up, the variance was assumed to have remained unchanged.

In cases where medians were presented with ranges, the mean was estimated by the median and the variance by using the range and the number of observations (Hozo 2005).

Assessment of heterogeneity

To check for statistical heterogeneity between studies, we used both the I^2 statistic and Chi^2 test of heterogeneity as well as visual inspection of the forest plots. The graphical representation of the data was inspected; if CIs for the results of individual studies have poor overlap it generally indicates the presence of statistical heterogeneity. In addition, the Chi^2 test was performed to check for differences between the results of each included trial. A P value of 0.10, rather than the conventional level of 0.05, was used to determine the statistical significance. A low P value provides evidence of heterogeneity of intervention effects Higgins 2011. The I^2 statistic was used to quantify inconsistency across studies.

We assessed clinical heterogeneity by examining the characteristics of the studies, the similarity between the types of participants and the interventions. We reported heterogeneity as important if it was at least moderate to substantial with the I^2 statistic greater than 60% (Higgins 2011). If this could be explained by clinical reasoning and a coherent argument could be made for combining the studies, these were entered into a meta-analysis. In cases where the heterogeneity could not be adequately explained, the data were not pooled.

Assessment of reporting biases

We followed the recommendations on testing for funnel plot asymmetry as described in section 10.4.3.1 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). In future updates of this review, tests for funnel plot asymmetry will be used only when there are at least 10 studies included in the meta-analysis. When there are fewer than 10 studies the power of the tests is too low to distinguish chance from real asymmetry. We will visually inspect the funnel plots and discuss reasons for funnel plot asymmetry in the discussion. We will follow the proposed tests for funnel plot asymmetry as outlined in table 10.4.b in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Data synthesis

One review author (BC) analysed the data in Review Manager 2020 and reported them in accordance with the advice in Chapter 9 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Where data could be pooled, for continuous outcomes an inverse variance approach was taken to meta-analysis fitting a random-effects model. The degree of heterogeneity was summarised with the I^2 statistic. The time-to-event data were pooled using the generic inverse variance method and the hazard ratio presented.

The methods outlined in Chapter 12 of the updated Cochrane handbook were used for outcomes where numerical data ware lacking or have been measured in diverse ways. We will apply the methods such as vote-counting based on the direction of effect as outlined by McKenzie 2022. Information from these studies will be presented in tabular format.

Subgroup analysis and investigation of heterogeneity

Subgroup analyses were conducted to test the interaction between the variables determined a priori and the overall treatment effect. Subgroup analysis was conducted when the data were available for extraction and analysis.

In this review, two of the six pre-specified subgroup analyses were possible using the available data: (1) different doses of psychological intervention (≤ 20 hours versus > 20 hours) and (2) group versus individually-delivered intervention.

The reason why some subgroup analysis were not possible included: the effect of the intervention was incompletely reported e.g. effect estimate with no measure of precision, the direction of effect with P value or statement of statistical significance, or direction of effect alone. If possible, in future review updates we will consider conducting the following.

- Age of participants (≤ 50 years versus > 50 years).
- Dose of psychological intervention (≤ 20 hours versus > 20 hours).
- Duration of psychological intervention (≤ 8 weeks versus > 8 weeks).
- Type of psychological intervention (individual versus group).
- Type of therapy received (total mastectomy versus conservative surgery, chemotherapy, radiotherapy and hormonal therapy).
- Time point at which the outcome (i.e. with placebo too) was assessed (≤ 4 months after surgery versus > 4 months).

Sensitivity analysis

The impact of the methodological quality on overall effect size was determined by sensitivity analyses. Sensitivity analyses were conducted to assess the robustness of the review results by carrying out the following, where possible:

- where heterogeneity existed, the removal of those studies that were considered to be estimating a different effect;
- removal of studies with high risk of bias and including studies with low risk of bias only.

Summary of findings and assessment of the certainty of the evidence

Two review authors (GJ and SD) assessed the certainty of evidence using the GRADE approach, used GRADEproGDT software, and presented the review results in Summary of findings 1. The GRADE approach incorporates five domains - risk of bias, inconsistency, indirectness, imprecision, and publication bias.

We presented the overall certainty of the evidence for the main outcomes listed below.

- Depression
- Anxiety
- Mood disturbance
- Quality of life
- Stress

RESULTS

Description of studies

See: Figure 1; Characteristics of included studies table and Characteristics of excluded studies table.

Figure 1. Figure 1. Study flow diagram.

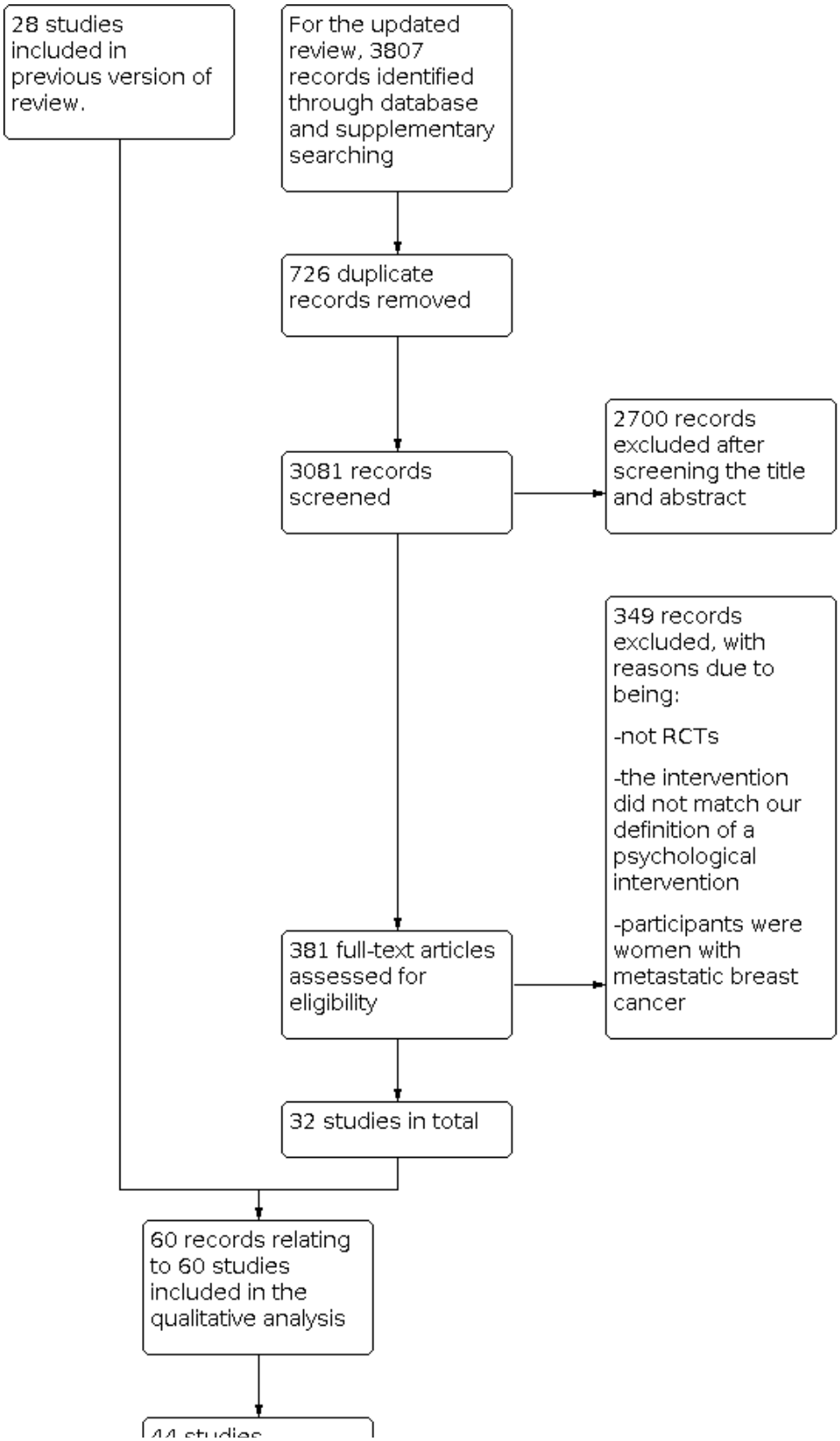
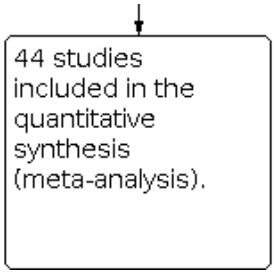


Figure 1. (Continued)



Results of the search

In this updated review, 3807 records were identified through database searching 2013 onwards. After examination of the titles and abstracts of these references, two review authors (GJ and SD) removed duplicate records and those which did not match our inclusion criteria. We assessed 381 full-text articles for eligibility and 32 studies proved to be eligible for inclusion in this review.

In total, we included 60 studies (28 from the previous review and 32 from the updated search) in this updated review. The reasons for the exclusion of key studies are provided in the Characteristics of excluded studies table. For further details see the 'Study flow diagram' (Figure 1).

Included studies

In total, 60 studies were included in this review, 28 from the previous review (Jassim 2015) and 32 new records added after the updated search. The 60 records comprise 7998 participants. The studies were very heterogeneous in the interventions studied, the reporting of outcomes, and the point at which the outcome was measured.

Characteristics of the trial setting and methods

We included randomised controlled trials(RCTs). Of the studies that were included overall, they were conducted in the USA (24 RCTs), Europe (15), Iran (4), Japan (2), Australia (2), Canada (3), China (2), Republic of Korea (3), Singapore (1), Hong Kong (1), Turkey (1), Israel (1) and Brazil (1). All but two trials (Marchioro 1996; Richardson 1997) were conducted in 2000 or beyond.

The duration of the intervention in studies ranged between two weeks and 24 months. Most studies had two groups (control and intervention), whereas six studies compared three different arms (Cohen 2007; Gudenkauf 2015; Ho 2016; Ren 2019; Richardson 1997; Vos 2004).

One study Conley 2019 was already captured in the previous review and represents a long-term outcome assessment of a previously included report Andersen 2004, so it will only be included narratively in the discussion in order not to replicate participants and findings.

Characteristics of the participants

The number of participants included in the individual studies varied widely from 14 to 575 participants. The age of the participants ranged from 18 to 80 years, with the most common lower and upper limits being 18 and 65 years, respectively. All the women had been diagnosed with early-stage breast cancer with no metastases. Five studies (Badger 2007; Baucom 2009; Manne 2007; Manne 2016; Nicolaisen 2018) included women with their partners, whereas all other studies included women only. The overall sample was generally skewed towards Caucasians. In 12 studies participants were undergoing adjuvant treatment (Badger 2007; Beutel 2013; Classen 2008; Cohen 2007; Kim 2013; Kim 2018; Manne 2016; Merckaert 2017; Mirmahmoodi 2020; Nunes 2007; Trindade 2020; Yates 2005), and in six studies they were awaiting chemotherapy (Andersen 2004; Antoni 2001; Antoni 2006; Garssen 2013; Marchioro 1996; Nicolaisen 2018). In the remaining studies, participants had completed adjuvant therapy.

Characteristics of the interventions

A wide range of interventions was evaluated. Most of the interventions were cognitive or mindfulness-based, supportive-expressive, and educational. The meditation that was used in one study (Kim 2013) involved Brain Wave Vibration meditation which is a traditional Korean training technique. In another study, (Charalampopoulou 2020), Pythagorean Self-Awareness was used which is a mental technique that incorporates the golden verses of Pythagoras to build the notion of self-awareness in individuals by adjusting the way they view themselves and others.

Most therapeutic interventions were delivered face-to-face and four were via the telephone (Badger 2007; Marcus 2010; Mishel 2005; Ashing 2014).

In some studies, mixed approaches were used (face-to-face and telephone calls or individual counselling) (Fillion 2008; Loprinzi 2011; Yates 2005), others used theoretical and practical approaches (GokMetin 2019). Five studies delivered the intervention to couples as opposed to women only (Badger 2007; Baucom 2009; Manne 2007; Manne 2016; Nicolaisen 2018). The majority of the interventions were delivered in groups, including two couple studies (Manne 2007; Manne 2016) and 10 were delivered individually, including three couple studies (Badger 2007; Baucom 2009; Nicolaisen 2018).

The mean ± SD of the total duration of the intervention was 14.02 ± 7.66 hours with a median of 12.37 (maximum 39 hours and minimum 1 hour). Three studies did not specify the duration of the intervention (Marchioro 1996; Nicolaisen 2018; Ren 2019). Most intervention sessions were delivered on a weekly basis.

The psychological interventions in the studies can be categorised into the following.

1. Cognitive-behavioural interventions: almost all studies used cognitive, cognitive-behavioural, and behavioural methods focused on changing specific thoughts or behaviours or on learning specific coping skills. Procedures coded here included

progressive muscle relaxation training, meditation, mindfulness stress reduction, problem-solving, coping strategies, systematic desensitisation, biofeedback, and behaviour modification or reinforcement.

2. Psychotherapy counselling: non-cognitive and non-behavioural verbal psychotherapy and counselling including psychodynamic, existential, supportive or general counselling, and crisis intervention (Ashing 2014; Badger 2007; Beutel 2013; Classen 2008; Dowlatabadi 2016; Marcus 2010; Nicolaisen 2018; Vos 2004).
3. Informational and psycho-educational: most of the trials included an element of education in the protocol to reinforce the existing therapy. No studies used this type of intervention solely; it was an add-on to the existing psychological treatment.

Characteristics of the outcome measures

In general, the methods of measurement and the timing of the assessments were not uniform across studies. Even when the same tool was used, in some studies only some subscales or domains were used. In other instances, the short form of the original questionnaire was used, which further increased the heterogeneity in the data.

Depression was measured by several tools such as the Beck Depression Inventory (BDI), the depression subscale of the Hospital Anxiety and Depression Scale (HADS), the Center for Epidemiological Studies-Depression Scale (CES-D), Hamilton depression rating scale (HAMD-17), and Depression Anxiety Stress scale (DASS-21).

Anxiety was measured using the State-Trait Anxiety Inventory (STAI), the Beck Anxiety Inventory (BAI), the anxiety subscale of the HADS, the Hamilton Rating Scale for Anxiety (HAM-A), and Depression Anxiety Stress scale (DASS-21), and the Smith Anxiety Scale.

Mood disturbance was mostly measured using the Profile of Mood States (POMS) and one study used the Affect Balance Scale (ABS) (Kissane 2003), which is composed of four positive and four negative subscales. The POMS has six subscales (anxiety, depression, vigour, anger, fatigue, and confusion) and a global score. The Total Mood Disturbance Score (TMDS) is the sum of five scales (anxiety, depression, anger, fatigue, and confusion) minus the score of the vigour scale. In some studies, not all subscales were used, for example in Fillion 2008 anxiety and depression subscales were used; in Antoni 2001 anxiety, depression and anger were used; however, in Vos 2004 all five subscales were used. In other studies, the short form was used (Mishel 2005; Richardson 1997).

Stress and distress were used interchangeably and were measured using the Impact of Events Scale (IES), perceived stress scale, Brief Symptom Inventory (BSI), and the Mental Health Inventory (MHI).

Coping and adjustment were measured using the Mental Adjustment to Cancer (MAC) scale, the Cancer Behavior Inventory (CBI), the 16-PF personality questionnaire Form A, the Index Introject Questionnaire, the Dealing with Illness Inventory, the Coping Strategies Questionnaire (CSQ), the Ways of Coping Questionnaire (WCQ) and the Utrecht Coping List (UCL).

Quality of life outcomes were measured using the EORTC C-30 and the QLQ-BR23, the Functional Assessment of Cancer Therapy-Breast (FACT-B) measure, the Fu (LASA) and Quality of life cancer survivors (QoL CS), Functional Living Index Cancer (FLIC), the Quality of Life Index (QLI), the Cancer Rehabilitation and Evaluation System short form (CARES-SF), Functional living index, functional living index, World Health Organization–5 Well-Being Index (WHO-5), The Medical Outcomes Study Short Form and the Linear Analog Self Assessment Scale. The EORTC score has been reported as a raw score or as a transformation score. To increase comparability the raw score was converted to the transformation score using the formula in the EORTC scoring manual.

All-cause survival was reported in three studies (Andersen 2008; Boesen 2011; Kissane 2004) and was measured as the time from randomisation to death at the end of the follow-up period. There was no survival outcome reported as a result of the updated search.

When two scales were used to measure the same outcome, the one which was used mostly by other studies was chosen for consistency of results and to increase comparability. Tools can consist of many subscales or domains. The total score was included in the meta-analysis.

Clinical diversity of the interventions

This is a pragmatic review and we have aimed to combine similar interventions where possible. Whilst we acknowledge the differences between interventions across studies, we are interested in investigating the generic type of intervention, for example, CBT, control, or psychotherapy. The composition of the standard care intervention (listed here as control) is dependent on the location and context of the study. In some studies, the control group received educational leaflets, whereas in others the control included access to seminars. In one study the control group had access to relaxation classes (Kissane 2003).

Excluded studies

We reported the reasons for exclusion for some of excluded studies in the 'Characteristics of excluded studies' table. The most frequent reasons for exclusion were non-randomised trials and inclusion of women with metastatic disease.

Risk of bias in included studies

We assessed the risk of bias for each included study and reported the judgements for the individual risk of bias domains in the 'Risk of bias' table. We have also presented these in the 'Risk of bias' summary in Figure 2. In addition, an overall risk of bias was determined for each study and 12 were categorised as high risk of bias because one or more risk domains received a judgement of high risk (Classen 2008; Cohen 2007; Graves 2003; Kissane 2003; Loprinzi 2011; Narváez 2008; Richardson 1997; Dowlatabadi 2016; Ashing 2014; Kim 2013; Tabrizi 2016; Trindade 2020). The remaining 46 studies were rated as unclear risk of bias because one or more criteria were assessed as unclear.

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

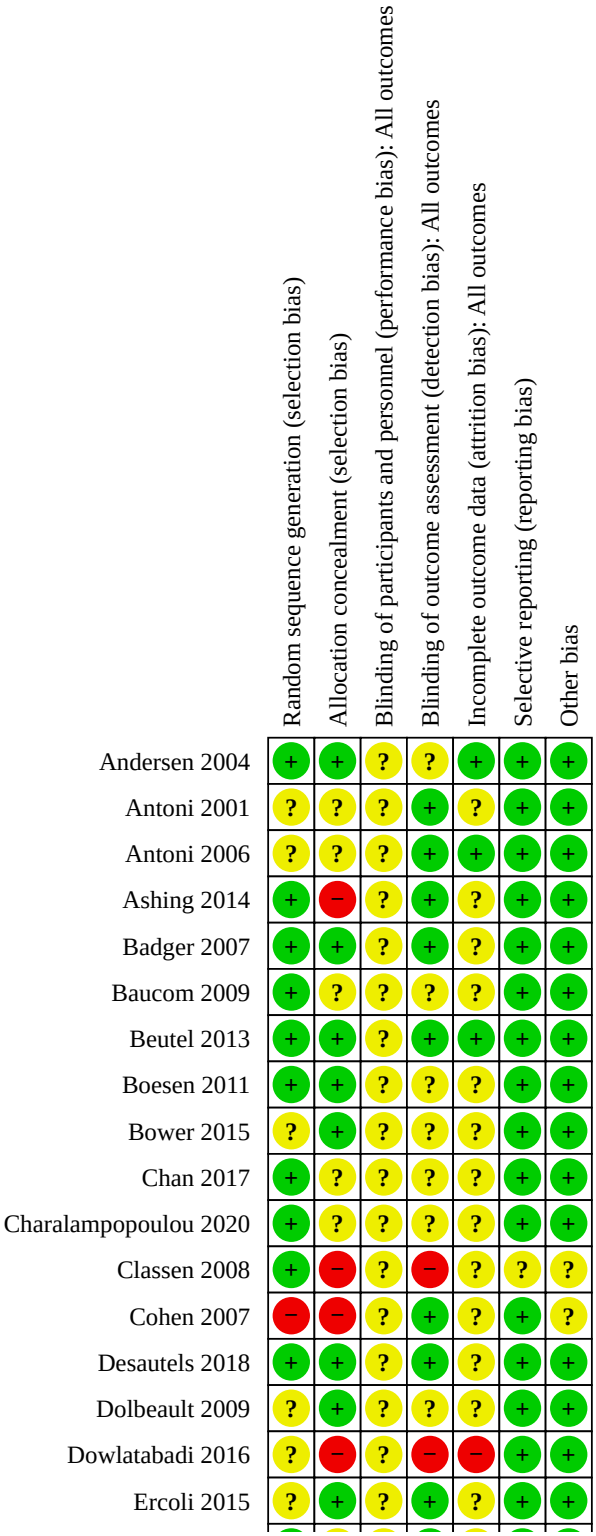


Figure 2. (Continued)

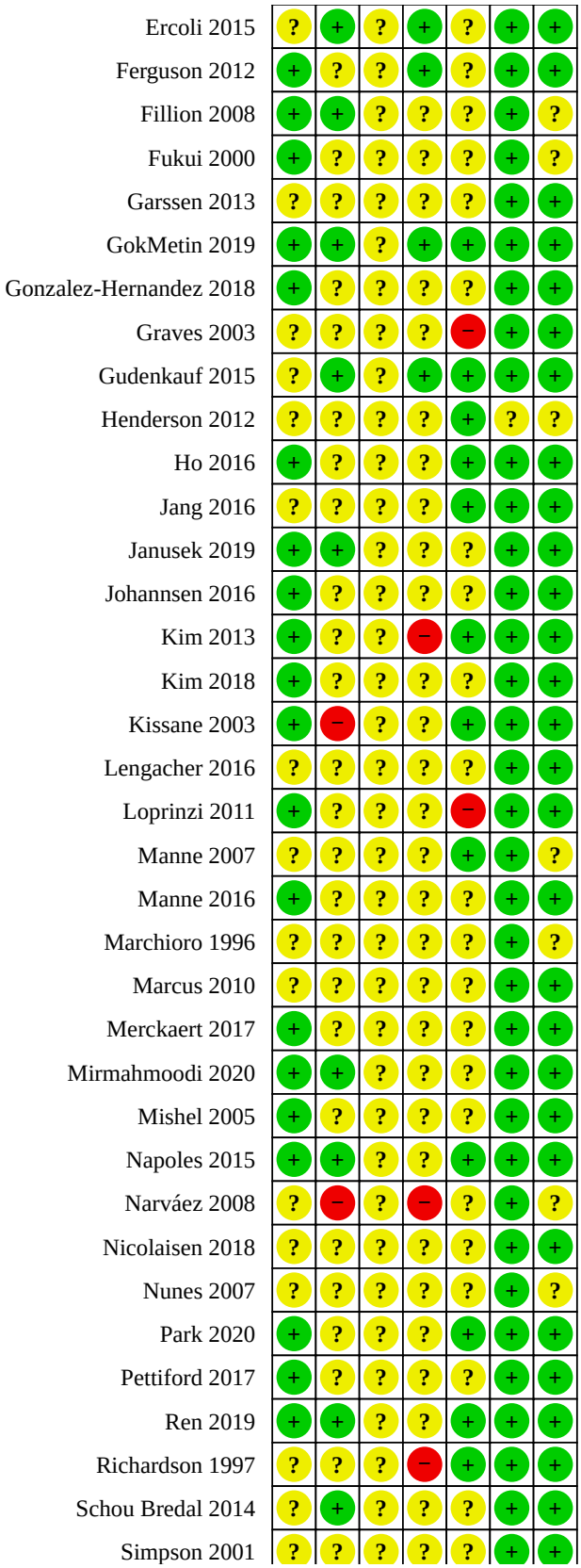


Figure 2. (Continued)

Some studies in this review did not provide sufficient details to enable accurate judgements to be made. We contacted 25 authors and were able to amend the judgements for a number of the risk domains after receiving a reply from eight trial investigators. However, if the authors mentioned in the e-mail communication that blinding or concealment was used without clarifying the method that was used for randomisation or allocation concealment the judgement remained as unclear.

Allocation

Random sequence generation

The description of the method used in random allocation was stated clearly in 35 studies (Andersen 2004; Ashing 2014; Badger 2007; Baucom 2009; Beutel 2013; Boesen 2011; Chan 2017; Charalampopoulou 2020; Classen 2008; Desautels 2018; Ferguson 2012; Fillion 2008; Fukui 2000; GokMetin 2019; Gonzalez-Hernandez 2018; Ho 2016; Janusek 2019; Johannsen 2016; Kim 2013; Kim 2018; Kissane 2003; Loprinzi 2011; Manne 2016; Merckaert 2017; Mirmahmoodi 2020; Mishel 2005; Napoles 2015; Park 2020; Pettiford 2017; Ren 2019; Tabrizi 2016; Wurtzen 2013; Yates 2005; Zahedian 2021; Zhang 2017). In Cohen 2007 a systematic order was used to allocate women, which was judged as inadequate. In the remaining studies, the information obtained about random allocation was not sufficient to permit a clear judgement.

Allocation concealment

Seven studies did not conceal allocation (Ashing 2014; Classen 2008; Cohen 2007; Dowlatabadi 2016; Kissane 2003; Narváez 2008; Tabrizi 2016) and were judged as high risk of bias. Inadequate reporting did not permit a clear judgement to be made for this domain in 35 studies, while sufficient information was obtained regarding allocation concealment in the remaining 18 trials (Andersen 2004; Badger 2007; Beutel 2013; Boesen 2011; Bower 2015; Desautels 2018; Dolbeault 2009; Ercoli 2015; Fillion 2008; GokMetin 2019; Gudenkauf 2015; Janusek 2019; Mirmahmoodi 2020; Napoles 2015; Ren 2019; Schou Bredal 2014; Zahedian 2021; Zhang 2017).

Blinding

Blinding of participants and personnel

Considering the nature of the intervention, it was not possible to blind participants or investigators to the intervention. As the effect of unblinding was unclear, studies were judged as being at unclear risk of bias.

Blinding of outcome assessors

Blinding of outcome assessors was achieved in 12 studies (Antoni 2001; Antoni 2006; Ashing 2014; Badger 2007; Beutel 2013; Cohen 2007; Desautels 2018; Ercoli 2015; Ferguson 2012; GokMetin 2019; Gudenkauf 2015; Zhang 2017). In five studies it was not done (Classen 2008; Dowlatabadi 2016; Kim 2013; Narváez 2008; Richardson 1997), and in the remaining studies, the available information was insufficient to allow a clear judgement of this domain.

Incomplete outcome data

In seven studies incomplete outcome data appeared to have been adequately addressed (Andersen 2004; Antoni 2006; Henderson 2012; Kissane 2003; Manne 2007; Richardson 1997; Yates 2005). The incomplete data were reasonably well-balanced across intervention groups, with intention-to-treat analyses reported. However, the high dropout rate and subsequent per protocol analysis of the data in two studies resulted in a judgement of high risk of bias for this domain (Graves 2003; Loprinzi 2011). In the remaining 19 studies, the number of dropouts was balanced between the groups. However, the percentage of dropouts (less than 28%) and subsequent per protocol analysis posed an unclear risk of bias.

Selective reporting

In Classen 2008 some outcomes were not reported and in Taylor 2003 only 12-month outcomes were reported because the intermediate assessment showed similar results. In Yates 2005 secondary outcomes were not reported due to non-significant results. In Henderson 2012, only major significant study outcomes were reported (with no data for distress and mental adjustment to cancer). The impact of selective reporting in these four studies was therefore unclear and this domain was judged as unclear risk of bias.

Other potential sources of bias

In 51 trials the information provided about this domain was sufficient and as a result this domain was judged as low risk of bias. In the remaining nine trials there was insufficient information to permit a clear judgement in this domain. Because of the non-therapeutic nature of the intervention, none of the studies reported any conflict of interest with pharmaceutical companies.

Effects of interventions

See: **Summary of findings 1** Cognitive behavioural therapy versus control for women with non-metastatic breast cancer

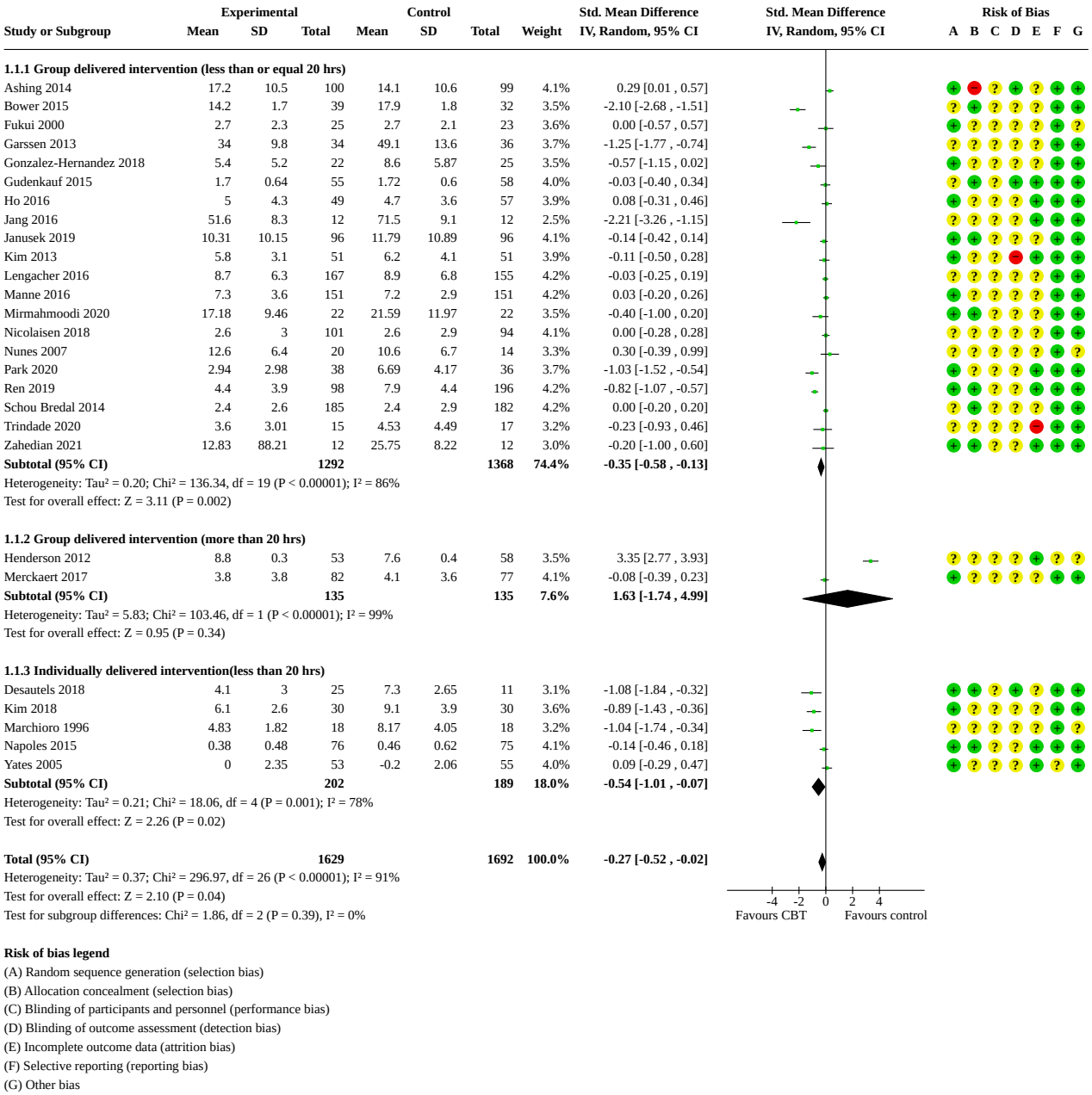
Primary outcomes

Depression

We identified 39 studies that included this outcome. Data were available from 27 studies only for meta-analysis Analysis 1.1.

The 27 studies included 1629 patients in the intervention arm and 1692 in the control arm. Overall, the pooled effect indicates a reduction in depression from baseline following the intervention compared to control. The pooled change from baseline standardised mean difference (SMD) comparing the group and individually-delivered interventions to standard care was -0.27 (95% CI -0.52 to -0.02; P = 0.04; I^2 = 91%; Chi^2 test P < 0.00001) (Analysis 1.1; Figure 3), indicating a small effect. We attempted to identify the sources of high heterogeneity by excluding one by one, excluding studies with the largest effects, and excluding studies with a high risk of bias, but we were not able to reduce the heterogeneity meaningfully.

Figure 3.



The majority of studies may have resulted in a small reduction in depression favouring the intervention. We rated this result as a low level of certainty evidence due to inconsistency in the magnitude of effect across the studies, unexplained high heterogeneity (I^2 = 91%, P < 0.00001), absence of allocation concealment in one study, unclear risk of bias in the remaining studies with respect to most domains and serious imprecision because the confidence interval for the pooled estimate is wide and crosses or nearly crosses unity.

Twenty studies carried out a group-delivered intervention for ≤ 20 hours and measured the mean difference (MD) in depression using any validated disease-specific tool at the end of the study (Ashing 2014; Bower 2015; Fukui 2000; Gonzalez-Hernandez 2018; Gudenkauf 2015; Garssen 2013; Ho 2016; Jang 2016; Janusek 2019; Kim 2013; Lengacher 2016; Manne 2016; Mirmahmoodi 2020; Nicolaisen 2018; Nunes 2007; Park 2020; Ren 2019; Schou Bredal 2014; Trindade 2020; Zahedian 2021). Two studies carried out a group-delivered intervention for more than 20 hours (Henderson 2012; Merckaert 2017), and five studies carried out an individually-delivered intervention for 20 hours or less (Desautels 2018; Kim 2018; Marchioro 1996; Napoles 2015; Yates 2005). There was no evidence to suggest any difference in interventional effect across the three subgroups (P = 0.39).

There are 12 studies that reported depression outcomes but the data were not extractable to be included in the meta-analysis. Five studies used the Center for Epidemiological Studies Depression Scale (CES-D; ; Antoni 2006; Badger 2007; Ferguson

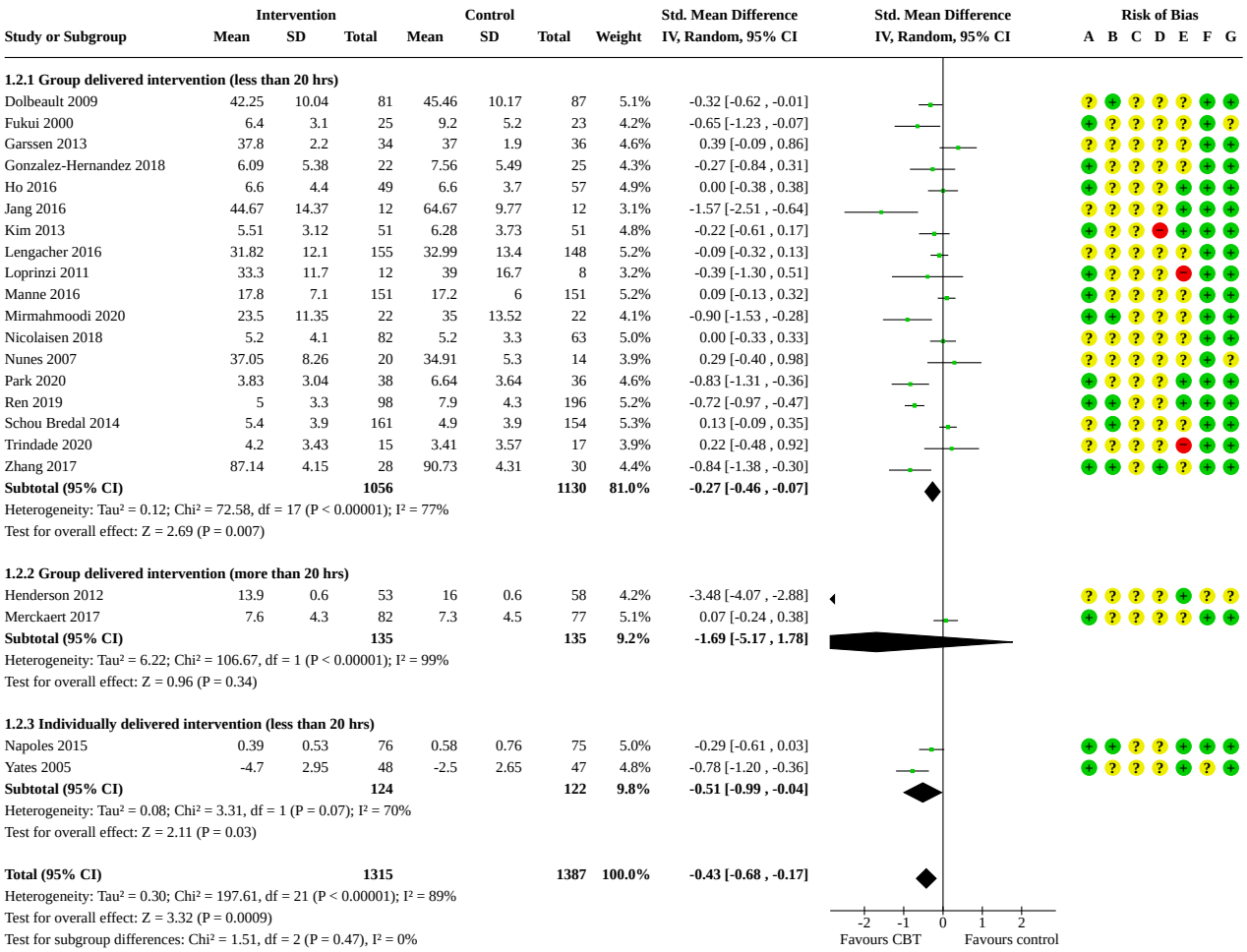
2012; Marcus 2010;Wurtzen 2013), three used Beck Depression Inventory (BDI) (Dowlatabadi 2016; Ercoli 2015; Narváez 2008), two used Hospital Anxiety and Depression Scale (HADs; Beutel 2013; Kissane 2003), one used the Depression Anxiety Stress Scale (DASS) (Charalampopoulou 2020) and oneHamilton Depression Rating Depression Rating Scale (HAM-D) (Ren 2019). The total sample size included in these studies was 1917 (856 in intervention and 1061 in control). The intervention was delivered in a group format except in three studies (Badger 2007; Ferguson 2012; Marcus 2010). Badger 2007 was an individual couple therapy. The dose of intervention was more than 20 hours in one study (30 hours - Kissane 2003). The 12 studies showed a favourable effect of the intervention in alleviating depression with varying degrees of clinical importance. With the exception of Beutel 2013, the certainty of evidence of these studies was judged as low because two or more risk of bias domains were rated as high or unclear risk of bias (Table 1).

Anxiety

Thirty-one studies reported anxiety as an outcome. We identified 22 studies that reported data that could be included in the meta-analysis and reported the change in anxiety with the intervention delivered as either group intervention for 20 hours or less (Dolbeault 2009; Fukui 2000; Garssen 2013; Gonzalez-Hernandez 2018; Ho 2016; Jang 2016; Kim 2013; Lengacher 2016; Loprinzi 2011; Manne 2016; Mirmahmoodi 2020; Nicolaisen 2018; Nunes 2007; Park 2020; Ren 2019; Schou Bredal 2014; Trindade 2020; Zhang 2017), group intervention for more than 20 hours (Merckaert 2017; Henderson 2012) or individually-delivered intervention (Napoles 2015; Yates 2005).

The 22 studies included 1315 patients in the intervention arm and 1387 in the control arm. The pooled standardised mean difference (SMD) between the intervention and control arms on the anxiety scale was -0.43 (95% CI -0.68 to -0.17; P = 0.0009; I^2 = 89%; Chi^2 test P < 0.0001) (Analysis 1.2; Figure 4), indicating a moderate effect. This suggests a reduction in anxiety in the intervention group compared to the control but the substantial heterogeneity left doubt over the comparability of these studies. Excluding studies with the largest effects and excluding studies one by one, did not explain the heterogeneity. We rated this result as a low certainty evidence due to inconsistency in the magnitude of effect across the studies, unexplained high heterogeneity, unclear risk of bias in all studies with respect to most domains, and serious imprecision because the confidence interval for the pooled estimate is wide and crosses or nearly crosses unity. There was no evidence to suggest any difference in interventional effect across the three subgroups (P = 0.47).

Figure 4. Forest plot of comparison: 1 CBT versus control, outcome: 1.3 Standardised mean difference for the change from baseline in anxiety.



Nine out of the 30 studies that reported anxiety were not included in the meta-analysis because data were not extractable. HADs was used by two studies (Kim 2018; Kissane 2003), whereas the remaining studies each used a different scale; for example Chan 2017 used Beck Anxiety Inventory (BAI) Antoni 2006 used the Hamilton rating scale for anxiety (HAM-A), Badger 2007 generated an anxiety index, and Narváez 2008 and Ferguson 2012 used the state-trait anxiety inventory (STAI). The total sample size included in these studies was 1093. The intervention was delivered in a group format except in Badger 2007, Kim 2018 and Ferguson 2012. The dose of intervention was ≤ 20 hours in all studies except Kissane 2003 (30 hours). All studies reported a possible improvement in anxiety scores favouring the intervention. The quality of these nine studies was judged as low because two or more risk of bias domains were rated as high or unclear risk of bias (Table 2).

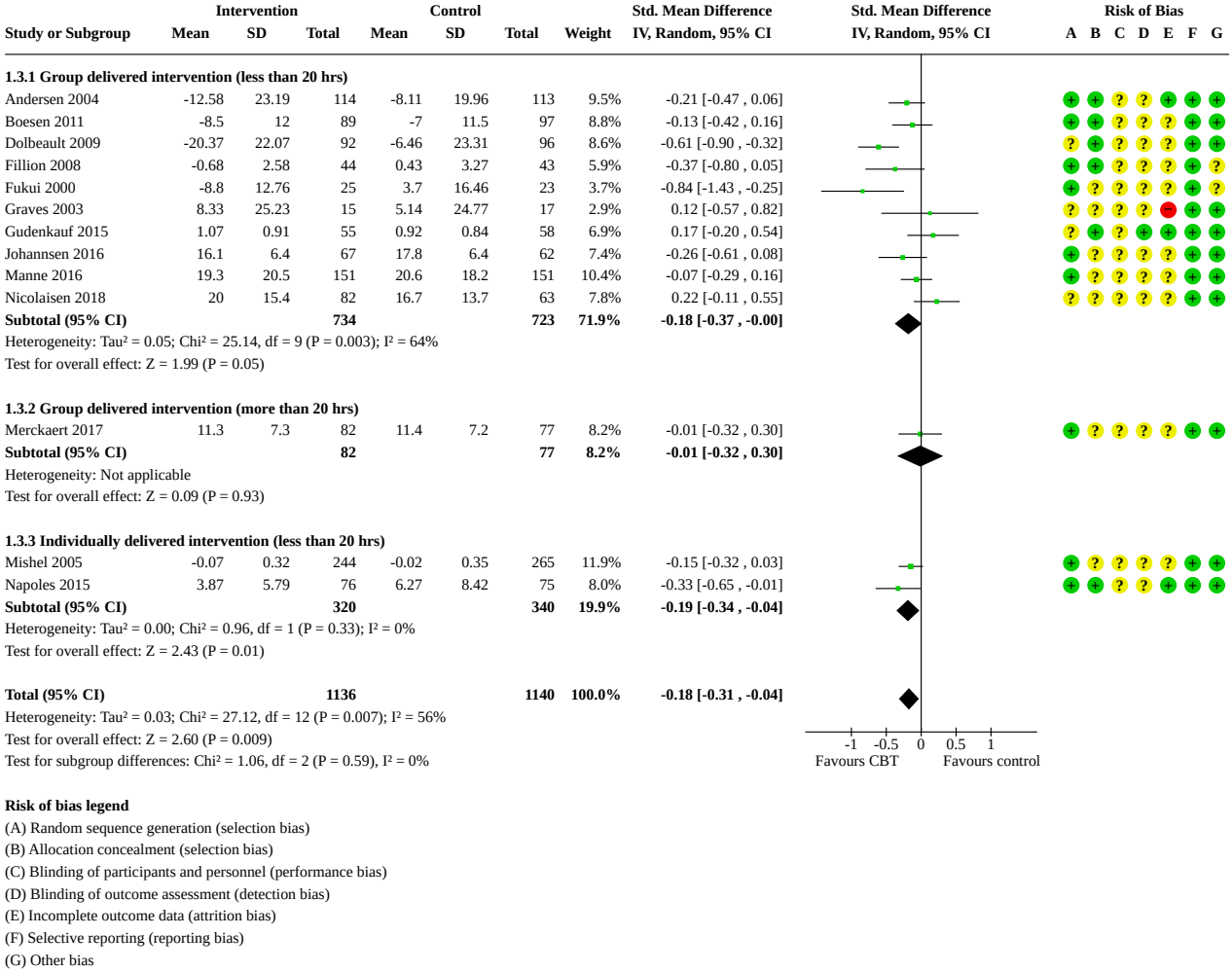
Mood disturbance

Twenty studies reported mood disturbance as an outcome. We identified 13 studies that reported data to be included in the meta-analysis and reported the change in mood with cognitive behavioural therapy delivered as a group intervention (Andersen 2004; Boesen 2011; Dolbeault 2009; Fillion 2008; Fukui 2000; Graves 2003; Gudenkauf 2015; Johannsen 2016; Manne 2016; Merckaert 2017; Nicolaisen 2018), or an individually-delivered intervention (Mishel 2005; Napoles 2015). Of the 13 studies, 10 carried out group interventions for 20 hours or less, one study carried out group interventions for more than 20 hours (Merckaert 2017), and two studies carried out individual interventions (Mishel 2005; Napoles 2015).

The 13 studies included 1136 participants in the intervention arm and 1140 participants in the control arm. The overall pooled results

showed a small reduction in mood disturbances scores in the intervention arm. The SMD between intervention and control was -0.18 (95% CI -0.31 to -0.04; P = 0.009; I^2 = 56%; P = 0.007; Analysis 1.3; Figure 5), indicating a small effect.

Figure 5. Forest plot of comparison: 1 CBT versus control, outcome: 1.4 Standardised mean difference for the change from baseline in mood disturbance.



The same result was reported for the three subgroups (group delivered ≤ 20 hours, group > 20 hours, and individual delivered ≤ 20 hours). There was no evidence to suggest any difference in interventional effect across the three subgroups (P = 0.59; I^2 = 0%). Excluding the two studies with the largest effects (Dolbeault 2009; Fukui 2000), reduced the heterogeneity substantially (I^2 = 16%, P = 0.29), however, the SMD was also reduced to -0.11 (95% CI -0.21 to -0.01; P = 0.03).

We rated the certainty of the evidence as low due to inconsistency in the magnitude of effect across the studies, unexplained moderate heterogeneity I^2 = 56%, and because two or more domains of risk of bias including allocation concealment and random allocation were judged as unclear risk of bias in the included studies.

Seven additional studies reported mood disturbance but the data were not extractable to be included in the meta-analysis. Profile of Mood States (POMS)was the most commonly used tool to measure mood disturbance, distress or emotional disturbance (used by five studies: Antoni 2001; Classen 2008; Richardson 1997; Taylor 2003; Vos 2004). One study used the affect balance state (Kissane 2003), and another one used the Mental Health Inventory (MHI)and Impact of Event Scale (IES; Manne 2007). The total sample size included in these studies was 1219. The intervention was delivered in a group format in all studies including groups of couples (Manne 2007). The dose of the intervention was 20 hours or less in five studies and more than 20 hours in two studies (Kissane 2003; Vos 2004). Five studies reported a marginal improvement in mood disturbance scores in the intervention arm from baseline or compared to other arms. Two studies reported no difference between intervention and control arms (Richardson 1997; Vos 2004). The certainty of evidence of these studies was judged as low because two or more domains were judged as unclear or high risk of bias (Table 3).

Secondary outcomes

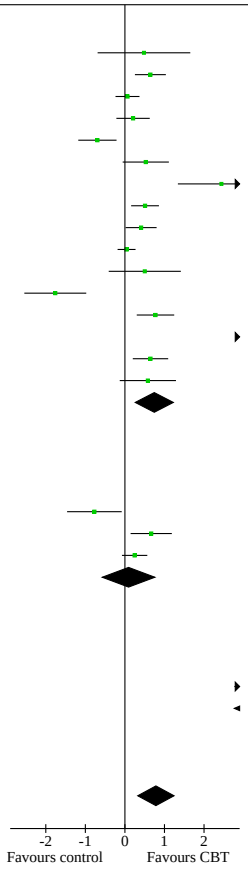
Quality of life (QoL)

We identified 20 studies that reported data to be included in the meta-analysis on the change in QoL in a group-delivered (Baucom 2009; Beutel 2013; Dolbeault 2009; Fillion 2008; Garssen 2013; Gonzalez-Hernandez 2018; Jang 2016; Johannsen 2016; Kim 2013; Lengacher 2016; Loprinzi 2011; Marchioro 1996; Park 2020; Pettiford 2017; Tabrizi 2016; Trindade 2020; Henderson 2012), or individually-delivered intervention setting (Kim 2018; Napoles 2015; Ferguson 2012).

In these studies, 869 women were allocated to the intervention arm and 878 to the control arm. The overall SMD was 0.78 (95% CI 0.32 to 0.1.24; P = 0.0008; I^2 = 95%; Chi^2 test P < 0.00001) (Analysis 1.4; Figure 6), indicating a large effect. The results suggest that psychological intervention appears to result in a large improvement in QoL in the intervention arm. There is evidence suggesting that there is subgroup differences favouring the group delivered intervention (Chi^2 = 64.99, df = 2 (P < 0.00001), I^2 = 96.9%).

Figure 6.

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
1.4.1 Group intervention less than or equal 20 hours									
Baucom 2009	3.22	0.34	7	2.89	0.91	5	4.1%	0.48 [-0.69 , 1.65]	+ ? ? ? ? + +
Beutel 2013	58.4	24	52	42.7	24.4	54	5.3%	0.64 [0.25 , 1.03]	+ + ? + + + +
Dolbeault 2009	4.88	1.11	81	4.81	1.03	87	5.4%	0.07 [-0.24 , 0.37]	? + ? ? ? + +
Fillion 2008	46.76	9.24	43	44.64	11.05	44	5.3%	0.21 [-0.22 , 0.63]	+ + ? ? ? + ?
Garssen 2013	72.9	3.8	34	75.5	3.6	36	5.2%	-0.70 [-1.18 , -0.21]	? ? ? ? ? + +
Gonzalez-Hernandez 2018	71.73	15.45	22	62.8	17.63	25	5.1%	0.53 [-0.06 , 1.11]	+ ? ? ? ? + +
Jang 2016	81.31	12.46	12	40.17	19.37	12	4.2%	2.44 [1.34 , 3.54]	? ? ? ? + + +
Johannsen 2016	56.2	20.6	67	45.1	22.8	62	5.4%	0.51 [0.16 , 0.86]	+ ? ? ? ? + +
Kim 2013	70.29	18.31	51	62.02	21.69	51	5.3%	0.41 [0.02 , 0.80]	+ ? ? − + + +
Lengacher 2016	68.76	21.5	153	67.85	21.99	146	5.5%	0.04 [-0.19 , 0.27]	? ? ? ? ? + +
Loprinzi 2011	44.5	3.5	12	42.2	5.5	8	4.6%	0.50 [-0.41 , 1.41]	+ ? ? ? − + +
Marchioro 1996	41.17	6.91	18	60.28	13.33	18	4.8%	-1.76 [-2.54 , -0.98]	? ? ? ? ? + ?
Park 2020	85.41	16.08	38	71.9	18.5	36	5.2%	0.77 [0.30 , 1.25]	+ ? ? ? + + +
Pettiford 2017	17.12	2.62	47	-6.08	2.36	56	3.8%	9.28 [7.93 , 10.63]	+ ? ? ? ? + +
Tabrizi 2016	65.5	16.7	41	53.8	19.1	40	5.3%	0.65 [0.20 , 1.09]	+ − ? ? + + +
Trindade 2020	67.22	11.12	15	58.33	17.62	17	4.9%	0.58 [-0.13 , 1.29]	? ? ? ? − + +
Subtotal (95% CI)			**693**			**697**	**79.4%**	**0.74 [0.26 , 1.22]**	
Heterogeneity: Tau^2 = 0.85; Chi^2 = 247.27, df = 15 (P < 0.00001); I^2 = 94%									
Test for overall effect: Z = 3.02 (P = 0.002)									
1.4.2 Individual intervention									
Ferguson 2012	5.37	1.22	17	6.4	1.38	18	4.9%	-0.77 [-1.46 , -0.08]	+ ? ? + ? + +
Kim 2018	64.4	15.6	30	51.4	22.4	30	5.2%	0.66 [0.14 , 1.19]	+ ? ? ? ? + +
Napoles 2015	80.64	13.64	76	77.02	15.62	75	5.4%	0.25 [-0.07 , 0.57]	+ + ? ? + + +
Subtotal (95% CI)			**123**			**123**	**15.5%**	**0.09 [-0.57 , 0.76]**	
Heterogeneity: Tau^2 = 0.28; Chi^2 = 10.74, df = 2 (P = 0.005); I^2 = 81%									
Test for overall effect: Z = 0.27 (P = 0.79)									
1.4.3 Group intervention more than 20 hours									
Henderson 2012	8.8	0.3	53	7.6	0.4	58	5.1%	3.35 [2.77 , 3.93]	? ? ? ? + ? ?
Subtotal (95% CI)			**53**			**58**	**5.1%**	**3.35 [2.77 , 3.93]**	
Heterogeneity: Not applicable									
Test for overall effect: Z = 11.26 (P < 0.00001)									
Total (95% CI)			**869**			**878**	**100.0%**	**0.78 [0.32 , 1.24]**	
Heterogeneity: Tau^2 = 0.99; Chi^2 = 360.78, df = 19 (P < 0.00001); I^2 = 95%									
Test for overall effect: Z = 3.35 (P = 0.0008)									
Test for subgroup differences: Chi^2 = 64.99, df = 2 (P < 0.00001), I^2 = 96.9%									



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

The SMD for the group-delivered intervention of less than or equal to 20 hours was 0.74 (95% CI 0.26 to 1.22; P = 0.002; I^2 = 94%, P < 0.00001) and for the individual-delivered intervention 0.09 (95%CI -0.57 to 0.76, P = 0.79; I^2 = 81%, P = 0.005). Excluding the three studies with the largest effects (Jang 2016; Marchioro 1996; Pettiford 2017), reduced heterogeneity to I^2= 48% (P = 0.04) and the SMD for the group-delivered intervention was halved (SMD = 0.39 from 0.22 to 0.57, P < 0.0001), and the overall SMD became 0.39 (from 0.24 to 0.54, P < 0.00001) with overall I^2 = 43% (P = 0.05).

We rated the certainty of evidence as low due to inconsistency in the magnitude of effect across the studies, unexplained high heterogeneity, absence of allocation concealment in one study, and

unclear risk of bias in the remaining studies with respect to most domains including allocation concealment and random allocation.

Six additional studies reported quality of life but the data were not extractable to be included in the meta-analysis. FACT-B was the most commonly used tool to measure QoL (Charalampopoulou 2020; Graves 2003; Richardson 1997) followed by EORTC QLQ-C30 (Chan 2017; Boesen 2011) and one used QoL index (Simpson 2001). The total sample size included in these studies was 571. The intervention was delivered in a group format in all studies. The dose of intervention was ≤ 20 hours. All studies reported improvement in QoL favouring the intervention arm with varying degrees of clinical importance. The quality of these studies was judged as low because three or more domains were judged as unclear or high risk of bias (Table 4).

Stress

Fourteen studies reported stress as an outcome. Eight studies reported data that could be included in the stress outcome analysis including 285 participants in the intervention arm and 279 in the control arm. All studies carried out group-delivered intervention for 20 hours or less (Bower 2015; Gonzalez-Hernandez 2018; Ho 2016; Janusek 2019; Loprinzi 2011; Mirmahmoodi 2020; Trindade 2020; Zhang 2017).

The pooled SMD was -0.34 (95% -0.55 to -0.12, P = 0.002; I^2 = 31% with P = 0.18) (Analysis 1.5), indicating a small effect in reducing stress in the intervention group compared to control group. We rated this result as low-certainty evidence due to the fact that two or more domains of risk of bias including allocation concealment and random allocation were judged as unclear risk of bias in the included studies.

Six studies out of the 14 reported stress but data were not extractable to be included in the meta-analysis. Three studies used the perceived stress scale (Charalampopoulou 2020; Cohen 2007; Lengacher 2016), one used impact of event scale (Andersen 2004), and one study used the Lipp Inventory of Stress Symptoms (Nunes 2007). Taylor 2003 used two scales (Impact of event scale - IES, and MHI). The total sample size included in these studies was 603. The intervention was delivered in a group format and the dose was ≤ 20 hours in all studies. All studies reported an improvement in stress scores from baseline or compared to other arms. The certainty of evidence of these studies was judged as low because two or more domains were judged as unclear or high risk of bias (Table 5).

Coping and adjustment

Seven studies reported data to be included in the meta-analysis on the change in coping/adjustment when the intervention was delivered either as a group intervention (Dolbeault 2009; Fukui 2000; Graves 2003; Gudenkauf 2015; Ho 2016; Nicolaisen 2018), or as an individually-delivered intervention (Marchioro 1996).

The total number of participants was 319 in the intervention arm and 314 in the control arm. The overall SMD suggests a small improvement in coping and adjustment in the intervention arm. The overall SMD was -0.24 (95% -0.6 to 0.12, P = 0.18; I^2 = 77%, P = 0.0002; Analysis 1.6), indicating a small effect. There was evidence suggesting differences in the effect of the intervention across the two subgroups (P < 0.0001; I^2= 94.2%). Individually-delivered intervention may result in a slightly larger effect compared to the group intervention favouring the intervention.

Mental Adjustment to Cancer (MAC) was the most frequently used tool to measure coping and adjustment which has five domains (fighting spirit, helplessness and hopelessness, anxious preoccupation, cognitive avoidance, and fatalism). However, several versions and subscales were used. For example, all five domains of MAC were used in Fukui 2000 and Simpson 2001, whereas two domains of MAC were used in Dolbeault 2009. Other studies used other tools such as the Cancer Behaviour Inventory (CBI, Graves 2003), adaptation to cancer (Marchioro 1996), Emotional Well-being (EWB) subscale of the Functional Assessment of Cancer Therapy – Breast (Gudenkauf 2015), Emotional Control Scale (Ho 2016), and Revised Dyadic Adjustment Scale (Nicolaisen 2018).

Two studies reported coping/adjustment but data were not extractable (Simpson 2001; Henderson 2012). Henderson 2012 used two scales to measure coping and adjustment: dealing with illness and Mental Adjustment to Cancer (MAC), whereas Simpson 2001 only used MAC. Both reported no important difference between the intervention and control arms.

We rated the certainty of evidence as low due to inconsistency in the magnitude of effect across the studies, unexplained high heterogeneity, and unclear risk of bias with respect to most domains including allocation concealment and random allocation.

Overall survival

Three studies reported on overall survival (Andersen 2004; Boesen 2011; Kissane 2004). One study did not describe their data though nine deaths were recorded (Boesen 2011).

From the remaining two studies included in the analysis, 268 patients were allocated to the intervention group and 262 were allocated to the control. In Andersen 2004, 54 of 227 (24%) women had died, 24 in the intervention arm and 30 in the assessment-only arm. Breast cancer was the primary cause of death for 44 of the 54 patients (19 patients from the intervention arm and 25 from the assessment-only arm). In Kissane 2004, the Kaplan-Meier analysis revealed a median survival of 81.9 months (95% CI 64.8 to 99.0) in the intervention group compared with 85.5 months (95% CI 67.5 to 103.6) in the control arm. Information regarding the number of deaths in each arm was not reported.

The pooled hazard ratio (HR) from two studies (Andersen 2004; Kissane 2004) was 0.76 (95% CI 0.25 to 2.32; P = 0.63; I^2 = 84%; Chi^2 test P = 0.01) but exhibited substantial heterogeneity, so the generalisability of this result should be considered with caution (Analysis 1.7). We rated the certainty of evidence as low because allocation concealment was absent in one of the two included studies and at least two other risks of bias domains were judged as unclear risk of bias in addition to the substantial heterogeneity.

Adverse events

No studies reported on adverse events.

Funnel plots

We assessed publication bias for analyses of depression, anxiety, mood disorder, and quality of life, where there were 10 or more studies in the meta-analysis. The funnel plots for depression, anxiety and mood disorder (not shown) appear to be symmetrical with no suggestion of publication bias, although it cannot be ruled out. The funnel plot for quality of life appears to be asymmetrical

suggesting publication bias, and the result should be interpreted with caution. Looking at the sample size of the studies included in this analysis, there is no suggestion that smaller studies tend to lead to more or fewer effects.

DISCUSSION

Summary of main results

The meta-analyses showed improved scores for depression, anxiety, stress, mood disturbance and quality of life favouring the psychological intervention. Individually-delivered interventions appeared more beneficial for coping and adjustment, but group-delivered interventions showed favourable effect in quality of life (QoL). Further studies comparing various doses of the therapy are needed before making any conclusive judgement. The reduction in depression and anxiety scores was more noticeable in patients with higher levels of depression and anxiety at baseline. This improvement was consistent throughout the follow-up. The scarcity of trials reporting and documenting pre-existing psychological conditions among participants did not allow subgroup analysis based on baseline depression and anxiety levels.

Overall completeness and applicability of evidence

This review considers randomised controlled trials (RCTs) of a wide range of psychological therapies for breast cancer (see Types of interventions). Studies included participants from different countries and backgrounds who had been diagnosed with and treated for, breast cancer (see Types of participants).

Many factors, however, limit the generalisability of the results. Most studies were conducted in the USA and Europe, limiting the generalisability of results to the rest of the world. Although we have included the full range of psychological therapies for breast cancer, insufficient data precluded meta-analysis of a number of outcomes in some treatment groups. There is a larger number of studies of group-led cognitive-behavioural interventions than for other therapies. However, it was hard to separate various types of psychological interventions because most studies used a combination of strategies and modalities (behavioural, cognitive, educational, social, and motivational). The emphasis of each therapy is different in each study, depending on the theoretical underpinning of the approach. Most studies did not include participants with comorbid psychiatric diagnoses such as depression and anxiety, therefore, excluding individuals who are arguably more difficult to treat. This may have resulted in the exclusion of individuals with high levels of stress who are more likely to benefit from the treatment.

Quality of the evidence

The clinical and methodological characteristics of the studies were highly variable which could potentially affect the direction and magnitude of the effect. The main areas of heterogeneity were types of intervention, control condition, inclusion criteria, outcome measurement, timing of follow-up, and quality of the studies.

Type of intervention

A wide range of psychological interventions was used and in most cases, a combination of two or more approaches and techniques have been employed making it by far the most challenging factor when comparing various studies. Details on the content and integrity of the intervention were not always available.

Control condition

Studies used standard of care as the control group and did not control for the potential effect of non-specific structured activities taking place at home or at a hospital. Variation in standard of care in the various trials should also be taken into consideration when comparing studies conducted in different settings.

Inclusion criteria

Although previous reports showed that women with higher levels of psychological disturbances benefited the most from psychological interventions compared to standard of care; most studies excluded women with psychological morbidities. Even when women with higher levels of distress were included in the study, they were rarely analysed separately.

Outcome measurement

There was substantial variation in the instruments used to assess outcomes in the studies included in this review. Most tools were validated, but a few were not. One should be cautious interpreting the results originating from different tools although measuring the same outcome.

Timing of follow-up

There is a body of literature showing that the longer time that has elapsed after diagnosis, the better the psychological status of women is. Therefore, time at which an outcome is measured can make a difference in the magnitude and direction of the effect of the intervention. The included studies showed a considerable amount of heterogeneity in the timing of outcome assessments, hence this should be taken into consideration when comparing studies with early and late assessments.

Quality of studies

One of the major methodological issues with this kind of intervention is that blinding of interventionists and patients is not possible due to the nature of the intervention. The absence of blinding on the magnitude and direction of the treatment effect is unclear and could potentially have led to performance bias. Most studies provided insufficient details on allocation concealment and sequence generation. Considering the nature of the intervention, which is primarily a psychological intervention as opposed to a drug intervention, pharmaceutical company funding did not constitute a threat.

Potential biases in the review process

This review was conducted in line with the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Although the methodology for conducting systematic reviews is well established, subjective judgement is inevitable throughout the process. The main limitation of this review is the lack of sufficient data in many studies to make a clear judgement in various bias domains. As a result, a false estimate of the underlying truth is inevitable. Another limitation is the heterogeneity in the intervention delivered, outcome measurement, the timing of follow-up, and participants' characteristics. The paucity of data, especially for the survival outcome, resulted in ambiguous study-specific effect estimates. Additionally, because most of the

included studies were primarily conducted among Caucasians and in developed countries, generalisability of the results to different ethnic groups and countries might not be feasible. Finally, the cut-off of 20 hours used in the subanalysis is almost certainly arbitrary with no 'scientific' rationale as such. This cut-off was used for comparison purposes with a previously conducted systematic review in the same field (Naaman 2009).

One of the important limitations is that adverse outcomes to the intervention were not reported in the included studies. The iatrogenic effect of psychological intervention has scarcely been studied (Barlow 2010; Roback 2000). For example, one study showed that peer discussion groups had a negative effect on women with breast cancer (Helgeson 1999). One should note that in this review we included only professional-led well-described interventions and not peer group discussions. Nevertheless, the possibility of the intervention causing harm cannot be ruled out by the reported data.

Agreements and disagreements with other studies or reviews

We identified a few meta-analyses investigating psychological intervention in women with breast cancer (Duijts 2011; Guarino 2020; Matsuda 2014; Mustafa 2013; Naaman 2009; Sebri 2021). However, the inclusion criteria were not uniform across the reviews. They varied drastically in terms of the stage of the disease, type of intervention, and the outcome measured. For example, Naaman and colleagues included women at the early and late stages of the disease (Naaman 2009), Duijts and colleagues investigated behavioural techniques and physical exercise (Duijts 2011), Matsuda confined the search to English-language trials (Matsuda 2014) and Mustafa and colleagues included only women with metastatic breast cancer (Mustafa 2013). Guarino 2020 included breast cancer of all stages and three types of interventions (cognitive-behavioural, supportive-expressive, or psycho-educational treatments) and limited the outcomes to depression, anxiety, mood, and quality of life. Body image was the only outcome in Sebri 2021.

Consistent with previous reviews on cancer patients (Jacobsen 2008; Meyer 1995; Osborn 2006; Raingruber 2011; Reshe 2003) and reviews on women with breast cancer (Guarino 2020; Naaman 2009), our results showed favourable effects of psychological interventions on some psychological outcomes, particularly anxiety, depression, mood disturbance, and quality of life. The overall effect size of depression in our study was slightly smaller than that reported in Guarino 2020. The highest effect size reported in our study was for anxiety and quality of life, and the smallest was for mood disturbance, which is in agreement with the literature (Guarino 2020; Naaman 2009). However, compared to Guarino 2020, our overall results reached statistical significance in depression, anxiety, stress, mood, and quality of life.

Interestingly, individually-delivered interventions showed a slightly larger effect size in depression, anxiety, and mood outcomes. This contradicts the results from Guarino 2020 and Naaman 2009 which showed that group interventions appeared to be more beneficial. This could be due to the fact that we based our conclusion on quantitative subgroup analysis compared to the narrative analysis in the case of Guarino 2020 and Naaman 2009. In our review, the group-delivered intervention was more beneficial only for quality of life which was represented in its larger effect size. This discrepancy on the superiority of the type of delivery of the intervention could also be attributed to the increasing number of trials with the individually-delivered interventions that were included in our review compared to previous reviews. The superiority of individually-delivered intervention was also noted in reviews in which all cancer patients were included (Osborn 2006). This may indicate the shift in patient preference.

In the subgroup analysis done in Guarino 2020, significant differences among studies were observed for types of intervention and types of provider specifically for anxiety and quality of life. However, in our meta-analysis, this subgroup analysis was not carried out because we only included professionally-led interventions. Further, it was observed that different types of interventions involved mixed approaches and were inseparable in most included studies.

There is considerable debate over the effect of psychological intervention on survival. Most meta-analyses of data from cancer patients found no survival benefit of such intervention (Chow 2004; Cwikel 1998; Newell 2002; Smedslund 2004; Zabalegui 2005). In line with the vast literature, our analysis showed no significant survival benefit for psychological intervention in women with non-metastatic disease. In contrast, Mustafa and colleagues reported a favourable effect of the intervention on survival at one year but this was not sustained at five years (Mustafa 2013). There is general agreement amongst researchers in the field that consistent long-term reporting of the effects of psychological interventions on survival is necessary (Mustafa 2013; Newell 2002; Smedslund 2004; Williams 2006).

The benefits for psychological outcomes seem to be less evident when the disease has already metastasised to other parts of the body (Mustafa 2013). It is noteworthy that in some reviews, depression was used interchangeably with mood disturbance. As a result, data originating from tools used to measure mood disturbance were pooled under depression as an outcome. This might explain the discrepancy in the effect size for depression. This also applies to other outcomes such as stress, distress, coping, and adjustment. The variation in the terminology used to describe various psychological outcomes and the interchangeability makes it difficult to classify and subsequently pool studies.

This Cochrane Review meta-analysis underlined the confounding effect of some factors. For example, the choice of some studies to include educational sessions as the placebo in the control groups. The positive effect of this intervention could have affected the overall estimation of the effect estimate. Additionally, the use of different tools to measure the same outcome could have influenced the results. All studies used self-reported measures of the outcomes which could have affected the objectivity of the data.

Moreover, this Cochrane Review considered the well-studied and documented psychological approaches, while future studies could consider the benefits of other types of therapies. For example, hypnosis-based psychotherapy, music, physical activity, and expressive writing-based interventions. Additionally, it was unclear if combining more than one approach is superior to a single intervention. For example, combining mindfulness with cognitive behavioural therapy as opposed to cognitive behavioural therapy alone.

It seems that cognitive behavioural therapy carried the most beneficial effect as shown in other studies (Guarino 2020), however one should be cautious interpreting this result because of the inconsistency in defining what constitutes cognitive behavioural therapy and other forms of psychological interventions.

In two previous reviews (Guarino 2020; Naaman 2009), short treatment duration yielded significant results. However, the results should be interpreted cautiously because first, only a handful of studies involved a long duration of intervention, and second, the classification of treatment duration was different in these reviews. Naaman 2009 used the 20 hours as a cut-off point while Guarino 2020 used the number of weeks (6 versus 12) to categorise short- and long-treatment duration. We used the hourly method because the method based on the number of weeks does not specify the number of hours. For example, there are studies that conducted weekly sessions of two hours duration and others that conducted biweekly sessions of two hours duration. Therefore, the hourly method captures the dose of intervention more precisely.

There are indications that psychological interventions targeting patients at a higher level of stress have greater clinical benefits than when targeting women with low or normal levels of stress (Sheard 1999). It was not possible to investigate this relationship in our Cochrane Review due to the paucity of studies that included people with such a profile. Furthermore, even when people with a higher level of distress were included, their results were not reported separately.

AUTHORS' CONCLUSIONS

Implications for practice

Psychological interventions seem to be effective in improving psychological symptoms and quality of life in women with non-metastatic breast cancer. Healthcare workers may focus on patients with pre-existing levels of anxiety, stress, and depression because they appeared to benefit most from psychological interventions. The studies included in this review had some methodological shortcomings and were highly variable in the range of interventions and outcome measures used, highlighting the importance of developing studies that collect information using similar measures to aid evidence synthesis.

Implications for research

There is an abundance of research in this area. However, more attention should be paid to maximising internal validity. Special attention should be given to randomisation and allocation concealment. Blinding might be difficult to achieve with psychological interventions, but blinding the assessors is possible and would add to the rigour of the studies. We also suggest that future trials recruit an adequate sample size to detect a statistically significant effect.

Meticulous definitions and descriptions of psychological interventions and the use of standardised outcome measurements are fundamental to allowing for meaningful pooling of data. Decisions about the type of intervention, measurement tool, duration of follow-up, and outcome assessment should take into account the existing reviews. Additionally, the sustainability of the effect of the psychological intervention needs to be assessed in long-term randomised controlled trials.

Future research could consider targeting women who present with clinically-important levels of anxiety and depression to confirm the potential favourable clinical effect in this subgroup of the population as recommended by the international guidelines for psycho-oncology (Coleman 2011). Future research can also consider including the newly studied psychological outcomes such as fear of recurrence (Bower 2015; Gonzalez-Hernandez 2018; Lengacher 2016).

Lastly, more focus and attention can be given to the possible adverse effects of psychological interventions so that we can better understand the settings and situations in which such interventions are best not used. This is in light of the preliminary results from observational studies showing a possible increase in stress associated with psychological intervention (Helgeson 1999). More rigorous studies are needed to confirm or reject this hypothesis.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Andersen 2004

Study characteristics	
Methods	Method: RCT Setting: USA Duration of intervention: 4 months
Participants	N = 227 (114 intervention arm, 113 control arm) • Power analyses suggested a total number of 200 patients, and 227 patients were accrued Participants were chosen using two methods: • Consecutive patients at a university affiliated National Cancer Institute–designated Comprehensive cancer centre (n = 189) • Self- and physician-referred patients from the community (n = 38) • The overall accrual was 57% Inclusion criteria: • Women who were diagnosed with stage II or III breast cancer • Surgically treated, and awaiting adjuvant therapy Exclusion criteria: • Prior cancer diagnosis • Refusal of cancer treatment • Age less than 20 years or more than 85 years • Residence more than 90 miles from the research site • Diagnoses of mental retardation, severe or untreated psychopathology (e.g. schizophrenia), neurologic disorders, dementia • Any immunological condition or disease
Interventions	• The intervention was conducted in small patient groups (range 8 to 12 patients), with one session per week for 4 months (Andersen 2004) • The intervention was over 12 months, weekly session (1.5 hours) for 4 weeks then monthly session for 8 months. Total 26 sessions (39 hours) (Andersen 2007 and Andersen 2008)

Andersen 2004 *(Continued)*

- The sessions included strategies to reduce stress, improve mood, alter health behaviours, and maintain adherence to cancer treatment and care
- Each session was conducted by two clinical psychologists. Cohorts met weekly for 1.5 hours for 18 sessions (27 therapy hours during 4 months)
- The topics and techniques used were consistent with psychosocial interventions but also included diet, exercise, smoking, and adherence components
- Participants completed 94% of the intervention session

Outcomes	Andersen 2004 and Andersen 2007: 1. Emotional distress by the POMS assessed negative mood. A Total Mood Disturbance score was the sum of five scales (anxiety, depression, anger, fatigue, and confusion) minus the score of a vigour scale 2. Stress by Impact of event scale • Assessment at baseline and 4 months (Andersen 2004) • Collected at baseline, 4 months, and 12 months (Andersen 2007) Andersen 2008: 3. Survival and recurrence: breast cancer specific survival defined as the time from randomisation to breast cancer death. Disease recurrence was defined as the detection of metastatic disease either at the same site (local) or distant from the original site
Notes	• Baseline assessment occurred before randomisation and adjuvant therapy • Analyses of socio-demographic variables and disease or prognostic factors or treatments received or planned revealed no significant differences between study arms

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomly assigned to either the intervention group or assessment only group" "White and Freedman's minimization method was used for randomization" Comment: this was judged at a low risk of bias
Allocation concealment (selection bias)	Low risk	The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment, was not reported Comment: there was insufficient information to permit a clear judgement After e-mail communication with investigators: "There would have been no way for them to know who was going into the intervention until they came to the group intervention as a third person was in charge of the allocation process" Comment: this was judged as adequate
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The method used in blinding the outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement

Andersen 2004 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	The numbers and reasons for dropouts and withdrawals (12.7%) from each group were reported and balanced across both groups Recurrence status was known for 93% (212 of 227 patients) of the patients, and mortality was known for 100% Analyses contrasting participants versus non-participants found no significant differences between study arms Data analysed using ITT analysis Comment: we judged this as at a low risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design Comment: we judged this as at a low risk of bias
Other bias	Low risk	The authors indicated no potential conflicts of interest Comment: we judged this as at a low risk of bias

Antoni 2001

Study characteristics	
Methods	Design: RCT Setting: USA Duration of intervention: 10 weeks
Participants	• A total of 136 randomised and 100 women analysed (47 intervention, 53 control) • Stage 0 to II • Participants were recruited from clinics through an invitation letter from their physicians, flyers • Of the women contacted by letter, 80% called for more information; of those who called, 98.6% of those who met inclusion criteria participated in initial assessment Inclusion criteria: • Stage II or below • Surgery within the last 8 weeks Exclusion criteria: • Prior cancer • Prior psychiatric treatment • Major concurrent disease • Lack of English fluency
Interventions	• Intervention arm: 10-weeks of 2 hour group cognitive behavioural stress management group intervention led by trained post-doctoral fellows • The control arm had a day seminar (5 to 6 hours) • Began 6 to 8 weeks after surgery
Outcomes	• Depression by CES-D (Centre for Epidemiology Studies-Depression) (also a clinical cut-off point of 16 was used to indicate clinically significant depression)

Antoni 2001 *(Continued)*

- Emotional distress (general mood disturbance) by POMS (only three subscales used, anxiety, depression and anger) and an average score was calculated
- Baseline, post-treatment, at 3 months post-intervention, 9 months post-intervention

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Randomly assigned" Comment: there was insufficient detail reported about the method used to generate the allocation sequence to allow a clear assessment of whether it would produce comparable groups
Allocation concealment (selection bias)	Unclear risk	The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment, was not reported Comment: there was insufficient information to permit a clear judgement
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel is not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention is unclear
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Assessments were handled by graduate students who were not conducting the intervention with that cohort" Comment: this was judged as at a low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Out of 136,11 dropped out at post-intervention, 9 dropped out at 3 months,16 dropped at 9 months and 100 completed all assessments 136 randomised, 100 analysed (26.4% dropout rate) Comparison between dropout and women who stayed in trial showed no difference Comment: although the numbers of dropouts were balanced between the groups, the percentage of dropouts and subsequent per protocol analysis posed an unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design Comment: we judged this as at a low risk of bias
Other bias	Low risk	Research grant from National Cancer Institute and training grant from Department of Defence Comment: we judged this as at a low risk of bias

Antoni 2006

Study characteristics

Antoni 2006 *(Continued)*

Methods	Design: RCT Setting: USA Duration of intervention: 10 weeks
Participants	• N = 199 (92 intervention, 107 control) Inclusion criteria: • Women with stage 0 to III breast cancer • Had surgery within the past 8 weeks Exclusion criteria: • Prior cancer • Prior psychiatric treatment for serious disorders for a serious disorder (hospitalisation or a formal diagnosis of psychosis, major depressive episode, panic attacks, suicidality, or substance dependence • Lack of fluency in English
Interventions	• Cognitive Behavioural Stress Management versus 5 to 6 hours educational seminar • Intervention: 10 week (2-hour) group sessions of cognitive behavioural stress management • Began 10 to 12 weeks after surgery • Intervention and control seminars were led by female post-doctoral fellows and advanced pre-doctoral trainees in clinical psychology
Outcomes	• Collected at study entry, 6 months and 12 months after entry • The second assessment occurred 3 months after the intervention ended (6 months after the initial assessment). A third assessment occurred 6 months later. Thus the period of follow-up spanned approximately 1 year after random assignment • Thought intrusion and avoidance (Impact of event scale) indicator of event related distress • Interviewer-rated anxiety (Hamilton Rating Scale for anxiety) • Emotional distress (ABS)
Notes	Quote: "Most women were completing adjuvant therapy by the second assessment, the third assessment reflects the durability of this effect" Participants were self-selected Women were not excluded for elevated levels of anxiety or depression

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Randomly assigned" Comment: there was insufficient detail reported about the method used to generate the allocation sequence to allow a clear assessment of whether it would produce comparable groups
Allocation concealment (selection bias)	Unclear risk	The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment was not reported Comment: there was insufficient information to permit a clear judgement

Antoni 2006 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Assessments were handled by persons who did not conduct the intervention with that cohort" Comment: this was judged as low risk
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition did not differ significantly by condition at Time 2, or Time 3 Dropout was 21% (42/199), 18 in the intervention group and 24 in the control group Quote (page 1792): "We used an intent-to-treat analysis, estimating missing data using full information maximum likelihood. Thus, the entire sample was represented in all analyses" "At each time point, those who dropped out were compared on key variables with those retained" Comment: we judged this as at a low risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Research Grant from National Cancer Institute Co-authors reported no competing interest Comment: we judged this as at a low risk of bias

Ashing 2014

Study characteristics	
Methods	Design: RCT Country: USA Setting: City of Hope National Medical Center Method of randomisation: computer-generated randomisation sequence Method of allocation: allocate participants in a 1:1 ratio to either intervention or control Outcome assessor blinding: self administered survey, the data were entered by a separate survey core service
Participants	N = 199 (100 intervention, 99 control) Inclusion criteria: age 18 years and older, identified as Latina, diagnosed within 1–6 years with stage 0–III breast cancer (BCA), and had at least moderate distress and burden levels as measured by the Center for Epidemiological Studies Depression scale (CES-D) defined as a score ≥16, and Functional Assessment of Cancer Therapy (FACT)-Breast Exclusion criteria: not specified

Ashing 2014 *(Continued)*

Interventions	Intervention group: received telephone based intervention Seven domains were addressed in the telephone sessions: (i) basic BCA information; (ii) managing medical and physical issues, follow-up care, and cancer resources; (iii) coping skills and problem solving training; (iv) balancing emotions and stress management; (v) family Two culturally competent and bilingual paraprofessional interventionists with >2-year college education and >3-year experience working with underserved communities were trained to deliver the sessions. and social concerns; (vi) sexual health concerns; and (vii) financial issues and employment concerns. A booster and debriefing session took place 1 month after completion of the telephone sessions Frequency: eight 40–50-min, biweekly psychoeducational telephone sessions. Duration: 4 weeks plus booster session 1 month after completion Control group: education booklet only
Outcomes	Depression measured by The 20-item CES-D Assessed at baseline and 4–6 months' follow-up assessment after randomisation (about 3–4 months after delivery of the intervention).
Notes	Funding: This research is supported by a grant from the Department of Defense (W81XWH-04-1-0548).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A computer-generated randomisation sequence was created to allocate participants in a 1:1 ratio to either intervention or control study conditions.
Allocation concealment (selection bias)	High risk	Assignment to study conditions was not masked to investigators and participants.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Low risk	self administered survey, the data were entered by a separate survey core service
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	221 were randomised (110 intervention, 111 control) 11 lost follow-up in each arm (total 22). Only those who finished the trial were analysed. Although the numbers of dropouts were balanced between the groups, the percentage of dropouts and subsequent per protocol analysis posed an unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Funded a grant from the Department of Defense (W81XWH-04-1-0548).

Badger 2007

Study characteristics

Badger 2007 *(Continued)*

Methods	Design: RCT Setting: USA Duration of intervention: 6 weeks
Participants	• N = 96 and their partners Eligibility criteria: • Diagnosis of Stage I to III breast cancer, • Currently receiving adjuvant treatment for breast cancer • Ability to speak English and talk on the telephone • No physical or psychological disabilities that would prevent participating in the intervention • Availability of a partner who was willing to participate
Interventions	Telephone-delivered psychosocial interventions Six-week programs: (a) telephone interpersonal counselling (TIP-C) n = 38 women and 38 partners; (b) self-managed exercise n = 23; or (c) attention control n = 37 TIP group received weekly phone calls, 34 minutes on average All interventions were delivered by counsellors trained in the intervention for which they were responsible
Outcomes	Assessment done at T1 baseline, T2 (T1 + 6 weeks), T3 (T1 + 10 weeks) Depression by 20-item Center for Epidemiological Studies V Depression Scale (CES-D) Anxiety by generated anxiety index (an eight-item composite index of anxiety was formed). The composite anxiety index was expressed on a 1 to 10 scale, with high scores indicating greater anxiety
Notes	Sample recruited from a local cancer centre, oncologists' offices, support groups, and through self-referral after reading brochures displayed in various settings

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The project director randomly assigned, stratified by stage and treatment, women and their partners" Comment: there was insufficient detail reported about the method used to generate the allocation sequence to allow a clear assessment of whether it would produce comparable groups After e-mail communication with investigators: "We generated a table of the two conditions randomly assigned to randomly generated subject identification numbers" Comment: this was judged as adequate
Allocation concealment (selection bias)	Low risk	The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment, was not reported Comment: there was insufficient information to permit a clear judgement After e-mail communication with investigators: "Only the PI and the program coordinator had access to the allocation procedure. The other researchers did not"

Badger 2007 *(Continued)*

		Comment: this was judged as adequate
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Low risk	There was insufficient information to permit a clear judgement of risk of bias After e-mail communication with investigators: they answered "the outcome assessment was done by data collectors who had no knowledge of the arms nor were they involved in the design." Comment: this was judged as adequate
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	In the intervention group 37/37 were analysed, in the control group 33/37 analysed, attrition rate at 4/37(10.8%) The numbers and reasons for dropouts and withdrawals from each group were reported and were balanced across both groups Dropouts were excluded from analysis so per protocol analysis was done Comment: although the numbers of dropouts were balanced between the groups and the percentage of dropouts was low, subsequent per protocol analysis posed an unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design Comment: this was judged as at a low risk of bias
Other bias	Low risk	Funding provided by the National Institute of Nursing Research Comment: this was judged as at a low risk of bias

Baucom 2009

Study characteristics	
Methods	Design: pilot RCT Setting: USA Duration of intervention: 6 weeks
Participants	• 14 couples (8 intervention and 6 control) Inclusion criteria: • Recently diagnosed with stage I or II breast cancer • No history of other breast cancer • No history of cancer within the last 5 years • Currently married or living together with a male romantic partner for at least 12 months • Both partners willing to participate and able to speak English
Interventions	• Couple-based relationship enhancement (RE) (n = 8) or treatment as usual (TAU) (n = 6)

Baucom 2009 *(Continued)*

	• RE condition attended six bi-weekly, face-to-face, 75-minute sessions with a therapist
Outcomes	• Distress Brief Symptom Inventory—18 (BSI-18 higher score indicates more distress) • Quality of life by Functional Assessment of Cancer Therapy (FACT-B) • Assessments were conducted before treatment, post-treatment, and 12 months later
Notes	These couples were 13% of eligible couples who were contacted for the study

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Using a computer-based random number generator, a staff member randomly assigned couples to one of the two treatment conditions after the initial assessment was completed" Comment: this was judged at a low risk of bias
Allocation concealment (selection bias)	Unclear risk	Both couples and assessors were blinded to treatment assignment Comment: there was insufficient information to permit a clear judgement
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The method used in blinding the outcome assessment was not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Two were dropped from analysis. One couple from the intervention because they felt the intervention did not meet their needs. One control woman died from breast cancer between posttest and follow-up. Thus, their data were excluded from the protocol analyses at the relevant time periods Comment: this was judged as at an unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Supported by a grant from the National Cancer Institute and a grant from the Lineberger Comprehensive Cancer Center at the University of North Carolina

Beutel 2013

Study characteristics

Methods	Design: prospective RCT Country: Germany Setting: Patients recruited from Mainz and Leipzig Oncology Centres, Germany and intervention took place in private practice Method of randomisation: computer generated

Beutel 2013 *(Continued)*

	Method of allocation: independent research staff using opaque envelopes Outcome assessor blinding: Yes
Participants	N = 158 (intervention 78, control 79) Patients were recruited after surgery, while still in oncological treatment (chemotherapy, radiation, hormonal treatment) Inclusion criteria: (1) breast cancer (stages T0-4, N0-1, M0), (2) curative treatment, (3) age 18–69 years, (4) German language competence, (5) depression score (HADS-D) ≥ 8, (6) depressive disorder according to SCID-I (ICD-10 diagnoses: depressive episode F32.-, recurrent depressive episode F33.-; dysthymia F34.1, adjustment disorder F43.2), (7) written consent with study participation. Exclusion criteria: (1) severe additional medical disorder, (2) psychotic disorder, suicidality, acute substance related disorder, personality disorders except for cluster C, organic mental disorder, (3) concurrent psychotherapy.
Interventions	Intervention group: In group format, 20 psychotherapy sessions were offered once weekly delivered by psychodynamic psychotherapists Frequency: average of 18 psychotherapy sessions (SD = 11.12) with a range of 0–31 sessions (including up to six pre-treatment sessions) Duration: average 18 weeks range 0-31 weeks Control group: obtained written information on local cancer counselling centres
Outcomes	Depression measured by Hospital Anxiety and Depression Scale, HADS-D) General and breast cancer-specific QoL measured by the EORTC Quality of Life Questionnaires C30 and BR23 Assessed at baseline, post-treatment (intervention: treatment termination; control: 6 months after baseline) and at follow-up (6 months after second assessment).
Notes	Funding: This work was supported by the German Cancer Aid (107457, 109379 and 107870, 109381).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomly assigned to short-term psychodynamic psychotherapy or TAU using computer-generated sets of numbers with random length (www.randomizer.org).
Allocation concealment (selection bias)	Low risk	Randomisation was carried out in each study centre by trial-independent research staff; group assignment was provided to the trial staff by closed, opaque envelopes. Quality assurance was carried out by the independent Interdisciplinary Center for Clinical Trials.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessors were blinded to the intervention.

Beutel 2013 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	157 were randomised, 26/78 excluded from analysis in the intervention and 25/79 excluded from the control. Both Intention to treat and Per protocol analyses were conducted with N = 52 (66.7%) in intervention and N = 54 patients (69.2%) in control. There was no difference between dropouts and completers regarding baseline characteristics or intermittent medical inpatient treatment.
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	This work was supported by the German Cancer Aid (107457, 109379 and 107870, 109381).

Boesen 2011

Study characteristics	
Methods	Design:RCT Setting: Denmark Duration of intervention: 10 weeks
Participants	N = 210 (intervention 102, control 103) Inclusion criteria: • 18 to 70 years of age • Stages I to IIIA primary breast cancer • Diagnosed and treated at the University Hospital of Copenhagen, Herlev, Denmark
Interventions	Two weekly 6-hour sessions of psycho-education and 8 weekly 2-hour sessions of group psychotherapy The intervention had two parts: • The first was 12 hours of education at the outpatient clinic, conducted as 2-weekly sessions • In the second part of the intervention, groups of eight women met 8 times over 8 weeks for 2.5-hour sessions in a cancer counselling clinic
Outcomes	Measured at 1, 6 and 12 months after the intervention Distress was measured by The Profile of Mood States (POMS) short-form scale Mental Adjustment was elicited by the Mental Adjustment to Cancer scale Quality of life was assessed from the QLQ-C30 core questionnaire of the European Organisation for Research and Treatment of Cancer (EORTC)34 and the complementary breast cancer module EORTC QLQ-BR23.35 Survival at 4 years. The overall survival of all patients was determined from the unique personal identification number assigned by the Central Population Register to all Danish residents who were alive on 1 April 1968 or born thereafter All women were followed from the date of operation for breast cancer until the date of death or end of follow-up (31 May 2009)
Notes	

Boesen 2011 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote page 1364: "randomised to the intervention or the control group in the following way: via the Internet, the nurse logged onto the database of the project which was housed in the Danish Cancer Society, typing the number of the baseline questionnaire. This number became the number of the patient and the randomisation status would appear. The number of the questionnaire was not known to the nurse before a sealed envelope with the questionnaire was broken by the patient." Comment: this was judged as low risk of bias
Allocation concealment (selection bias)	Low risk	Quote page 1364: "The number of the questionnaire was not known to the nurse before a sealed envelope with the questionnaire was broken by the patient." Comment: this was judged as low risk of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of the lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	205 randomised and 176 analysed 19 dropped out for various reasons mentioned in the paper CONSORT diagram presented on page 1365 Comment: although the numbers of dropouts were balanced between the groups, the percentage of dropouts and subsequent per protocol analysis posed an unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Supported by the Psychosocial Research Committee, the Danish Cancer Society, the IMK Foundation and the University of Southern Denmark

Bower 2015

Study characteristics

Methods	Design: RCT Duration of trial: 6 week intervention Country: Los Angeles, CA Setting: group therapy at UCLA Medical Center

Bower 2015 *(Continued)*

	Method of randomisation: randomised in blocks. Once a sufficient number of participants to comprise the mindfulness and control groups (8–14 women) had been screened as eligible and completed the baseline assessment, they were randomised (4:3) to the intervention and wait-list control group, with slightly more allocated to the intervention to maintain adequate group size. Method of allocation: randomised condition assignments were kept in sealed envelopes in the research office Outcome assessor blinding: There is no sufficient information about outcome assessor blinding
Participants	N = 71 (intervention 39, control 32) Inclusion criteria: Inclusion criteria were: 1) diagnosed with Stage 0 – III breast cancer at or before age 50; and 2) completed local and/or adjuvant cancer therapy (except hormonal therapy) at least 3 months previously. We included women up to 10 years after cancer treatment, as the need for and benefits from stress management are not time-limited Exclusion criteria: 1) breast cancer recurrence, metastasis, or another cancer diagnosis (excluding non-melanoma skin cancer); 2) active, uncontrolled medical illness that could impact inflammation; and 3) unable to commit to intervention schedule.
Interventions	Intervention group: brief mindfulness intervention (group) Frequency: before and within 1–2 weeks after the intervention Duration: 6 weekly, 2-hour group sessions Control group: Wait list, they were offered intervention after the 3-month follow-ups
Outcomes	Perceived stress measured by Perceived stress scale Depressive symptoms measured by CED-S scale Cancer-specific distress was assessed using measures of fear of cancer recurrence (Quality of Life in Adult Cancer Survivors (QLACS) scale) and cancer-related intrusive thoughts (Impact of Event Scale) Assessed at All were assessed at baseline, post-intervention, and 3-month follow-up.
Notes	Funding: Supported by Susan G. Komen for the Cure, Komen Scholar Grant to PAG. CMC was supported in part by NIH CA 16042.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Participants were randomised (4:3) to the intervention and wait-list control group. However, there was insufficient detail reported about the method used to generate the allocation sequence to allow a clear assessment of whether it would produce comparable groups
Allocation concealment (selection bias)	Low risk	Randomised condition assignments were kept in sealed envelopes in the research office
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported

Bower 2015 *(Continued)*

		Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Eight people lost follow up in the intervention and 4 in the control group. Dropouts were not included in the analysis. Although the number of dropouts is small the absence of data from the remaining 12 dropouts poses unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Supported by Susan G. Komen for the Cure, Komen Scholar Grant to PAG. CMC was supported in part by NIH CA 16042.

Chan 2017

Study characteristics	
Methods	Design: Single-centre, prospective, randomised, and controlled study Country: National Cancer Centre Singapore Setting: outpatient Method of randomisation: software based by a research assistant Method of allocation: participants were informed about their assignment only after all baseline measurements were completed Outcome assessor blinding: Not clear
Participants	N= 88 (intervention 45, xontrol 43) Inclusion criteria: women 21 years and older who were diagnosed as having stages I to III breast cancer, had no known psychiatric diagnosis, and could read and comprehend English. Recruited patients must have completed their adjuvant chemotherapy. Patients requiring adjuvant radiation, adjuvant targeted therapy (such as trastuzumab), and/or endocrine therapies (such as tamoxifen and aromatase inhibitors) are allowed to participate in this study Exclusion criteria: not reported
Interventions	Intervention group: psychoeducation group intervention programme led by healthcare professionals. This programme was conducted based on the principles of cognitive behavioural therapy Frequency: 3 educational sessions. Each educational session covered 3 different segments that consisted of 3 different topics Duration: Each session was 4.5 hours long, and each patient participated in 3 sessions Control group: Patients in the control group received usual care, whereby patients are provided with an information booklet on self-management of cancer and treatment-related symptoms, which is routinely provided by the National Cancer Centre Singapore after cancer diagnosis
Outcomes	The primary endpoints measured in this study were the mean change in both the RSCL physical symptom distress scores and psychological distress scores for each group (distress level) Distress level measured by 23 items describing physical symptom distress, 7 items describing psychological distress (part of Rotterdam Symptom Checklist (RSCL). The severity of each item is rated with 4 options (not at all, a little, quite a bit and very much). The score on the distress level caused by physical

Chan 2017 *(Continued)*

	and psychological symptoms can be obtained from the total score of physical symptom items (score of 23-92) and the psychological symptom items (score of 7-28). Anxiety measured by Beck Anxiety Inventory (BAI) (mean change in the total BAI score) Quality of life mean change in the EORTC QLQ-C30 functional scale scores Assessed at month before intervention (baseline) and within 2 months after intervention when the patients returned during follow-up appointments
Notes	Funding: supported by the National Cancer Centre Community Cancer Fund Grant Call (COMCF-YR2014-NOV-SD3) and Pretty in Pink 2014 event.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Patients were enrolled by a research assistant and were randomly allocated to 1 of 2 groups: the intervention group (PEG intervention programme) or control group (usual care). The research assistant completed the random assignment using the randomisation function of the Statistical Package for the Social Sciences program version 23.
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was ensured to ensure that the results from the randomisation were not told to the patient prior to recruitment. Patients were informed of their assignment only after all baseline measurements were completed. However, It is not clear if the investigators were blinded to the allocation as well.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The study investigators and patients were not blinded to the intervention due to the nature of the intervention. Absence of blindness in this type of intervention poses unclear risk of bias
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	To avoid possible interviewer bias,different research assistants were involved in collecting baseline and postintervention measures. However, blinding of assessors was not described.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	88 were randomised to intervention (45) and control (43). 5/43 lost follow-up in control; 11/45 lost follow-up in intervention. Dropouts were not included in the analysis. Although the number of dropouts is small the absence of data from the dropouts poses unclear risk of bias.
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design.
Other bias	Low risk	Supported by the National Cancer Centre Community Cancer Fund Grant Call (COMCF-YR2014-NOV-SD3) and Pretty in Pink 2014 event.

Charalampopoulou 2020

Study characteristics

Methods	Pilot RCT
Participants	N = 60 (30 intervention, 30 control)

Charalampopoulou 2020 *(Continued)*

	Inclusion criteria were age older than 18 years, diagnosis of primary malignancy of the breast confirmed with biopsy and active anti-cancer adjuvant treatment (chemotherapy, radiation therapy or hormonal therapy). Exclusion criteria included any psychiatric co-morbidity (i.e. major depression, psychosis or drug abuse), any metastasis or autoimmune disease, systematic corticosteroid intake, previous participation in any study related to stress management and inability to read or write in the Greek language.
Interventions	Pythagorean Self-Awareness Intervention (PSAI) vs control once a week for 8 weeks each lasting for 2 hours
Outcomes	Perceived stress was evaluated by Perceived Stress Scale the total score ranges from 0 to 56. Higher PSS scores indicate higher levels of perceived stress. Symptoms of depression, anxiety and distress were evaluated using the Greek version of the DASS-21questionnaire which consists of 21 items that generate 3 subscales (depression, anxiety, stress). Quality of life was assessed with the FACT-B questionnaire
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random numbers generated by an online random number generator (www.random.org).
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Self-report questionnaires. Blinding of outcome assessment was not reported. Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Although there were no dropouts from either arm, the exclusions due to receiving cortisol was significant and the subsequent per protocol analysis posed an unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors

Classen 2008

Study characteristics

Classen 2008 *(Continued)*

Methods	Design: RCT Setting: USA (nine Community Clinical Oncology Program practice groups in the community and two academic sites, Stanford University and the University of Rochester Duration of intervention: 12 weeks
Participants	N = 353 Inclusion criteria: • Diagnosis of primary, biopsy proven breast cancer, stages I through IIIA • Diagnosis occurred no more than 12 months prior to recruitment • Completion of initial surgical treatment • No detectable disease present Exclusion criteria: • Evidence of metastases beyond adjacent lymph nodes • Diagnosis of other cancers (except for basal cell or squamous cell carcinoma of the skin or in situ cervical cancer) within the past 10 years • Any other major medical problems likely to limit life expectancy to less than 10 years • Major psychiatric illness for which the patient was hospitalised or medicated, except for a diagnosis of depression or anxiety treated for a period of less than one year • Attendance at a cancer support group for more than two months
Interventions	• 12-week supportive–expressive group therapy (n = 177) versus education control (n = 176) • Groups met weekly for 12 weeks. Each meeting lasted 90 min and was composed of up to 10 members and two co-therapists. On average, women attended 8 out of 12 sessions
Outcomes	• Six different time points: baseline (before randomisation), 3 (immediately post-intervention), 6, 12, 18 and 24 months • Mood disturbance by Profile of Mood States Questionnaire (POMS) • Anxiety and depression by the Hospital Anxiety and Depression Scale (HADS) • Adjustment by Mini-Mental Adjustment to Cancer Scale (MAC)
Notes	• Of those women who were invited to participate in this trial, the acceptance rate was approximately 25% at rural sites and 35% to 45% at urban sites • There were no differences between the randomised treatment and control groups (N = 177 and N = 176, respectively) at baseline on demographic or medical status variables except for stage of disease • Only one third of the sample met the cut-off for high distress at entry

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Random assignment followed a method combining elements of biased coin randomisation with adaptive randomisation" Comment: this was probably done and judged as at a low risk of bias
Allocation concealment (selection bias)	High risk	The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment was not reported Comment: there was insufficient information to permit a clear judgement. We e-mailed the trialist who replied that there was no allocation concealment in this study

Classen 2008 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	High risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias. We e-mailed the trialist After e-mail communication with investigators: "Assessment was by patient completion of standard questionnaires who were aware of their assignment". Because patients were aware of their assignment this was judged as at high risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Figure 1 page 441 described the number and reasons for dropouts Comment: although the numbers of dropouts were balanced between the groups, the percentage of dropouts and subsequent per protocol analysis posed an unclear risk of bias
Selective reporting (reporting bias)	Unclear risk	These measures were mentioned in the methods but were not reported in results. Quote: "Courtauld Emotional Control Scale, Impact of Event Scale, Stanford Self-Efficacy Scale for Serious Illness, CARES Medical Interaction Subscale, Family Relations Index, Sleep Measure adapted from the Stanford Sleep Questionnaire and Assessment of Wakefulness, Pain Measure and Yale Social Support Index" Comment: this was judged as at an unclear risk of bias
Other bias	Unclear risk	There was an uneven distribution of high and low distressed participants. There were no declarations of potential conflicts of interest or indication of funding or support Comment: there was insufficient information reported assessing whether there were other sources of important risk of bias

Cohen 2007

Study characteristics	
Methods	Design: RCT Duration of follow-up: 4 months Setting: oncology department that covers cancer patients from the northern area of Israel
Participants	N = 114 (CBT 38, relaxation and guided imagery 39, standard care 37) Inclusion criteria: • Early stage breast cancer stage I and II who were 2 to 12 months since surgery • Receiving treatment, chemotherapy or radiotherapy • Speaking Hebrew • Absence of a psychiatric illness

Cohen 2007 *(Continued)*

Interventions	Cognitive behaviour therapy (n = 38) versus relaxation and guided imagery (n = 39) versus control (standard care) (n = 37) • Delivered by senior social worker with experience in psycho-oncology • Each group comprised 6 to 8 participants who met weekly for nine (90-minute) sessions for 3 months
Outcomes	• Assessment done at pre-intervention, post-intervention, at the end of 4-month follow-up • Psychological distress by Brief symptom inventory • Stress by Perceived Stress Scale
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "Women were randomly assigned to one of three groups" Comment: there was insufficient detail reported about the method used to generate the allocation sequence to allow a clear assessment of whether it would produce comparable groups After e-mail communication with investigators:"When a women agreed to participate, she was allocated to one of the groups 1, 2, 3 in a systematic order" Comment: this was judged as inadequate
Allocation concealment (selection bias)	High risk	The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment, was not reported Comment: there was insufficient information to permit a clear judgement After e-mail communication with investigators: "The allocation was done by a nurse who did not take a part in the study and it was totally concealed from the researchers" Comment: this was judged as inadequate
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote (page 316): "The assessors were not aware of participants' group affiliation, and their data were obtained and analysed independently of the intervention"; "the author who conducted the interventions kept strictly away from all procedures of data collection and data recording on the computer" Comment: this was judged as at a low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Quote: "Demographic and clinical characteristics of the active participants in each of the groups and of those who dropped out are comparable and presented in Tables 1 and 2" 170 agreed to participate and 26 declined. 14 from the relaxation and guided imagery group and 16 from the cognitive behaviour group were not included in the analysis

Cohen 2007 *(Continued)*

		Comment: although the numbers of dropouts were balanced between the groups, the percentage of dropouts and subsequent per protocol analysis posed an unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Unclear risk	There were no declarations of potential conflicts of interest or indication of funding or support Comment: there was insufficient information reported to assess whether there were other sources of important risk of bias

Desautels 2018

Study characteristics	
Methods	Design: RCT Country: Canada Setting: outpatient Method of randomisation: The group allocation was prepared by a statistician prior to study initiation using the SAS PROC PLAN procedure and allocation block sizes of 12 (i.e., each block of 12 allocations included in random order 5 CT, 5 BLT, and 2 WLC allocations). Method of allocation: The group allocation was contained in individually sealed and opaque envelopes. The research personnel was blind to the randomisation sequence. Outcome assessor blinding: To limit interviewer biases, the evaluator was blind to the participants' experimental condition.
Participants	N= 60 randomised CT (25), BLT (26), or WLC (11) Inclusion criteria: (a) diagnosis of nonmetastatic breast cancer in the past two years; (b) score ≥ 7 on the depression subscale of the Hospital Anxiety and Depression Scale (HADS-D; or ≥ 14 on the Beck Depression Inventory-II (c) between 18 and 75 years; and (d) able to read and understand French. Exclusion criteria: (a) BLT in the past month or CBT for depression in the past year; (b) severe cognitive impairments (e.g., Alzheimer's disease or a score ≥ 23 on the Mini-Mental State Examination [MMSE]; (c) severe psychiatric disorder (e.g., severe major depressive disorder, as assessed with the Structured Clinical Interview for DSM–IV [SCID]; (d) suicidal ideations with a risk of acting out, as assessed with the Scale for Suicide Ideation or suicide attempt in the past five years; (e) initiation of a psychotropic medication or dosage change in the past month or expected during the intervention phase; (f) photosensitive medication (e.g., imipramine); and (g) disease contraindicating BLT (e.g., severe cataracts, diabetes).
Interventions	Intervention group: cognitive therapy (CT), bright light therapy (BLT), and a waiting-list control Frequency: the intervention was administered individually by a doctoral-level student in clinical psychology and involved 8 weekly sessions of approximately 60 minutes Duration: 8 weeks BLT: Participants assigned to BLT were instructed to expose themselves to a 10,000 lux light box (30 minutes, every morning, before 10:00 a.m. Control group: wait list

Desautels 2018 *(Continued)*

Outcomes	Depression measured by the HADS. A 14-item questionnaire divided into two subscales of seven items each, assessing depressive (HADS-D) and anxiety symptoms. Only scores on the depression subscale are used in this report. The 4-point Likert scale ranges from "0" to "3", and a score ≥7 on the HADS-D suggests a clinical level of depressive symptoms. Depressive symptoms measured by the BDI-II includes 21 items evaluating the severity of depressive symptoms, each with four response choices ranging from 0 to 3.A total score ≥14 suggests a clinical level of depressive symptoms. Severity of depressive symptoms measured by the Structured Interview Guide for the Hamilton Depression Rating Scale (HDRS). This structured interview contains 17 items. Each item is rated on a scale ranging from 0 to 2 or 0 to 4, yielding a total score ranging from 0 to 52. Assessed at post treatment, 3 and 6 months
Notes	Funding: supported by training awards from the Canadian Institutes of Health Research, the Psychosocial Oncology Research Training program, and the CHU de Québec—Université Laval Research Center.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The group allocation was prepared by a statistician prior to study initiation using the SAS PROC PLAN procedure and allocation block sizes of 12 (i.e., each block of 12 allocations included in random order 5 CT, 5 BLT, and 2 WLC allocations).
Allocation concealment (selection bias)	Low risk	The group allocation was contained in individually sealed and opaque envelopes. The research personnel was blind to the randomisation sequence.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Low risk	To limit interviewer biases, the evaluator was blind to the participants' experimental condition
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Although the dropout was minimal and balanced between the three arms, the per protocol analysis pose unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Supported by training awards from the Canadian Institutes of Health Research, the Psychosocial Oncology Research Training program, and the CHU de Québec—Université Laval Research Center

Dolbeault 2009

Study characteristics

Methods	Design: RCT

Dolbeault 2009 *(Continued)*

	Setting: 3 French cancer centres
Participants	N = 203 (intervention 102, control 101) Inclusion criteria: • 18 years or older • Completed primary breast cancer treatment (radiation alone or combined chemoradiotherapy 15 days to 1 year before testing) • No recurrence or metastases • Had working knowledge of French • No psychiatric diagnosis such as severe cognitive disorders, mood disorders (ongoing or recent history of depression requiring hospitalisation) or serious personality disorder
Interventions	• 102 in the psycho-education group versus 101 in the waiting list • Led by two therapists, either psychologists or psychiatrists, 8 (2 hour) group sessions of cognitive behavioural therapy
Outcomes	• One week before starting the immediate intervention (E1), the second after completion of the intervention (E2) after 8 sessions, and the third after 1 month of completion week before the beginning of the deferred intervention (E3) • Stress by State-Trait Anxiety Inventory (STAI) (whose scores range from 20 to 80 with a higher score reflecting a higher level of anxiety) • Depression by Profile of mood states (POMS), total score and subscales scores were calculated • Coping by the Mental Adjustment to Cancer scale (MAC) • QoL by EORTC QLQ-C30,BR23 (administered only at E1 and E3 to reduce evaluation fatigue)
Notes	• Only 20% of those approached by letter answered positively • After randomisation, patients who dropped out were not replaced • Patients who missed four group sessions were excluded from the analyses

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Women were randomised" Comment: there was insufficient detail reported about the method used to generate the allocation sequence to allow a clear assessment of whether it would produce comparable groups
Allocation concealment (selection bias)	Low risk	Quote: "Randomization by sealed letter was performed at each site, with a readjustment of the number of subjects in each group after every eighth subject" Comment: this was judged as at a low risk of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias

Dolbeault 2009 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Quote (page 468): "patients who dropped out were not replaced. Patients who missed four group sessions were excluded from the analyses" Quote (page 654): "lack of complete data for one-fifth of the patients, who did not complete the questionnaires at all three evaluation times" Overall dropouts 35/203 (17.2%) (21% dropped out from intervention and 14% from control) and were excluded from analysis Comment: although the numbers of dropouts were balanced between the groups, the percentage of dropouts and subsequent per protocol analysis posed an unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	This research received a grant from a French Hospital Programme of Clinical Research Comment: this was judged as at a low risk of bias

Dowlatabadi 2016

Study characteristics	
Methods	Design: randomised controlled trial Duration of trial: September 10, 2013 to December 25, 2015 Country: Iran Setting: Oncology Center in Kermanshah Method of randomisation: not reported Method of allocation: not reported Outcome assessor blinding: not reported
Participants	N= 42 (intervention 21, control 21) Inclusion criteria: 1) gaining equivalent score of mild to moderate depression (14-28 in BDI-II), 2) being 25-50 years old, and 3) having had breast cancer for at least 3 months Exclusion criteria: 1) intense depression score or lack of depression and 2) receiving simultaneous psychiatry therapy or other psychotherapies
Interventions	Intervention group: positive psychotherapy Frequency: 10 sessions (1.5 hours weekly) of positive psychotherapy Duration: 10 weeks Control group: usual care
Outcomes	Depression measured by Beck's depression inventory (BDI-II) has 21 items, and each item is one graded from 0 to 13, and each individual's score is from 0 to 63. Four groups were established based on the ranges of scores as 0-13: minimum score, 14-19: mild depression, 20-28: moderate depression, and 29-63: intense depression.

Dowlatabadi 2016 *(Continued)*

	Assessed before the first session and after the last session
Notes	Funding: the authors received financial support for the research from Kermanshah University of Medical Sciences.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation was not reported
Allocation concealment (selection bias)	High risk	Allocation concealment was not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	High risk	Blinding of outcome assessment was not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	Five members of experimental group and four members of the control group were omitted.
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	The authors received financial support for the research from Kermanshah University of Medical Sciences.

Ercoli 2015

Study characteristics

Methods	Design: RCT Country: Los Angeles, CA, USA Setting: outpatient Method of randomisation: randomisation was carried out in blocks of 3, with a 2:1 ratio of assignment to CR versus WL Method of allocation: random assignments were placed in consecutively ordered sealed envelopes that were opened after baseline testing Outcome assessor blinding: mood assessment was completed by patients
Participants	N = 48 (intervention 32, control 16) Inclusion criteria: female; age 21 to 75 years; history of stage 0, I, II, III breast cancer with treatments completed between 18 months and 5 years earlier; current endocrine therapy allowed; able to read and

Ercoli 2015 *(Continued)*

	speak English; self-reported cognitive difficulties interfering with everyday activities; able to provide written informed consent. Exclusion criteria: current uncontrolled depression using a standardised screening measure; another current psychiatric disorder; concurrent psychoactive medications such as sedatives, hypnotics, opiates taken chronically; central nervous system disorders or past cranial radiation or intrathecal chemotherapy; history of head trauma, seizure disorder, learning disability, or regular and heavy use of illicit substances or alcohol.
Interventions	Intervention group: cognitive rehabilitation (CR) intervention Frequency: 5-week, 2 hours per week, annualised group intervention delivered by clinicians Duration: 5 weeks Control group: wait list control
Outcomes	Depression measured by The Beck Depression Inventory, 2nd Edition [18] (BDI-II) was used to assess depressive symptoms. Standard cutoff scores indicate minimal (0–9), mild (10–18), moderate (19–29), or severe (30–63) depression. Assessed at baseline assessment (T1) prior to randomisation and post-intervention (T2) (within a week of completing the CR or at the same time interval for those in the WL group in the cohort) and 2 months following the intervention (T3) for the CR and WL groups in the cohort
Notes	Funding: funding for this research was provided by the Breast Cancer Research Foundation and the Jonsson Cancer Center Foundation.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation was not reported
Allocation concealment (selection bias)	Low risk	Random assignments were placed in consecutively ordered sealed envelopes that were opened after baseline testing
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Mood assessment was self-administered and completed by patients. Other outcomes were assessed by investigators who were masked to the intervention assignment
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	One dropped from control and 6 from intervention. The dropouts are not balanced and there are insufficient information about dropouts.
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Funding for this research was provided by the Breast Cancer Research Foundation and the Jonsson Cancer Center Foundation.

Ferguson 2012

Study characteristics	
Methods	Design: RCT Setting: Dartmouth-Hitchcock Medical Center, USA

Participants	N = 40 (intervention 19, wait list control 21)
	Inclusion criteria:
	
	• Adult female breast cancer survivors:
	  ○ Received adjuvant chemotherapy for stage I and II
	  ○ Were at least 18 months post-treatment currently disease free (not excluding individuals on hormonal therapies such as selective oestrogen receptor modulators or aromatase inhibitors)
	  ○ Treatment involved standard dose adjuvant chemotherapy
	  ○ Complaint of memory and attention problems following chemotherapy
	  ○ Able to speak and read English
	  ○ At least 18 years of age at diagnosis and able to provide informed written consent
	
	Exclusion criteria:
	
	• History of Central Nervous System (CNS) disease
	• History of CNS radiation
	• Intrathecal therapy or CNS-involved surgery
	• Neuro-behavioural risk factors such as traumatic brain injury, history of neurological disorder
	• Learning disability or substance addiction
	• Current psychiatric disorder

Interventions	• Memory and Attention Adaptation Training (MAAT) was a brief cognitive behavioural therapy (CBT) aimed at enhancing cancer survivor skills for self-managing and coping with cognitive failures of daily life, four biweekly individual office visits • 30 to 50 minutes in duration with phone contacts between visits
Outcomes	Measured at baseline, post-treatment, 2-month follow-up QoL measured by Quality of Life—Cancer Survivors (QOL-CS), higher scores represented better outcomes Depression by Center for Epidemiological Study–Depression (CES-D) Anxiety by Spielberger State-Trait Anxiety Inventory (STAI)
Notes	

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote page 178: "randomized to treatment and wait list conditions using computer generated assignment" Comment: this was judged as low risk of bias
Allocation concealment (selection bias)	Unclear risk	The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment, was not reported Comment: there was insufficient information to permit a clear judgement

Ferguson 2012 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote page 178: "The research assistant completing all assessment and testing was blind to participant group membership" Comment: this was judged as low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	40 randomised, intervention 19 and control 21, 2 dropped out from intervention and 3 dropped out from control, attrition rate 12.5% Quote page 178: "These participants did not differ significantly from the final sample demographic or dependent variables" Missing data were accounted for using linear interpolation Comment: interpolation may potentially lead to type I error the effect of which was unclear so this was judged as unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Funded by a grant from the Lance Armstrong Foundation

Fillion 2008

Study characteristics	
Methods	Design: RCT Setting: Canada Duration of intervention: 3 months
Participants	N = 94 (intervention 48, control 46) Inclusion criteria: • Non-metastatic breast cancer • Completed their initial breast cancer treatment no longer than 2 years before enrolment • Received 1 series of adjuvant treatments of radiotherapy, or having received radiotherapy in combination with other adjuvant treatments (e.g. chemotherapy or hormonal therapy) • Understanding and speaking French • Passing the revised Physical Activity Readiness Medical Examination • Living near the cancer centre and being available to take part in a series of 4-weekly sessions • Accepting the randomisation procedure Exclusion criteria: • Showed clinical levels of depression symptoms • Insomnia • Any symptoms of recurrence • Any known severe health problems other than cancer

Fillion 2008 *(Continued)*

Interventions	• The intervention was composed of 4-weekly group meetings of 2.5 hours and 1 short telephone booster session (5 to 15 minutes), stress and fatigue management program
Outcomes	• Follow-up at baseline, after intervention 5 weeks and 3 months • Quality of life by the Medical Outcomes Study Short Form 12. It provides 2 scores: a mental health and a physical health component • Emotional distress combines the mean scores of the anxiety and depression subscales of the Profile of Mood State
Notes	• Of the 498 patients eligible and invited to participate, 149 (30%) showed interest in participating in the study • 94 (19%) participants met all eligibility criteria and were randomly assigned to the study conditions

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote (page 153): "The sequence of randomisation was computer generated, after a preliminary stratification, according to the adjuvant treatments received" Comment: this was judged as at a low risk of bias
Allocation concealment (selection bias)	Low risk	Quote (page 152): "randomly assigned each participant to either the control or experimental group using sealed envelopes which were concealed to both kinesiologist and patient until then." Comment: this was judged as at a low risk of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Of 94 participants, 7 withdrew for reasons reported on the flowchart (Figure 1, page 149), 87 analysed Comment: although the numbers of dropouts were balanced between the groups and the percentage of dropouts was low, subsequent per protocol analysis posed an unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Unclear risk	Quote: "Significant differences between groups were observed for the following variables: employment status, physical activity level, physical menopausal symptoms, cancer stage, hormonal therapy, and partial and total mastectomy" Supported by grant from the "Fonds de recherche en sante´ du Quebec" and by an Investigator Award to Lise Fillion

Fukui 2000

Study characteristics	
Methods	Design: RCT Setting: National Cancer Center Hospital East, Japan Duration of intervention: 6 weeks
Participants	N = 50 (intervention 25, control 25) Inclusion criteria: • Younger than 65 years • Identified and informed of being at higher risk of recurrence (defined as lymph node metastasis positive or histological or nuclear grade 2 to 3, or both) • Surgery within the previous 4 to 18 months • No chemotherapy or completed chemotherapy Exclusion criteria: • Severe mental disorders or dementia • If they had cancer at another site diagnosed
Interventions	• The intervention consisted of health education, coping skills training, stress management, and psychologic support • 6 weekly 1.5-hour group intervention led by a psychiatrist and a clinical psychologist • Waiting list control group
Outcomes	• Psychological distress by Profile of Mood States (POMS) • Coping by Mental Adjustment to Cancer (MAC) scale • Anxiety and depression by Hospital Anxiety and Depression (HADS) scale Assessment done at baseline, at 6 weeks, and at 6 months
Notes	

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote (page 1027): "Participants were randomly assigned to either an experimental group or a wait-list control group by using a table of random numbers" Comment: this was judged as at a low risk of bias
Allocation concealment (selection bias)	Unclear risk	The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment was not reported Comment: there was insufficient information to permit a clear judgement
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote: "We were unable to blind the participants to treatment allocation". Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcomes in this type of intervention was unclear

Fukui 2000 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Four participants dropped out (8%), two of them in the intervention arm, reasons mentioned. Quote: "The dropouts were not significantly different regarding any demographic or clinical variables or any dependent measures at the baseline from those who completed all assessments" Comment: although the numbers of dropouts were balanced between the groups and the percentage of dropouts was low, subsequent per protocol analysis posed an unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Unclear risk	• Small sample size • There was a significant difference in age between the participants who participated and those who did not • Supported by a Grant-in-Aid for Cancer Research and Second-Term Comprehensive 10-Year Strategy for Cancer Control from the Japanese Ministry of Health and Welfare, Japan. Also was supported by the Fumiko Yamaji Trust for Academic Nursing Education and Research, Tokyo, Japan

Garssen 2013

Study characteristics	
Methods	Design: RCT Setting: Medical Centre Alkmaar, the Netherlands Duration of intervention: 4 sessions
Participants	N = 85 (intervention 42, control 43) Inclusion criteria: • Clinically-proven breast cancer stage I to III Exclusion criteria: • Age > 75 years • Serious psychiatric disorder • Immune-related comorbidity • Other malignant tumours now present • Chemotherapy or immunotherapy • Use of steroid medicines, Primperan or non-steroid anti-inflammatory drugs
Interventions	• The intervention delivered was Stress Management Training consisting of four sessions of relaxation, guided imagery techniques, and counselling that aimed to promote active coping, alert relaxation, and a positive attitude to change. The training sessions were conducted by the same trained clinical psychologist • The control group received care as usual without any contact with the psychologist who delivered the training in the intervention group

Garssen 2013 *(Continued)*

Outcomes	Measured at 6 measurement points: day 6 and day 1 pre-surgery, and day 2, 5, 30 and 90 post-surgery • Anxiety: the state scale from the State-Trait Anxiety Inventory • Depression by the eight-item depression subscale from the Profile of Mood States was used (POMS) • Quality of life by the three general quality of life questions from the European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire (EORTC)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote page 573: "Subjects were randomly assigned to the intervention and control condition by using block randomization. The first week, patients were allocated to the intervention condition and the next week to the control condition" Comment: there was insufficient detail reported about the method used to generate the allocation sequence to allow a clear assessment of whether it would produce comparable groups
Allocation concealment (selection bias)	Unclear risk	The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment, was not reported Comment: there was insufficient information to permit a clear judgement
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Dropouts = 15 for reasons mentioned in figure 2 page 576 Comment: although the numbers of dropouts were balanced between the groups and the percentage of dropouts was low, subsequent per protocol analysis posed an unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Financed by the Dutch Cancer Society

GokMetin 2019

Study characteristics

Methods	RCT
Participants	N = 92

GokMetin 2019 *(Continued)*

	Progressive muscle relaxation(PMR) (n = 31) Mindfulness meditation MM (n = 32) Control group (CG) (n = 29). Patients with EBC, scheduled to receive the first dose of adjuvant paclitaxel regimen included in this study.
Interventions	Progressive muscle relaxation(PMR), Mindfulness meditation MM (n = 32). Once a day for 20 minutes for a total of 12 weeks
Outcomes	Follow-up at week 14 Brief Fatigue Inventory Coping measured by Brief COPE, The higher score represents greater coping strategies used by the participants. QoL by Functional Living Index-Cancer, The scale scores vary between 22 and 154, with higher scores indicating higher levels of QOL.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised using a random number allocation list generated by the software MS Excel 2013.
Allocation concealment (selection bias)	Low risk	The principal investigator who was not involved in the intervention procedures divided participants into three groups (Group A: 31, Group B: 32, and Group C: 29) using a random number allocation list including six different combinations.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Author conducting the intervention was not blinded to the study groups. The participants were also not blinded to the interventions. Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Low risk	All assessments were performed by a single data collector who was blinded to the study groups, and data were analysed by an independent statistician
Incomplete outcome data (attrition bias) All outcomes	Low risk	2 lost follow-up in PMR, 1 in MM, 1 in control
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	This study was supported by the Scientific Research Projects Coordination Unit of Hacettepe University, Turkey (project no. THD-2018-17089).

Gonzalez-Hernandez 2018

Study characteristics	
Methods	Design: RCT Country: Spain Setting: outpatient Method of randomisation: Randomizer software Method of allocation: not reported Outcome assessor blinding: outcome assessors, data analysts, and staff were blinded to the allocation at all times during study
Participants	N = 56 (intervention 28, control 28) Inclusion criteria: (1) age between 18 and 75 years, (2) being able to read and write using the Spanish language, (3) history of treated BC within the past 15 years, (4) being free from oncological illness, (5) not receiving any kind of chemotherapy and/or radiotherapy treatment during study, and (6) being free from severe psychiatric disorders assessed with the Mini International Neuropsychiatric Interview (MINI) Exclusion criteria: active severe mental disorders (schizophrenia, bipolar disorder, eating disorders, and major depression), substance use disorders, cognitive impairment, or impaired medical condition.
Interventions	Intervention group: cognitively-Based Compassion Training Frequency: 2-hour session Duration: 8 weeks Control group: treatment-as-usual control group. TAU participants were offered the CBCT protocol at the end of research
Outcomes	Health-related QoL in BC as measured by the Functional Assessment of Cancer Therapy– Breast Cancer (FACT-B+4 Assessed before and two months after baseline evaluation (posttest) and at 6 months (follow-up).
Notes	Funding: the author(s) received no financial support for the research, authorship, and/or publication of this article.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Participants were randomised by a list of random numbers generated by Research Randomizer software [http://www.randomizer.org])
Allocation concealment (selection bias)	Unclear risk	Study participants were blinded to group assignment until completion of all baseline assessments. Moreover, outcome assessors, data analysts, and staff were blinded to the allocation at all times during study. However, the method of blinding was not reported, the absence of which poses unclear risk.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear

Gonzalez-Hernandez 2018 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors, data analysts, and staff were blinded to the allocation at all times during study. However, the method of blinding was not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	6/28 dropped from intervention and 3/28 dropped from control.
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Funding: the author(s) received no financial support for the research, authorship, and/or publication of this article.

Graves 2003

Study characteristics	
Methods	Design: pilot randomised two group design Setting: USA Duration of intervention: 8 weeks
Participants	N = 32 (intervention 15, control 17) Women of any stage within the past five years were included but none of them were at stage IV of the disease Age was not specified
Interventions	Intervention versus standard care The intervention: 8 sessions of social cognitive theory, that is, one session (1.5 hour/session) for 8 weeks Women assigned to the intervention ~n = 15 attended the program in small groups
Outcomes	Collected at baseline and post-test • QoL assessed by Functional Assessment of Cancer Therapy-Breast (FACT-B) • Mood assessed by Profile of Mood States (POMS) • Coping assessed by Cancer Behaviour Inventory (CBI)
Notes	For the post-test only 7 completed the test in the intervention arm and 7 in the control arm

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Women were randomised to either the skill-building intervention or standard care control group Comment: there was insufficient detail reported about the method used to generate the allocation sequence to allow a clear assessment of whether it would produce comparable groups

Graves 2003 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment was not reported Comment: there was insufficient information to permit a clear judgement
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	High risk	• For the post-test, only 7 completed the test in the intervention arm and 7 in the control arm • Women who completed post-test did not differ from the 18 women who did not complete the study on any demographic or clinical characteristics • Women who completed the intervention appeared to be more distressed at baseline than women who dropped out of the study • Baseline differences between women who completed the program and those who did not complete the program were evident across all variables • The consistent finding that all of the baseline scores were lower for completers was intriguing • Dropout 14/32 = 44% Comment: the high dropout rate and per protocol analysis posed a high risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Comment: this project was funded in part by the Graduate Student Association of Virginia Tech

Gudenkauf 2015

Study characteristics	
Methods	Design: RCT Country: Miami, USA Setting: community clinics and cancer centres Method of randomisation: not reported Method of allocation: a project coordinator not involved in intervention administration or assessment generated the random allocation sequence, enrolled participants, and assigned participants to groups Outcome assessor blinding: research assistants who were blinded to the condition mailed or administered the T2 questionnaire
Participants	N = 183 (Cognitive-Behavioral Training intervention 55, Relaxation Training RT intervention 70, control 58)

Gudenkauf 2015 *(Continued)*

	Inclusion criteria: women age 21 or older with stage 0 – III BCa were recruited within 10 weeks of primary surgery Exclusion criteria: prior cancer or neo-adjuvant treatment, severe psychiatric illness, acute or chronic medical conditions, or were not fluent in English
Interventions	Intervention group: CBT intervention, RT intervention Frequency:Groups met weekly at the University of Miami for 1.5-hour sessions and were co-led by Master's level students in a clinical psychology doctoral program who were trained in the protocols for each condition Duration: 5 weeks Control group: Health Education (HE) control
Outcomes	Depressive affect was assessed using the depression subscale of the 40-item Affects Balance Scale Response options range from Never (1) to Always (5). The ABS-depressive affect subscale score was calculated as the mean response score of five items: sad, hopeless, worthless, miserable, unhappy Cancer-specific distress—Intrusion of cancer-related thoughts was assessed using the Intrusions subscale of the Impact of Event Scale – Revised. Response options range from Not at all (0) to Extremely (4). The IES-I subscale score was calculated as the mean score of these seven item responses. Emotional adjustment was measured using the Emotional Well-being (EWB) subscale of the Functional Assessment of Cancer Therapy – Breast. Response options range from Not at all (1) to Very much (5). The FACT-EWB subscale was calculated as the mean score of six such item responses. Assessed at baseline (T1) and post-intervention (T2)
Notes	Funding: this study was funded by the National Cancer Institute of the National Institutes of Health

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	A project coordinator not involved in intervention administration or assessment generated the random allocation sequence, enrolled participants, and assigned participants to groups. Comment: The allocation although concealed, the method used for randomisation was not reported and thus this posses unclear risk of bias. failure of random assignment to equate the study groups at baseline. This creates an ambiguity concerning the meaning of the results that cannot be entirely discounted.
Allocation concealment (selection bias)	Low risk	A project coordinator not involved in intervention administration or assessment generated the random allocation sequence, enrolled participants, and assigned participants to groups
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Research assistants who were blinded to the condition mailed or administered the T2 questionnaire.

Gudenkauf 2015 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	15/55 dropped from CBT, 21/70 dropped from RT, 9/58 dropped from control. Intention to treat analysis was performed so this was judged as low risk of bias.
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	This study was funded by the National Cancer Institute of the National Institutes of Health

Henderson 2012

Study characteristics	
Methods	Design: RCT Setting: USA Duration of intervention: 8 weeks
Participants	N = 172 newly diagnosed (within the past two years) stage I or II cancer of the breast Inclusion criteria: • Between 20 and 65 years of age • Capable of understanding informed consent in English • Planned to maintain residence in the study area for at least two years following recruitment • Eastern Cooperative Oncology Group performance status 0, 1, or 2 (i.e. able to function normally 50% of the time); were willing to accept randomisation • Had a working home telephone • Willing to be contacted Exclusion criteria: • Previous diagnosis of cancer in the past 5 years, except non-melanoma skin cancer • Current chronic substance abuse (either drug or alcohol) • Past or present psychiatric or neurologic disorder that would preclude or severely limit participation in the study
Interventions	Three-arm RCT Mindfulness-based stress reduction (MBSR) (n = 58) versus nutrition education program (n = 52) versus usual supportive care (n = 53) MBSR included elements consistent with cognitive behavioural therapy, group support, experiential focus, and a strong educational orientation Intervention included 7 weekly 2.5 to 3.5-hour sessions and one 7.5-hour intensive silent retreat session in the sixth week
Outcomes	Follow-up was performed at three post-intervention points: 4 months, 1, and 2 years • Cancer specific QoL, as measured by the breast cancer version of the Functional Assessment of Cancer Therapy (FACT-B) • Coping mechanisms, measured by the Dealing with Illness questionnaire (focuses on three broad dimensions of coping strategies: (a) active behavioral coping (b) active cognitive coping; and (c) avoidance coping)

Henderson 2012 *(Continued)*

- Depressive symptoms, measured by the Beck Depression Inventory-I (BDI)
- Anxiety symptoms, measured by the Beck Anxiety Inventory (BAI)
- General distress, measured by the Symptom Checklist- 90-Revised (SCL-90-R)
- Cancer specific coping and emotional responses were measured by the short form of the Mental Adjustment to Cancer Scale (Mini-MAC)

Notes		

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Women were block randomised by stage of disease (I or II), by age (± 5 years) within menopausal group, and by institution Comment: there was insufficient detail reported about the method used to generate the allocation sequence to allow a clear assessment of whether it would produce comparable groups
Allocation concealment (selection bias)	Unclear risk	The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment, was not reported Comment: there was insufficient information to permit a clear judgement
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	Dropouts = 17 out of 180, attrition rate (9.4%) Analyses were conducted using both intention-to-treat (ITT), which only takes into account whether or not a subject was randomised, and post-hoc analyses in which models were fit that included information on co-variates from participants who provided data at each measurement point Comment: this was judged as low risk of bias
Selective reporting (reporting bias)	Unclear risk	No data for distress and mental adjustment to cancer
Other bias	Unclear risk	Funded by grant from the US Army Medical Research and Material Command Career Development Award. Established Investigator Award in Cancer Prevention and Control

Ho 2016

Study characteristics

Methods	Design: RCT

Ho 2016 *(Continued)*

	Country: Hong Kong Setting: outpatient Method of randomisation: Simple randomisation with computer generated random numbers (1:1:1 ratio) Method of allocation: not clear Outcome assessor blinding: not reported
Participants	N = 157 randomised (BMS 51, SEG 49, control 57) Inclusion criteria: diagnosis of stages I to stage III breast cancer and completion of active treatment. Exclusion criteria: diagnosis of other cancers within the past 10 years, metastasis or recurrence of cancer, major psychiatric illness such as schizophrenia, pregnancy, or the inability to speak or read Chinese.
Interventions	Intervention group: supportive-expressive group therapy and body-mind-spirit intervention Frequency: 2-hour weekly sessions for 8 weeks Duration: 8 weeks Control group: was organised in the form of a social support self-help group and did not include any structured program. It comprised eight weekly sessions that lasted 2 hours each with small groups of 8–12 participants
Outcomes	Emotional suppression was assessed by the 21-item, 4-point Chinese Courtauld Emotional Control Scale with its total score ranging from 21 to 84 Perceived stress was assessed by the 10-item, 5-point Chinese Perceived Stress Scale with its total score ranging from 0 to 40. Anxiety and depression were measured by the 14-item, 4-point Chinese Hospital Anxiety and Depression Scale with their total scores ranging from 0 to 21 Assessed at baseline (T0) and three follow-up assessments in the 4th (T1), 8th (T2), and 12th month (T3).
Notes	Funding: Hong Kong Cancer Fund and Hong Kong Research Grants Council

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Simple randomisation with computer generated random numbers (1:1:1 ratio)
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was done however the method used to achieve this was not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported

Ho 2016 *(Continued)*

		Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	One-year dropout rate (11.5 %). The study completers (n = 139) did not differ significantly from the drop-outs (n = 18) in terms of baseline characteristics. Per protocol analysis was performed.
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Hong Kong Cancer Fund and Hong Kong Research Grants Council

Jang 2016

Study characteristics	
Methods	Design: Randomised controlled trial (RCT) Country: Republic of Korea Setting: outpatient Method of randomisation: not reported Method of allocation: not reported Outcome assessor blinding: not reported
Participants	N = 24 (intervention 12, control 12) Inclusion criteria: received diagnosis for breast cancer and surgery at Wonkwang University Hospital. They then underwent radiation treatment or chemotherapy. All the patients had completed surgery, chemotherapy, or radiation treatment less than two years before. Exclusion criteria: (1)they were in stage IV of breast cancer;(2)they were unable to consent to the research due to damage to their intellectual capacity; or(3)they had experienced drug abuse, had suicidal thoughts, or mental symptoms.
Interventions	Intervention group: Mindfulness-based art therapy (MBAT) Frequency: 12 sessions lasting 45 minutes each. Duration: 12 weeks Control group: the participants in the wait listed control group received the same MBAT intervention as the experimental one.
Outcomes	QoL measured by EORTC-QLQ- C30 Depression and anxiety by Personality assessment inventory, self-report type evaluation assessed at pre- and post-intervention
Notes	Funding: Wonkwang University, South Korea

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Jang 2016 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Random sequence generation was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only one dropped from the intervention and results were analysed based on intention to treat ITT.
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Funded by Wonkwang University, South Korea

Janusek 2019

Study characteristics	
Methods	RCT
Participants	N = 192 (intervention 96, control 96) Inclusion criteria: 28–75 years of age, newly diagnosed with early stage breast cancer. Women were identified after their breast surgery. Exclusion criteria: prior MBSR training, recurrent breast cancer, other current or past cancers, immune-based disease, psychoses, cognitive dysfunction, and inability to read or write English; were substance abusers, or used immune-altering medications.
Interventions	MBBS Mindfulness based stress reduction Eight-week (2.5 hours/week) program with a 6-hour silent mindful retreat after the fifth week. ACC active control condition consists of cancer recovery and health education classes
Outcomes	Stress by Perceived Stress Scale (PSS) Depression by Center for Epidemiologic Studies, Depression Scale (CES-D) Scores range from 0 to 60 and a score greater than 16 indicates risk for clinical depression. Assessed at T1 baseline at least 2 weeks after surgery

Janusek 2019 *(Continued)*

	T2 at 4 weeks T3 at 8 weeks T4 at 1 month post program T5 at 6 months post program
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The study biostatistician used a computer generated randomisation scheme to prepare sequentially numbered and sealed envelopes, blocked by age.
Allocation concealment (selection bias)	Low risk	Women were assigned to MBSR or ACC by sequential selection of a sealed envelope containing the words: MBSR or ACC. Research assistants and participants were blinded to the randomisation sequence. Sealed envelopes were stored in a locked file at Loyola University Chicago.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	63/96 completed the trial in intervention arm 61/96 completed the trial in control arm Dropout rate more than 30% Analyses were ITT Comment: Although analysis was based on ITT the high drop out rate poses unclear risk of bias.
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	The study was supported by funds from the National Cancer Institute, United States, R01 CA125455 and the Gloria Capek Gift Fund.

Johannsen 2016

Study characteristics

Methods	Design: RCT Country: Denmark Setting: outpatient

Johannsen 2016 *(Continued)*

	Method of randomisation: randomisation was conducted independently using Power and Sample Size (PASS), v.12 (NCSS, Kaysville, UT) Method of allocation: not reported Outcome assessor blinding: not reported
Participants	N = 129 randomised (intervention 67, control 62) Inclusion criteria: primary BC, 3 months after surgery, completed chemotherapy and/or radiotherapy, a score of 3 on perceived pain intensity or pain burden on a 10-point numerical rating scale (NRS), and ability to understand Danish. Exclusion criteria: metastatic BC, other cancers, male sex, serious psychiatric diagnoses (e.g. psychosis), and other severe medical conditions related to the musculoskeletal system (e.g. arthritis)
Interventions	Intervention group: mindfulness-based cognitive therapy (MBCT) Frequency: weekly 2-hour sessions delivered in groups of 13 to 17 participants in weekly sessions over 8 consecutive weeks. Duration: 8 weeks Control group: Wait list control
Outcomes	QoL was assessed with the World Health Organization–5 Well-Being Index (WHO-5). A standardized percentage score is calculated, with higher scores indicating better QoL Psychological distress was assessed with the Hospital Anxiety and Depression Scale (HADS). The HADS total score has shown good psychometric qualities as an overall measure of distress. Assessed at baseline (T1), immediately after intervention (T2), 3 months after (T3), and 6 months after (T4)
Notes	Funding: Supported by The Danish Cancer Society, Aase & Ejnar Danielsens Fond, Einar Willumsens Mindelegat, and Radiumstationens Forskningsfond.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was conducted independently using Power and Sample Size (PASS), v.12 (NCSS, Kaysville, UT)
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias)	Unclear risk	Unbalanced dropout at T2, with more dropouts in the intervention group than in controls possibly introducing biased estimates. However, dropout analyses

Johannsen 2016 *(Continued)*

All outcomes		did not reveal any baseline differences between dropouts and respondents on any primary outcome measures
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Supported by The Danish Cancer Society, Aase & Ejnar Danielsens Fond, Einar Willumsens Mindelegat, and Radiumstationens Forskningsfond.

Kim 2013

Study characteristics	
Methods	Design: open-label, randomised clinical trial Country: Republic of Korea Setting: outpatient unit of ‘‘Asan Medical Center’’ general hospital located in Seoul, Korea Method of randomisation: random numbers were generated by the website program http://randomization.com/ Method of allocation: one of the authors of the study Outcome assessor blinding: self-reporting
Participants	N = 102 (intervention 51, control 51) Inclusion criteria: women aged 20 or over with breast cancer, all of whom started radiation therapy after a breast conserving operation Exclusion criteria: receiving psychiatric treatment, or patients with metastasis or recurrence
Interventions	Intervention group: meditation therapy sessions (Brain Wave Vibration meditation) during their 6-week radiation therapy period Frequency: 12 meditation therapy sessions Duration: 60-minute sessions twice a week for 6 weeks Control group: conventional radiation therapy
Outcomes	Depression measured by the Hospital Anxiety and Depression scale (HADS) Anxiety Hospital Anxiety and Depression scale (HADS) QoL by EORTC QLQ-C30 Assessed at pre- and post-intervention
Notes	Funding: The Korea Breast Cancer Foundation (KBCF) funded this study

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random numbers were generated by the website program - http://randomization.com/

Kim 2013 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	One of the authors who did not have contact with patients managed the random numbers. It is not clear if the author who managed the random numbers is blinded to allocation or not.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcomes measured using a self-reporting questionnaire but patients were not blinded to intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	13 dropped from the study (5 from intervention and 8 from control arm). Both ITT and per protocol analyses were done.
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	The Korea Breast Cancer Foundation (KBCF) funded this study

Kim 2018

Study characteristics	
Methods	Design: randomised clinical trial Country: South Korea Setting: outpatient Method of randomisation: random numbers generated on the website, http://randomization.com/ Method of allocation: not reported Outcome assessor blinding: not reported
Participants	N = 60 (intervention 30, control 30) Inclusion criteria: (i) had been diagnosed with stage I to III breast cancer and were undergoing adjuvant chemotherapy; (ii) were at a high risk of depression, as determined by a score of ≥16 on the Center for Epidemiologic Studies Depression scale (CES-D); (iii) were ≥20 years old; (iv) could read, understand and write in Korean; and (v) provided written consent to participate in the study Exclusion criteria: patients who had been diagnosed with a psychiatric disorder or who had taken any psychiatric medication and those who did not want to participate in the study, were too busy or hoped to overcome their situation on their own.
Interventions	Intervention group: individually delivered nurse-led psychological intervention Frequency: seven weekly counselling sessions each session lasting 30 minutes to 1 hour Duration: 7 weeks each session lasting 30 minutes to 1 hour Control group: usual care

Kim 2018 *(Continued)*

Outcomes	Affective mood disturbance was measured using the Korean version of Profile of Mood States-Brief (K-POMS-B) The K-POMS-B consists of 30 adjectives to be judged on a five-point scale (0 = not at all, 1 = a little, 2 = moderately, 3 = quite a bit and 4 = extremely).comprises six subscales (with five items per subscale and each with a score range from 0 to 20), namely tension, depression, anger, vigour, fatigue and confusion. The total mood disturbance score was calculated by subtracting the vigour score from the sum of the five other subscale scores (tension, depression, anger, fatigue and confusion); higher scores indicated worse mood states (score range: -20 to 80) Anxiety and depression were assessed using the Hospital Anxiety and Depression Scale (HADS). The HADS comprises two subscales, anxiety and depression, each of which contains seven items; all items are rated using a four-point scale (score range: 0–3). The sum of the seven items of each subscale indicates levels of anxiety and depression. For quality of life, the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life questionnaire—Core Questionnaire (QLQ-C30, version 3.0) was used.It contains three domains that measure global health status/quality of life, functional status and symptom status. Global quality of life is assessed using global health status (one item, range: 1–7) and quality of life (one item: range: 1–7). Functional status (15 items in total, range: 1– 4 per item) consists of the following five subscales: physical function (five items), role function (two items), emotional function (four items), cognitive function (two items) and social function (two items). Symptom status (13 items in total, range: 1–4 per item) consists of the following nine subscales: fatigue (three items), nausea and vomiting (two items), pain (two items), dyspnoea (one item), insomnia (one item), appetite loss (one item), constipation (one item), diarrhoea (one item) and financial difficulties (one item). Each score had a range of 0–100. High scores on global health status/ quality of life and functional status reflect high quality of life and a high level of functioning, respectively, whereas high scores on symptom status represent a high symptomatology. Assessed at immediately after the intervention (T1, 6 weeks after T0) and 3 weeks after the intervention (T2, 9 weeks after T0).
Notes	Funding: this study was part of a research project for a doctoral dissertation and had no funding sources.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomly assigned to either the intervention group or control group using random numbers generated on the website - http://randomization.com/
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Of the total 60 patients, one patient (3.3%) from the intervention group (between T0–T1) and six patients (20%) from the control group (four between T0–T1, and two between T1–T2) dropped out during the course of the study.

Kim 2018 *(Continued)*

Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	This study was part of a research project for a doctoral dissertation and had no funding sources.

Kissane 2003

Study characteristics	
Methods	Design: RCT Setting: oncology departments of nine metropolitan hospitals in Melbourne, Australia Duration of intervention: 20 weeks
Participants	N = 303 (intervention 154, control 149) Inclusion criteria: • Age under 65 • Histologically confirmed diagnosis of early stage breast cancer, operational English • Geographic accessibility Exclusion criteria: • Prior history of cancer (other than non-melanocytic skin cancers) • Psychotic illness • Dementia and intellectual disability
Interventions	Intervention versus control • The intervention: cognitive-existential group therapy, 20 sessions one session/week for 90 minutes plus three relaxation classes • Intervention group consisted of 6 to 8 patients • Control consisted of 3 relaxation classes
Outcomes	• Assessed at baseline, 6 months, 12 months • Change in affective state by Affects Balance Scale (ABS) • Anxiety and depression by Hospitals Anxiety and Depression Scale (HADs) • Adjustment to cancer by Mental Adjustment to Cancer scale (MAC) Kissane 2004 • Survival: patients' medical records were reviewed at 3 and 5 years after recruitment. Dates of confirmed recurrence or death were recorded
Notes	Baseline assessment of psychiatric disorder in control and intervention; no significant differences found Quote: "On an intention-to-treat analysis, there was a trend for those receiving group therapy (n = 154) to have reduced anxiety compared to controls (n = 149)"
Risk of bias	

Bias	Authors' judgement	Support for judgement

Kissane 2003 *(Continued)*

Random sequence generation (selection bias)	Low risk	Quote: "Randomisation was independently directed by our statistician, using a computer-generated allocation schedule". Stratified on nodal status, hormone receptor status, and tumour size Comment: this was judged as at a low risk of bias
Allocation concealment (selection bias)	High risk	Quote: "The blinding of research assistants to the randomisation allocation is not methodologically possible in research of this type" Comment: this was judged as at a high risk of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported in Kissane 2003. Quote: "Trained research assistants conducted baseline and follow-up assessments" In Kissane 2004, quote (page 4256): a different research assistant, who was blinded to randomization, reviewed patients' medical records at 3 and 5 years after recruitment" Comment: there was insufficient information to permit a clear judgement of risk of bias inKissane 2003
Incomplete outcome data (attrition bias) All outcomes	Low risk	Overall dropout rate (less than 6 sessions) from group therapy was 12%, reasons for and numbers of dropouts found in figure 1 page 534 Intention-to-treat (ITT) analysis was performed Comment: the ITT analysis and balanced dropouts between groups poses a low risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Supported by funding grants from the Research and Development Grants Advisory Committee of the Australian Commonwealth Department of Health and Human Services, the National Health and Medical Research Council of Australia and the Pratt Foundation

Lengacher 2016

Study characteristics	
Methods	Design: RCT Country: USA Setting: Moffitt Cancer Center, Carol and Frank Morsani Center for Advanced Healthcare, and Life Hope Medical Group, located in Tampa, Florida Method of randomisation: not reported Method of allocation: not reported Outcome assessor blinding: not reported

Lengacher 2016 *(Continued)*

Participants	N = 322 (intervention 167, control 155) Inclusion criteria: age 21 years or older with a diagnosis of stage 0 to III BC who had completed treatment from 2 weeks to 2 years before Exclusion criteria: a diagnosis of stage IV BC, severe mental disorder, and/or BC recurrence.
Interventions	Intervention group: Mindfulness-Based Stress Reduction (MBSR) Frequency: 2-hour sessions once per week for 6 weeks Duration: 6 weeks Control group: usual care with wait-listed MBSR
Outcomes	Depression measured by The Center for Epidemiologic Studies Depression Scale Anxiety measured by The State-Trait Anxiety Inventory–State, a subscale of the State-Trait Anxiety Inventory Stress measured by the Perceived Stress Scale, a 14-item questionnaire. Higher scores are characteristic of greater stress QOL. The Medical Outcomes Study Short Form was used to assess mental and physical health as related to QOL; higher scores are demonstrative of better mental and physical health. The Concerns About Recurrence Scale was used to measure overall FOR and problems related to FORs; higher scores are indicative of greater overall fear and worry Assessed at baseline and updated at 6 and 12 weeks.
Notes	Funding: supported by Award No. 1R01CA131080- 01A2 from the National Cancer Institute and in part by the Survey Methods Core Facility at the H. Lee Moffitt Cancer Center and Research Institute.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Participants were randomly assigned at a one-to-one ratio to MBSR or UC. Stratified block randomisation was done. However, Insufficient information was provided on method of randomisation to permit judgement of "low risk" or "high risk"
Allocation concealment (selection bias)	Unclear risk	Insufficient information to permit judgement of "low risk" or "high risk"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	The unbalanced drop out between the two arms and the per protocol analysis pose an unclear risk of bias

Lengacher 2016 *(Continued)*

Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Supported by Award No. 1R01CA131080- 01A2 from the National Cancer Institute and in part by the Survey Methods Core Facility at the H. Lee Moffitt Cancer Center and Research Institute.

Loprinzi 2011

Study characteristics	
Methods	Design: RCT Setting: USA Duration of intervention: 12 weeks
Participants	N = 24 (intervention 12, wait list 12) Inclusion criteria: • Being a Pink Ribbon Mentor • Able and willing to participate in all aspects of the study • Signed the appropriate informed consent form Exclusion criteria: • Recent (within past 6 months) psychotic episode • Clinically significant acute unstable neurologic, psychiatric, hepatic, renal, cardiovascular, or respiratory disease that prevented participation in the study
Interventions	Two 90-minute group sessions, a 30 to 60-minute brief individual session and 3 phone calls lasting 15 minutes Stress Management and Resiliency Training
Outcomes	Measured at baseline and 12 weeks Stress by Perceived Stress Scale Anxiety by Smith Anxiety Scale QoL by Linear Analog Self Assessment Scale
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Participants were divided with the help of a random number generator, into 2 groups: an active arm and a wait list control arm Comment: this was judged as low risk of bias
Allocation concealment (selection bias)	Unclear risk	Twenty-four patients were randomised in single-blind, wait list controlled clinical trial

Loprinzi 2011 *(Continued)*

		The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment, was not reported Comment: there was insufficient information to permit a clear judgement After e-mail communication with investigators: Quote: "The allocation sequence was concealed to the researchers" Comment: this was judged as insufficient information about the method of concealment
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention. The interventionist knew which participants belonged to which group Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias After e-mail communication with investigators: Quote: "Data assessors and statistician were blinded" Comment: the method used for blinding was unclear, so this was judged as at unclear risk of bias
Incomplete outcome data (attrition bias) All outcomes	High risk	No attrition in the intervention group but attrition rate in control group was 33.3% (4 out of 12 dropped) Comment: the high attrition rate in the wait-list arm and the per protocol analysis posed a high risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Funded by the Sponsorship Research Committee, Mayo Clinic College of Medicine

Manne 2007

Study characteristics	
Methods	Design: RCT Setting: USA Duration of intervention: 6 weeks
Participants	N = 238 (intervention 120, usual care 118) Inclusion criteria: • Diagnosed with early stage breast cancer • Undergone breast cancer surgery within the last six months • Eastern Cooperative Oncology Group (ECOG) status of 0 or 1 • Married or cohabiting with a significant other

Manne 2007 *(Continued)*

	• 18 years of age or older • English-speaking
Interventions	Intervention: 6-weekly 90-minute sessions (6 sessions of a couple-focused group)
Outcomes	• Assessment at pre-intervention (time 1), 1 week post-intervention (time 2), and 6 months post-intervention (time 3) • General distress: by Mental Health inventory (MHI) • Cancer specific distress: by Impact of Event Scale (IES)
Notes	• There were no differences between participants and refusers in terms of ethnicity or cancer stage but participants were younger and had higher performance on ECOG

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Participants were randomly assigned" Quote: "Participants were randomised in blocks of 14" Comment: there was insufficient detail reported about the method used to generate the allocation sequence to allow a clear assessment of whether it would produce comparable groups
Allocation concealment (selection bias)	Unclear risk	The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment was not reported Comment: there was insufficient information to permit a clear judgement
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	• Of the 238 participants, 201 completed post-intervention surveys (84.5%) and 174 completed 6-month follow-up surveys (73%) • Attrition analysis showed that participants who dropped were significantly younger, married for a shorter duration and had more physical impairment, had higher ECOG ratings • There were no significant differences in survey completion rate across conditions • ITT analysis was done Comment: this was judged as at a low risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with outcomes of interest reported in the trial design
Other bias	Unclear risk	There were no declarations of potential conflicts of interest or indication of funding or support

Manne 2007 *(Continued)*

	Comment: there was insufficient information to permit a clear judgement of the risk of bias

Manne 2016

Study characteristics	
Methods	Design: RCT Country: USA Setting: outpatient clinics of oncologists practising in three comprehensive cancer centres in the Northeastern USA or in several smaller local community hospital oncology practices Method of randomisation: by a computerised program from the Biostatistics Program at Fox Chase Cancer Center (PRESAGE). Method of allocation: not reported Outcome assessor blinding: not reported
Participants	N = 302 (intervention 151, control 151) Inclusion criteria: a) patient had a primary diagnosis of ductal surgery in the last 12 months, but could be in active treatment (e.g. radiation or chemotherapy); b) patient and spouse were 18 years of age or older; c) patient and spouse were able to give informed consent; d) patient and spouse were English-speaking, e) patient currently married or living with a significant other of either sex, and; f0 couple lives within one hour commuting distance to the centre from which they were recruited
Interventions	Intervention group: couple-focused group intervention (ECG) Frequency: 8 sessions 90-minute weekly groups led by two therapists Duration: eight 90-minute weekly groups led by two therapists Control group: couples' support group (SG)
Outcomes	Anxiety (9 items) and Depression (4 items), and the Well-being (10 items) subscales of the Mental Health Inventory-38 Cancer distress by Impact of Events Scale which is a 21-item measure focusing on intrusive and avoidant ideation associated with a stressor. Using a 4-point Likert scale, participants rated how true each statement was during the past week (scale range = 0–75) Assessed at pre-intervention, one week post-group, six months, and one year.
Notes	Funding: funded by grant CA 77857 from the National Cancer Institute

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation done by a computerised program from the Biostatistics Program at Fox Chase Cancer Center (PRESAGE).
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias

Manne 2016 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Differences between completers and non completers, participants and refusals and the relatively high rate of drop and refusal and the lack of intention to treat analysis all pose unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Funded by grant CA 77857 from the National Cancer Institute

Marchioro 1996

Study characteristics	
Methods	Design: RCT Setting: Italy Duration of intervention: not specified
Participants	N = 36 (intervention 18, control 18) Inclusion criteria: • Women with non-metastatic breast cancer assigned to chemotherapy • Upper age limit 65 years • No history of psychiatric illness • No prior history of cancer • Ability to read and communicate in Italian
Interventions	Intervention versus control The intervention: psychological intervention (weekly individual 50-minute cognitive psychotherapy sessions plus bimonthly family counselling) All sessions were delivered by same psychologist
Outcomes	QoL and depression measured at initial evaluation, after 1, 3, 6 and 9 months • QoL by Functional living Index cancer • Depression by Beck Depression Inventory • Adaptation to cancer by 16-PF, A form and Index Introject Questionnaire
Notes	
Risk of bias	

Marchioro 1996 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Patients were randomly assigned to intervention versus no intervention Comment: there was insufficient detail reported about the method used to generate the allocation sequence to allow a clear assessment of whether it would produce comparable groups
Allocation concealment (selection bias)	Unclear risk	The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment, was not reported Comment: there was insufficient information to permit a clear judgement
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	36/40 participated (3 showed low compliance, 1 refused consent) It was not clear if data analysis was per protocol or intention-to-treat Comment: there was insufficient information to permit a clear judgement of risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Unclear risk	Comment: there was insufficient information reported to assess whether there were other sources of important risk of bias

Marcus 2010

Study characteristics	
Methods	Methods Design: RCT Setting: USA Duration of intervention: 12 months
Participants	N = 304 (intervention 152, control 152) Inclusion criteria: • Stage 1, 2 and 3 disease (with no greater than 10 positive lymph nodes involved) • Completed treatment for breast cancer • No evidence of overt psychosis or suicidal behaviour • Treatment plan does not include bone marrow transplantation • Not currently enrolled in another quality of life intervention study

Marcus 2010 *(Continued)*

	• Can receive the counselling sessions and assessment questionnaires in English
Interventions	Interventions 152 intervention, 152 control • The intervention group received a one-year, 16 sessions telephone counselling program augmented with additional print. The 16 counselling sessions lasted on average about 45 minutes each delivered by four Masters-level psychosocial oncology counsellors • The control group received a resource directory for breast cancer
Outcomes	• Distress by Intrusion sub-scale of Impact of Event Scale • Depression by Center for Epidemiologic Studies Depression Scale • Assessments at baseline, and at 3-, 6-, 12- and 18-month intervals
Notes	Of 354 eligible women, 304 (86%) agreed to participate and were subsequently enrolled • There were no differences by experimental condition on any of the sociodemographic variables • Similarly, there were no differences on any of the health status or breast cancer diagnostic or treatment variables obtained at baseline

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Randomized two-group design" Comment: there was insufficient detail reported about the method used to generate the allocation sequence to allow a clear assessment of whether it would produce comparable groups
Allocation concealment (selection bias)	Unclear risk	The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment was not reported. Comment: there was insufficient information to permit a clear judgement
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported. Comment: there was insufficient information to permit a clear judgement of risk of bias.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	The response rates at each follow-up were as follows: 3 months 93%(n = 282); 6 months 88% (n = 266); 12 months 86% (n = 261) ; 18 months 80% (n = 243) 22% (n = 34) declined to complete the program. Most of the dropouts occurred during or immediately following session one (44%), or after sessions two or three (36%). When participants dropped out from the counselling program, they were encouraged to complete the follow-up questionnaires, and 71% (n = 24) complied. These data were included in all analyses. Comment: absence of data from the remaining 10 drop out poses unclear risk of bias.
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design

Marcus 2010 *(Continued)*

Other bias	Low risk	86% of breast cancer patients approached for study enrolment agreed to participate. The research reported herein was supported by a grant from the National Cancer Institute.

Merckaert 2017

Study characteristics	
Methods	Design: RCT Country: Brussels, Belgium Method of randomisation: computer-generated Method of allocation: computer-generated group allocation was done inside each institution and concealed until baseline completion Outcome assessor blinding: not reported
Participants	N = 170 (intervention 87, control 83) Inclusion criteria: women diagnosed with nonmetastatic breast cancer who had been surgically treated were approached during radiotherapy or 1 month after intraoperative radiotherapy Exclusion criteria: age <18 years, nonfluency in French, severe cognitive impairment, severe and/or acute psychiatric disorder, and completion of treatment >1 year previously
Interventions	Intervention group: multiple-component group intervention (MGI) combining support with cognitive-behavioural and hypnosis components Frequency: 15 weekly 120-minute sessions occurring within a 6-month period. Duration: 15 weekly 120-minute sessions occurring within a 6-month period. Control group: single-component group intervention (SGI) standard care based on support (from peers and the group therapist) and on experience sharing
Outcomes	Psychological distress by the Hospital Anxiety and Depression Scale ((HADS), a 14-item 4-point self-report instrument. The use of the total score is recommended to assess psychological distress. Everyday anxiety regulation. Patients were asked to report the level of anxiety felt in their everyday lives on a 10-cm VAS, with the extreme left defined as “never anxious” and the extreme right defined as “always anxious.” The Fear of Cancer Recurrence Inventory (FCRI) is a 47-item 5-point self-report scale. The total score was not used in this study because authors hypothesised that contrary to the other subscales, the coping strategies subscale score would increase at T2. The Mental Adjustment to Cancer (MAC) scale is a 40-item 4-point self-report measure of 5 psychological dimensions of mental adjustment in patients with cancer Assessed at T1 before study entry and T2 occurred immediately after intervention completion
Notes	Funding: supported by the Plan Cancer of Belgium

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Merckaert 2017 *(Continued)*

Random sequence generation (selection bias)	Low risk	Computer-generated group allocation was done inside each institution and concealed till baseline completion
Allocation concealment (selection bias)	Unclear risk	Computer-generated group allocation was done inside each institution and concealed till baseline completion. However, there was insufficient information regarding allocation concealment to permit a clear judgement of risk of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	The substantial difference in attendance rates, dropout rates, and missed T2 assessment in favour of the MGI group and subsequent per protocol analysis pose unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Supported by the Plan Cancer of Belgium

Mirmahmoodi 2020

Study characteristics	
Methods	RCT
Participants	N = 51 (Intervention 27, Control 24) diagnosed disease between 3 months and 5 years, no use of psychological treatment before and during the intervention, no drug addiction, no acute psychiatric disorders (psychosis, severe mood disorder, etc.), no mental disorders, no use of anxiolytic and antidepressant medications, undergoing at least 1 chemotherapy period or surgery, ages between 18 and 70 years, breast cancer without metastasis,38 and no use of corticosteroids, psychoactive and hormonal drugs.
Interventions	Mindfulness-based stress reduction Control group received the routine care, which included consulting with the psychiatric nurses, and psychologists if requested. Intervention received the mindfulness-based stress reduction intervention in 90-minute sessions for 8 weeks (1 session a week)
Outcomes	Depression by Beck Depression Inventory, scored on the scale value of 0 (no specific sign) to 3 (severe signs). The scores totally range from 0 to 63. The cut-off point of this test is 13, meaning that scores ranging from 0 to 3 would be considered healthy, scores ranging from 14 to 19. Would be considered mild depression, scores ranging from 20 to 28 would be considered moderate depression, and scores ranging from 29 to 63 would be considered severe depression. Anxiety by Beck anxiety inventory (BAI) scored on a scale value of 0 (not at all) to 3 (severely). The scores totally range from 0 to 63 (scores ranging from 0 to 7 would be considered minimal anxiety,

Mirmahmoodi 2020 *(Continued)*

	scores ranging from 8 to 15 would be considered mild anxiety, scores ranging from 16 to 25 would be considered moderate anxiety, and scores ranging from 26 to 63 would be considered severe anxiety) Sress by perceived stress scale The scale was scored based on a 5-point Likert scale (never = 0, almost never = 1, sometimes = 2, often = 3, and most of the time = 4). Scores range from 0 to 56 with the higher score indicating more perceived stress laboratory data including cortisol and CRP levels
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised using block randomisation. Labels of A, or B (A = MBSR and B = routine care) were assigned to each group, and the block size was considered. Then the randomisation list was generated by free online software (https://www.sealedenvelope.com/simple-randomiser/v1/lists). The fourth researcher generated the random allocation sequence, and the first researcher enrolled and assigned participants to the groups.
Allocation concealment (selection bias)	Low risk	The fourth researcher generated the random allocation sequence, and the first researcher enrolled and assigned participants to the groups.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Five drop-outs in intervention, 2 from control The percentage of dropouts and subsequent per protocol analysis posed an unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	The author(s) received no financial support for the research, authorship, and/or publication of this article

Mishel 2005

Study characteristics

Methods	Design: RCT Setting: USA Duration of intervention: 4 weeks Gil 2006 is a subset reporting the outcomes after 10 months from baseline

Mishel 2005 *(Continued)*

Participants	Mishel 2005: N = 509 (intervention 244, control 265) Gil 2006: only 483 completed the trial at T3 Inclusion criteria: • African American and Caucasian 5 to 9 years post-treatment • Recurrence free • No concurrent treatment, could be on tamoxifen • Had a telephone and planned to reside in their current community for 2 years following entry into the study
Interventions	• Four-weekly telephone sessions guided by a nurse • Cognitive strategies delivered via audiotapes and behavioural strategies via self-help manual • Control (usual care) group: no attempt was made to limit their exposure to naturally occurring learning contexts such as media, public health programs • Nurses guided women through the intervention over the course of four weekly 30-minute telephone call
Outcomes	• Psychological distress by profile of mood states short form (POMS-SF) • Coping by modified version of the cognitive Coping Strategies Questionnaire (CSQ) • T1 at baseline and T2 10 months after baseline • 20 months post-baseline (T3) was reported in Gil 2006
Notes	• A total of 1053 eligible women were contacted as potential participants. Of these, 575 or 55% agreed to participate • There were no significant differences at baseline between women in the intervention and control groups • Quote: "Since these women were 5–9 years post-treated, it might be expected that they would not be disturbed by triggers of recurrence fears and by long-term treatment side effects" • Those who participated were significantly younger, and the participation rate for African American women was higher than for white women • Quote: "The study utilized a standard care control condition and therefore did not control for potential non-specific effects such as time spent with a nurse or time spent at home on a structured activity"

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomised to intervention or control. SAS program Proc Plan was used to construct a randomisation plan Comment: this was judged as at a low risk of bias
Allocation concealment (selection bias)	Unclear risk	The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment, was not reported Comment: there was insufficient information to permit a clear judgement
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported

Mishel 2005 *(Continued)*

		Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition rate was 11% with 66 dropouts 575 agreed to participate and only 509 completed T2 (89% of those who entered the study was retained) Quote: "Five percent of women (n = 15 in intervention; n = 11 controls) were not included at follow-up due to dropout, unable to contact, and so on" In Gil 2006: "the 20-month follow-up sample represented 95% (n = 483) of the 509 women" this should be from 575 who first entered the study and not those who retained at T2; 483/575 = 84% Comment: although the numbers of dropouts were balanced between the groups, the percentage of dropouts and subsequent per protocol analysis posed an unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	This was supported by National Cancer Institute

Napoles 2015

Study characteristics	
Methods	Design: RCT Country: USA Setting: Participants' homes Method of randomisation: before initiating recruitment, stratum-specific sequential identification numbers were generated and randomly pre-assigned in blocks of random sizes. Method of allocation:after the baseline assessment, each participant was handed a sealed opaque envelope preprinted with the next sequential identification number from her stratum that revealed her group assignment Outcome assessor blinding: not reported
Participants	N = 151 (intervention 76, control 75) Inclusion criteria: (1) 1 year or less since diagnosis with stage 0 to stage IIIC primary breast cancer; (2) living in Alameda, Contra Costa, San Francisco, San Mateo, or Santa Clara County; (3) primarily Spanish speaking or Spanish monolingual; and (4) self-identifying as Latina Exclusion criteria: (1) previous cancer diagnosis except for non-melanoma skin cancer, (2) terminal illness, or (3) stage IV breast cancer (distant metastasis).
Interventions	Intervention group: Nuevo Amanecer (the program emphasised cognitive behavioural coping skills training, coaching, and modelling to actively manage stress and emotions) Frequency: eight weekly Nuevo Amanecer program was delivered face-to-face in participants' homes for 8 weeks. Each week, one 90-minute module was presented (individual) Duration: 8 weekly sessions for 90-minutes each for 8 weeks

Napoles 2015 *(Continued)*

	Control group: wait list control
Outcomes	Breast cancer-specific quality of life. The Functional Assessment of Cancer Therapy Breast (FACT-B) was our breast cancer-specific quality-of-life outcome measure.A total overall score is the sum of all subscales. The total FACT-B score was the sum of the 5 modified subscales (range = 0-108) General distress symptoms. We used 3 scales from the Brief Symptom Inventory (BSI), anxiety, depression and somatisation. Higher scores indicate more distress. Breast cancer-specific distress. We measured breast cancer distress with the 7-item Intrusive Thoughts Scale, a subscale of the revised Impact of Event Scale. We summed items after recoding responses to 0, 1, 3, and 5 (possible range = 0-35); higher scores indicate greater distress Assessed at baseline, 3 and 6 months
Notes	Funding: supported by the California Breast Cancer Research Grants Program Office of the University of California (15BB-1300 and 15BB-1301), National Cancer Institute (1U54CA153511), and National Institute on Aging (1 P30 AG15272).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Before initiating recruitment, stratum specific sequential identification numbers were generated and randomly pre-assigned in blocks of random sizes.
Allocation concealment (selection bias)	Low risk	After the baseline assessment, each participant was handed a sealed opaque envelope preprinted with the next sequential identification number from her stratum that revealed her group assignment
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Incomplete outcome data (attrition bias) All outcomes	Low risk	Overall study retention rate of 95% and intention-to-treat analysis pose low risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Supported by the California Breast Cancer Research Grants Program Office of the University of California (15BB-1300 and 15BB-1301), National Cancer Institute (1U54CA153511), and National Institute on Aging (1 P30 AG15272).

Narváez 2008

Study characteristics

Methods	Design: RCT

Narváez 2008 *(Continued)*

	Setting: Madrid, Spain Duration of intervention: 9 weeks
Participants	N = 38 (intervention 19, control 19) Inclusion criteria: • Diagnosis of breast cancer • To be currently disease free and to have been so for three years • To have undergone a mastectomy in the last three years and to be currently receiving hormonal therapy as the sole treatment • Minimum age of 30 and maximum age of 60 years Exclusion criteria: • Presence of prior psychopathology that requires treatment with specific medication • Presence of active disease • To be in a phase of active treatment (except for hormonal therapy)
Interventions	Nine weekly 90-minute sessions of structured cognitive behavioural group therapy
Outcomes	• Depression assessed by Beck Depression Inventory (BDI) • Anxiety measured by The State Anxiety Scale from the State-Trait Anxiety Inventory (STAI)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote:"The women were assigned to the groups randomly" Comment: there was insufficient detail reported about the method used to generate the allocation sequence to allow a clear assessment of whether it would produce comparable groups After e-mail communication with investigators: Quote: "randomization was simple random sampling and not used any software" Comment: this was judged as inadequate
Allocation concealment (selection bias)	High risk	The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment, was not reported Comment: there was insufficient information to permit a clear judgement After e-mail communication with investigators: Quote: "randomization was performed by one of the researchers and the result was known by all researchers" Comment: this was judged as at high risk of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	After e-mail communication with investigators: Quote: "randomization was blind for patients and not blind for researchers" Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias)	High risk	Blinding of outcome assessment was not reported. There was insufficient information to permit a clear judgement of risk of bias

Narváez 2008 *(Continued)*

All outcomes		After e-mail communication with investigators: Quote: "the results of the investigation were known to researchers" Comment: this was judged as at high risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No dropouts were reported. It was not clear if data analysis was per protocol or intention-to-treat Comment: there was insufficient information to permit a clear judgement of risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Unclear risk	There were no declarations of potential conflicts of interest or indication of funding or support Comment: there was insufficient information to permit a clear judgement of the risk of bias

Nicolaisen 2018

Study characteristics	
Methods	Design: RCT Country: Denmark Setting: 3 Danish breast surgery departments Method of randomisation: not reported Method of allocation: not reported Outcome assessor blinding: not reported
Participants	N =198 couples (intervention 102 couples, control 96 couples) Inclusion criteria: women newly diagnosed with primary BC, who were ≥18 years, cohabited with a male partner, had no previous cancer diagnoses, had received no neoadjuvant treatment, had no history of hospitalisation due to psychosis, were able to read and speak Danish, and were not referred to or consulting any of the trial psychologists Exclusion criteria: not reported
Interventions	Intervention group: Hand in Hand (HiH) intervention Frequency: 4 to 8 couple sessions led by a clinical psychologist up to 5 months after primary surgery. Duration: not clear Control group: usual care consisted of verbal and written information on normal psychological reactions in relation to a cancer diagnosis
Outcomes	Cancer-related distress measured by The Impact of Event Scale (IES), The IES is a 14-item scale with sum scores ranging from 0 to 70. Scores of 0 to 8 indicate no meaningful impact, 9 to 25 some impact, 26 to 43 a powerful impact, and ≥44 a severe impact.

Nicolaisen 2018 *(Continued)*

	Symptoms of anxiety and depression measured by the Hospital Anxiety and Depression Scale Total scores of the subscales anxiety and depression range from 0 to 21 with >10 indicating a probable diagnosis, 8 to 10 indicating a possible diagnosis, and <8 low occurrence of anxiety and depression. Dyadic adjustment measured by The Revised Dyadic Adjustment Scale. Total scores range from 0 to 69. Higher scores indicate greater dyadic adjustment measured by the degree of consensus, satisfaction, and cohesion in the relationship. Assessed at time of primary surgery (T0) and self-assessment questionnaires at pre-intervention (T1), postintervention, 5months after surgery (T2), and follow-up 10 months after surgery (T3)
Notes	Funding: University of Southern Denmark; Danish Cancer Society

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Participants were randomised to intervention and usual care. However, there is insufficient information about the method of randomisation.
Allocation concealment (selection bias)	Unclear risk	All except the independent statistician were blinded to block sizes and allocation sequence. Participants were for obvious reasons not blinded. Comment: the method of concealment was not reported which poses unclear risk of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition rate: 26-27% at T3 and absence of Intention to treat analysis pose unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Funding from University of Southern Denmark; Danish Cancer Society

Nunes 2007

Study characteristics

Methods	Design: RCT Setting: Radiotherapy Service at São Lucas Hospital (Porto Alegre, Brazil) Duration of the study: 24 days
Participants	N = 34 (intervention 20, control 14) Inclusion criteria:

Nunes 2007 *(Continued)*

	• participants with breast cancer (stage I or II) undergoing radiotherapy Exclusion criteria: • presence of acute or chronic: • heart disease • anorexia • anaemia • leucopenia (reduction in white blood cells) • clinical depression • post traumatic stress disorder • neurodegenerative disease • use of glucocorticoids
Interventions	• Intervention (n = 20) relaxation and visualisation therapy (RVT) for 24 consecutive days or control group (n = 14) who were on radiotherapy only • The RVT intervention consisted of 24 daily, 30-minute structured group (n less than 4) sessions at the Breast Cancer Unit • The participants were always led by the same trained investigator (psychologist) at all times • The RVT included a relaxation period (20 minutes), in which the participant was induced to mentally create an image of the desired objective or result, included progressive muscle relaxation, guided imagery, meditation, and deep breathing
Outcomes	• Stress by the Lipp Stress Symptoms Inventory for adults (LSSI) • Anxiety by The State Trait Anxiety Inventory (STAI) and Beck Anxiety Inventory (BAI) • Depression by The Beck Depression Inventory (BDI) • Assessment done at baseline and after 24-day intervention
Notes	Patients of the experimental group were more anxious than the control group at baseline Had at least 2 weeks of chemotherapy washout

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Subjects were randomly assigned into two groups" Comment: there was insufficient detail reported about the method used to generate the allocation sequence to allow a clear assessment of whether it would produce comparable groups
Allocation concealment (selection bias)	Unclear risk	The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment, was not reported Comment: there was insufficient information to permit a clear judgement
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias

Nunes 2007 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Quote: "All subjects completed the two assessments" No dropouts were reported. It was not clear if data analysis was per protocol or intention-to-treat
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Unclear risk	There were no declarations of potential conflicts of interest or indication of funding or support Comment: there was insufficient information to permit a clear judgement of the risk of bias

Park 2020

Study characteristics	
Methods	RCT
Participants	N = 74 (intervention 38, control 36) 1) clinical diagnosis of stage 0-III breast cancer, 2) aged between 20 and 74 years, 3) the Hospital Anxiety and Depression Scale (HADS) total score of five or higher, 4) Eastern Cooperative Oncology Group performance status of 0-2, 5) expected clinical prognosis of one year or longer, 6) ability to communicate in Japanese, and 7) submission of written informed consent. Patients were excluded if they had the experience of MBCT or MBSR, or if they had any serious physical or psychiatric symptoms
Interventions	Mindfulness-based interventions versus wait list control
Outcomes	Psychological distress (anxiety and depression) measured by HADS. Subscale ranged from zero (no distress) to 21 (maximum distress). Higher scores indicate a greater level of psychological distress. QOL (Functional Assessment of Cancer Therapy -General) with a higher score indicating better QOL. The secondary outcomes were FCR (Concerns About Recurrence Scaled overall anxiety subscale), fatigue (Brief Fatigue Inventory), spiritual well-being (Functional Assessment of Chronic Illness Therapy-Spiritual), and mindfulness skills (Five Facet Mindfulness Questionnaire). The participants were assessed at baseline (T0), Week 8 (T1), and Week 12 (T2).
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	The randomisation was managed by an organisation independent of the research team (Keio University Clinical and Translational Research Center). Block randomisation was conducted by a computer-generated random number list using an electronic software (http://www.randomization.com)
Allocation concealment (selection bias)	Unclear risk	Method of allocation concealment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias

Park 2020 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	The dropout rate was (7.9%) and intention-to-treat analysis pose low risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	This study was supported by Keio Gijuku Academic Development Funds and Japan Society for the Promotion of Science KAKENHI (grant number: JP15K09875)

Pettiford 2017

Study characteristics	
Methods	Design: RCT Country: USA Setting: outpatient Method of randomisation: computer-generated, unblocked, sequence of random numbers Method of allocation: not reported Outcome assessor blinding: not reported
Participants	N= 120 (intervention 47, control 56) Inclusion criteria: women with an established diagnosis of breast cancer, diagnosed after January 2010, and including newly diagnosed patients were eligible to participate Exclusion criteria: women declining randomisation were excluded
Interventions	Intervention group: bio-psychosocial intervention (BPSI) Frequency: 4-hour BPSI coping skills class once a month Duration: A 4-hour session Control group: routine multidisciplinary breast cancer care.
Outcomes	Quality of life measured by FACT-B QoL Assessed at enrolment and every 6 months for 2 years
Notes	Funding: The David and Nona Payne Foundation provided funding for this research.

Pettiford 2017 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Women were randomised individually via a computer-generated, unblocked, sequence of random numbers
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	86% patients were available for analysis. Dropouts were excluded of analysis. This poses unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	The David and Nona Payne Foundation provided funding for this research.

Ren 2019

Study characteristics	
Methods	RCT
Participants	N = 392 (CBT intervention 98, self-management intervention 98, control 196) Inclusion criteria: (1) were women diagnosed with breast cancer; (2) had symptoms of depression and/or anxiety, as defined by the Chinese version of the 17-item Hamilton Depression Rating Scale (HAMD-17) score ≥ 8, and/or the Chinese version of the 14-item Hamilton anxiety scale (HAMA-14) score ≥8; (3) were 20–65 years old; (4) had undergone a radical mastectomy 1 week to 1 year prior to the study; and (5) were able to read Chinese and were competent to consent to participate Exclusion criteria: participants with serious diseases such as cardiovascular, liver or kidney diseases as well as those with severe visual or auditory impairments and active alcohol or drug abuse, participants with suicidal tendencies. Participants with previous diagnosis of mental disorder or bipolar disorder or who had recently accepted antidepressants or antipsychotics, as well as those who had participated in any psychological treatments or clinical trials within one month before the screening, participants with a HAMD-17 score ≥ 24
Interventions	Women in the CBT and SCM groups received a series of nine sessions for 12 weeks, while women in the UC group received their usual medical care only

Ren 2019 *(Continued)*

Outcomes	Depressive and anxiety symptoms were assessed using the Hamilton Depression Rating Scale (HAMD) and the Hamilton Anxiety Scale (HAMA) score at baseline, 2, 4, 8, 12, 16, and 24 weeks with higher scores indicating higher symptom levels. Depression measured by 17-item Hamilton Depression Rating Scale (HAMD-17). Participants with a HAMD-17 score of ≥ 8 were considered to have existing depressive symptoms, with higher scores indicating higher symptom levels. HAMD score: normal (0–7), mild depression (8–16), moderate depression (17–23), and severe depression (≥ 24). Anxiety symptoms by 14- item Hamilton anxiety scale (HAMA-14). Participants with a HAMA- 14 score of ≥ 8 were considered to have existing anxiety symptoms, with higher scores indicating higher levels. HAMA score: normal (0–7), mild or probable anxiety (8–14), moderate or definite anxiety (15–21), and severe anxiety (≥ 22). Quality of life by Functional Assessment of Cancer Therapy-Breast (FACT-B) questionnaire (Qiu 2018). The FACT-B consisted of five subscales including social well-being (SWB), physical well-being (PWB), functional well-being (FWB), emotional well-being (EWB), as well as breast cancer-specific concerns (BCS), with higher scores indicating better QOL. Assessed at baseline, 2, 4, 8, 12, 16 and 24 weeks
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomised by picking an envelope that contained random numbers corresponding to the assigned group.
Allocation concealment (selection bias)	Low risk	The primary investigators and evaluators were kept blinded to the allocation.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The therapists, blind to the outcome data and the study hypotheses, provided the treatment conditions. It was impossible to blind the participants, but they did not know the group assignments until the first meeting. Comment: although the therapists were blinded, the effect of lack of blinding of participants on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Evaluators were kept blind to the allocation. It is not clear what method was used to keep evaluators blind to outcome assessment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	The numbers of dropouts were balanced between the groups, the percentage of dropouts and subsequent intention-to-treat analysis pose low risk of bias.
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	This work was funded by the National Key Technologies R&D program in the 11th 5-year plan from the Ministry of Science and Technology of the People's Republic of China (grant number: 2009BAI77B06). These sources had no further role in study design, data collection and analysis, decision to publish, or preparation of the article.

Richardson 1997

Study characteristics	
Methods	Design: (pilot) prospective experimental pre-test post-test study design Setting: USA Study duration: 6 weeks
Participants	N = 47 Inclusion criteria: • Diagnosed with breast cancer (excluded stage IV) • Postoperative > 6 weeks • Chemotherapy and radiation completed (> 1 month and < 30 months) • Stayed in Houston area • Understood English • > 18 years of age Exclusion criteria: • On corticosteroid therapy • Known psychiatric disease • Active substance abuse • Evidence of heart disease • Tamoxifen • Immune disorder
Interventions	Standard care (15) versus support group (16) versus imagery (16) Support group: (6 weekly group sessions) not psychotherapy but aimed at decreasing stress, sharing feelings, enhance self-esteem delivered by social workers Imagery and relaxation: 5 weekly (1-hour group sessions) and 1-hour individual session delivered by psychotherapist, social worker and hypnotherapist Designed to develop imaging ability, breathing techniques, relaxation skills, role of immune system, setting goals, coping with fears, giving and receiving support
Outcomes	• Outcome measured before randomisation and after last session • Coping: ways of coping with cancer assesses the type and frequency of coping strategies used over the past 6 months to deal with the most stressful aspect of a cancer diagnosis • QoL by FACT-B • Emotional well-being: Profile of Mood States-brief
Notes	Methodology paper: Moye LA, Richardson MA, Post-White J, Justice B. Research methodology in psychoneuroimmunology:rationale and design of the IMAGES-P clinical trial. Alternative Therapies in Health and Medicine 1995:1(2):34-9

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "Randomly assigned"

Richardson 1997 *(Continued)*

		Comment: there was insufficient detail reported about the method used to generate the allocation sequence to allow a clear assessment of whether it would produce comparable groups
Allocation concealment (selection bias)	Unclear risk	The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment was not reported Comment: there was insufficient information to permit a clear judgement
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants and interventionist know the experimental group status. Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	High risk	Only evaluators of immunoassays were blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up was complete with no attrition (there were partial attendants n = 4, that is, those who missed one or more session)
Selective reporting (reporting bias)	Low risk	All outcomes were reported
Other bias	Low risk	Supported by grants from the National Institute of Health and National Cancer Institute

Schou Bredal 2014

Study characteristics	
Methods	Design: RCT Country: Norway Setting: outpatient Method of randomisation: sealed letter Method of allocation: sealed letter Outcome assessor blinding: not reported
Participants	N = 367 (intervention 185, control 182) Inclusion criteria: women between 18 and 70 years of age who had undergone surgery for primary breast cancer with no distant metastases, had sufficient knowledge of the Norwegian language, had no psychiatric illness or dementia, and wanted to participate in group interventions. Exclusion criteria: not reported
Interventions	Intervention group: psychoeducational group (PEG) versus support group (SG) interventions. The PEG intervention included health education, enhancement of problem-solving skills, stress management, and psychological support Frequency: 5 weekly 2-hour sessions

Schou Bredal 2014 *(Continued)*

	Duration: 5 weeks Control group: support group (SG) interventions which is a component of the hospitals' routine breast cancer care. 3 weekly 2-hour sessions. Group support and a surgeon, a physiotherapist, and a volunteer from the Breast Cancer Society (a breast cancer survivor) attended the group for 30 minutes each. The information provided by these individuals was given mostly in a question-and-answer format.
Outcomes	Anxiety and depression were measured using the Hospital Anxiety and Depression Scale. Consisting of 14 items: 7 measuring anxiety and 7 measuring depression. Each item is scored on a 4-point scale (0 to 3). Coping was measured using the Mini-Mental Adjustment to Cancer (Mini-MAC) scale 25 which is a 29-item questionnaire. It was initially assessed using 5 subscales: fighting spirit, anxious preoccupation (AP), hopelessness/helplessness (HH), and fatalism. It also includes 4 items that cover cognitive avoidance (CA). Each item is scored on a 4-point scale (1 = definitely does not apply tome to 4 = definitely applies to me). Higher scores indicate a higher level of mental adjustment. Dispositional optimism/pessimism was measured using the Life Orientation Test Revised (LOT-R). Assessed at 4 time points: at baseline (T0; the time of diagnosis, before intervention) and after intervention (via mail), at 2 months (T1) and 6 months (T2) after completion of the intervention and at 12 months after surgery (T3).
Notes	Funding: Eastern Norway Regional Health Authority

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation by sealed letter. Comment: It is not clear how these letters were randomised.
Allocation concealment (selection bias)	Low risk	Randomisation by sealed letter. The sealed letter was opened by a study nurse.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	There was insufficient data to allow a clear judgement of this domain
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Although the dropout was balanced between the two arms (23 and 28 dropped from the intervention and usual care, respectively), the subsequent per protocol analysis pose unclear risk of bias.
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Funded by Eastern Norway Regional Health Authority

Simpson 2001

Study characteristics	
Methods	Design: RCT Setting: Tom Baker Cancer Centre, Canada Duration of intervention: 6 weeks
Participants	N = 89 (intervention 46, control 43) Inclusion criteria: • Completed treatment for stage 0 to III • Diagnosed after 1992 up to 2 years post-treatment • Age < 70 years Exclusion criteria: • Older than 70 years • Residence more than 40 km from the cancer centre • Diagnosis earlier than Jan 1992 • Tumour stage III or IV • More than one diagnosis of cancer or active chronic illness • Psychotic illness or active substance abuse
Interventions	• Intervention: 6 weeks of CBT (90 minutes) led by psychiatrist • Group size 7 to 10 • Control: received information package
Outcomes	• Assessment done at pre-intervention, immediately post-intervention, 1 year and 2 years • Depressive symptoms by Beck Depression inventory (BDI) • Coping by Mental Adjustment to Cancer scale (MAC) • Mood disturbance by Profile of Mood States (POMS) • QoL by quality of life index • Coping strategy that was used by Dealing with Illness Inventory
Notes	The intervention was carried out in waves as soon as 7 to 10 patients were recruited Participants were enrolled from time of completion of treatment up to 2 years post-treatment 89/315 were included, accrual rate (28.2) Those in whom anxiety and mood disorders were diagnosed were not excluded

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Patients were randomised to intervention and control Comment: there was insufficient detail reported about the method used to generate the allocation sequence to allow a clear assessment of whether it would produce comparable groups
Allocation concealment (selection bias)	Unclear risk	The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment, was not reported

Simpson 2001 *(Continued)*

		Comment: there was insufficient information to permit a clear judgement
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote: "Participants were informed about their assignment by mail" Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	At time 2, assessment data were collected for 43 (93.5%) in intervention and 34 (79.1%) in control. At time 3, data collected for 38 (82.6%) in intervention and 33 for control (76.7%) At time 4, data were collected for 30 (65.2%) in intervention and 25 (58.1%) in control Comment: although the numbers of dropouts were balanced between the groups, the percentage of dropouts and subsequent per protocol analysis posed an unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Funded by the Health Services Research Innovation Fund of the Albert Heritage Foundation for Medical Research Comment: this was judged as at a low risk of bias

Tabrizi 2016

Study characteristics	
Methods	Design: randomised clinical trial Country: Iran Setting: outpatient Method of randomisation: random assignment followed a method combining elements of biased coin randomisation with adaptive randomisation Method of allocation: allocation was not blinded Outcome assessor blinding: not reported
Participants	N = 81 (intervention 41, control 40) Inclusion criteria: (a) diagnosis of primary, biopsy-proven breast cancer, stages I through IIIA, (b) surgery within the previous 4–18 months, (c) completed chemotherapy, and (d) no detectable disease present. Exclusion criteria: (a) evidence of metastases beyond lymph nodes, including chest wall involvement, bone or viscera, (b) recurrence of the cancer prior to randomisation, (c) diagnosis of other cancers, (d) any other major medical complications likely to limit life expectancy to less than 10 years, (e) a history

Tabrizi 2016 *(Continued)*

	of major psychiatric illness for which the patient was hospitalised or medicated, and (f) attendance at a cancer support group for more than two months.
Interventions	Intervention group: supportive expressive discussion groups Frequency: twelve weekly 90-minute sessions Duration: 12 weeks Control group: routine care
Outcomes	Quality of life measured by The European Organization for Research and Treatment of Cancer QoL Core Questionnaire (EORTCQLQ-C30). Higher scores for this scale (range, 0–100) indicate better HRQoL Hope and loneliness Assessed at pre-to -post the intervention and at 8-week follow-up
Notes	Funding: funded by Urmia University of Medical Sciences

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random assignment followed a method combining elements of biased coin randomisation with adaptive randomisation
Allocation concealment (selection bias)	High risk	Although the data entry and analysis were conducted by blinded researchers, student as a tutor could not be blinded to treatment allocation for practical reasons
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	There was no dropout/withdrawal in this study
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Funded by Urmia University of Medical Sciences

Taylor 2003

Study characteristics

Methods	Design: RCT Setting: USA

Taylor 2003 *(Continued)*

	Duration of intervention: 8 weeks
Participants	N = 93 agreed to participate and N = 73 (intervention 40, control 33) completed the trial and data were analysed Inclusion criteria: • African American women with stage 0 to IIIA breast cancer • Had undergone surgery within the previous 10 months Exclusion criteria: • Psychotic illness • Drug or alcohol abuse • Severe cognitive impairment • Previous systemic cancer diagnosis
Interventions	Intervention n = 40, assessment only control n = 33 Intervention: 8 weekly, 2 hours; 8 members, semi-structured meetings delivered by psychologist and psychiatrist
Outcomes	Assessed at 1 week, 3 months, 6 months and 12 months Only 12-month outcome reported: • Cancer-related QoL by CARES-SF (only measured at baseline). • Mood state by Profile of Mood States (POMS) • General psychological distress by Mental Health Inventory (MHI) • Cancer-related distress by Impact of Event Scale
Notes	Randomly assigned, 2:1 random assignment: • Quote: "Of 148 eligible women, 62.8% (n = 93) agreed to participate and completed the baseline interview, 33.1% (n = 49) declined to participate (because they felt burdened by the illness and treatment, work, or family commitments), and 4% (n = 6) were unreachable" • Accrual rate 63% • The only significant difference between decliners and participants was age (decliners were older) • Of the 93 participants, the 3 final participants recruited were not randomised because of a lack of a complete cohort, and 5 were deceased prior to the 12-month assessment • Quote: "Of the remaining 85 participants, 1 did not return a complete baseline questionnaire packet, and at the 12-month follow-up assessment, 8 did not return a complete questionnaire and 3 declined to participate"

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Participants were randomly assigned to either the support group intervention or the assessment-only control condition" Comment: there was insufficient detail reported about the method used to generate the allocation sequence to allow a clear assessment of whether it would produce comparable groups
Allocation concealment (selection bias)	Unclear risk	The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment, was not reported Comment: there was insufficient information to permit a clear judgement

Taylor 2003 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Accrual rate (63%; 93 out of 148 individuals) Percentage retained at 12 months was 50% The overall percentage retained at the 12-month assessment was 50% (73 out of 148) Quote: "Thus, 73 participants (85.8%) completed the questionnaire packet at both assessments and are included in these analyses. There were no demographic or medical differences between those who did and did not complete the 12-month assessment" Comment: although the numbers of dropouts were balanced between the groups and the percentage of dropouts was low, subsequent per protocol analysis posed an unclear risk of bias
Selective reporting (reporting bias)	Unclear risk	Quote: "We focus only on the long-term, 12-month outcomes, as the results obtained at the intermediate assessments were virtually identical" Comment: this was judged as unclear risk of bias
Other bias	Low risk	Nathan Cummings Foundation Grant, American Cancer Society, National Cancer Institute Grant, and the Mary DeWitt Petit Award (Alumni Association of the Medical College of Pennsylvania)

Trindade 2020

Study characteristics	
Methods	RCT
Participants	N = 49 (intervention 18, control 31). Recruited at the Radiotherapy Service of the CHUC usually after a treatment of Radiotherapy for breast cancer. All participants were recruited at the first week of their Radiotherapy treatment. Inclusion criteria included a diagnosis of nonmetastatic breast cancer, age between 35 and 70 years old, and absence of current suicidal ideation, substance abuse, borderline personality disorder, dementia, and developmental disorders.
Interventions	Eight weekly group sessions of approximately 1.5–2 hours each. Intervention (Treatment as usual + mind program) vs control (treatment as usual)
Outcomes	QoL by WHOQOL-BREF has 4 domains higher score indicates better QoL. Depression by Depression Anxiety Stress Scales (DASS-21)
Notes	

Trindade 2020 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Blinding and method of blinding was not described in the study.
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not described in the study.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Partciapnts filled the surveys using a paper-pencil form or via an online platform. However, blinding of outcome measurement was not described in the study.
Incomplete outcome data (attrition bias) All outcomes	High risk	Three dropped from the intervention and 14 from control arm. Unbalanced dropout rate and per protocol analysis pose high risk of bias.
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Sponsored by FCT (Portuguese Foundation for Science and Technology)

Vos 2004

Study characteristics	
Methods	Design: RCT Setting: Rotterdam, the Netherlands Duration of intervention: 12 weeks
Participants	Vos 2004: out of 87 agreed to participate, N = 69 completed study at T2 (34 intervention versus 35 control) Vos 2007: out of 87 enrolled, 67 completed trial (33 psychotherapy, 34 support group) Inclusion criteria: • Had surgery no longer than 4 months ago • No metastases • Knows Dutch • No history of psychiatric illness • Age between 18 and 70 years
Interventions	Vos 2004: intervention (group psychotherapy n = 15) versus intervention (group social support n = 19) versus waiting list (n = 35) Vos 2007: group psychotherapy (n = 33) versus support group (n = 34)

Vos 2004 *(Continued)*

	• Psychotherapy and social intervention were 12-weekly sessions (12 sessions in total), 2.5 hours each plus 2 additional sessions at 1 and 2 months • The psychotherapy intervention based on experiential existential premises enriched with cognitive behavioural component
Outcomes	• Emotional Adjustment by Profile of Mood States (POMS) Vos 2004: outcome measured at T0 within 4 months of surgery before randomisation and T1 after completion of intervention (baseline and 3 months later) Vos 2007: at T0, T1 and T3 (taken at 12 months after completion of intervention)
Notes	• 87 (34.7%) women enrolled into the study. The reasons for 164 women not participating were mentioned • They did not differ on any other demographic, medical, and psychosocial adjustment variables at baseline • Participants in intervention did not differ from those in control on any medical or demographic variable • Coping excluded as an outcome from our analysis because it was measured only at T2 and only in the intervention and not in the control group

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Participants were randomly allocated to study arms Comment: there was insufficient detail reported about the method used to generate the allocation sequence to allow a clear assessment of whether it would produce comparable groups
Allocation concealment (selection bias)	Unclear risk	The method used to conceal the allocation sequence, that is to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment, was not reported Comment: there was insufficient information to permit a clear judgement
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Vos 2004: Dropouts 18/87 (20.6%) numbers and reasons for dropouts were reported. Women who stopped did not differ from women who completed on any medical and demographic variable. However, they reported less social support than completers Vos 2007: Of the 87 women who participated in the study, 67 women (77.0%) completed the study, and 20 dropped out (23%). Numbers and reasons for not attending were described. With the exception of age, those who dropped out did not differ on any other demographic, medical, and psychosocial adjustment variables at baseline (women who stopped participating were significantly older). Numbers and reasons for dropouts were reported

Vos 2004 *(Continued)*

		Comment: although the numbers of dropouts were balanced between the groups, the percentage of dropouts and subsequent per protocol analysis posed an unclear risk of bias
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design Coping excluded from our analysis as it was measured only at T2 and only in intervention and not in control Comment: this was judged as at a low risk of bias
Other bias	Low risk	Funded by a grant of the Dutch Cancer Society

Wurtzen 2013

Study characteristics	
Methods	Design: RCT Country: Denmark Setting: outpatient Method of randomisation: consenting patients were randomised (1:1) via a web interface by use of computer-generated sequences of 10 patients. Method of allocation: not reported Outcome assessor blinding: questionnaires were mailed to participants
Participants	N = 336 (intervention 168, control 168) Inclusion criteria: aged 18 –75 years and operated for stage I – III breast cancer at one of the two specialised breast surgery departments in which patients were recruited to the study and had received their diagnosis 3 – 18 months earlier Exclusion criteria: current major psychiatric disease or another medical condition that would limit participation, insufficient Danish language to fill in a questionnaire, or a diagnosis of another cancer within 10 years.
Interventions	Intervention group: mindfulness-based stress reduction (MBSR) program Frequency: eight weekly 2-hour group sessions Duration: 8 weeks Control group: usual care control included no specific psychosocial intervention
Outcomes	Anxiety and depression on the Danish version of the Symptom Checklist-90-r (SCL-90r),20 scored on a five-point scale from 0 (absence of the symptom) to 4 (maximum disturbance with nine scales or indexes and a cut-off for probable psychiatric illness Depression (13 items) and anxiety (10 items) subscales, and distress (GSI index, 90 items). 20- item Center for Epidemiological Studies-Depression (CES-D) scale, focusing primarily on cognitive and affective manifestations of depression. Items are assessed from 0 (‘rarely or none of the time’) to 3 (‘most or all of the time’). Assessed at 2, 6 and 12 months after the start of the intervention.

Wurtzen 2013 *(Continued)*

Notes	Funding: funded by the Danish Cancer Society; the Psychosocial Research Committee (Grant number R13-A640-09-S3) and the CAM Research Committee (Grant number UP7001), University of Copenhagen; Multidisciplinary CAMresearch (Grant number 603-44-204/SD), Danish Cancer Research Foundation (Grant number 50-08- 2008) and the Danish Cancer Society Research Centre.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Consenting patients were randomised (1:1) via a web interface by use of computer-generated sequences of 10 patients.
Allocation concealment (selection bias)	Unclear risk	Participants were informed about the allocation result. However, allocation concealment of investigators was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Questionnaires were mailed to participants. Self report bias could not be excluded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comparisons of self-report data regarding psychological well-being shoved more burden among participants when compared to refuters providing such data. 35 lost follow-up from intervention arm and 18 from control arm. Baseline values of distress, mindfulness skills and spiritual well-being, interactions between study group and these variables were included in all three intention-to-treat analyses. Regression approach was performed for each outcome as an intention-to-treat analysis of the total sample, regardless of missing data, and also by using the last observation carried forward to handle the effects of missing data.
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Funded by the Danish Cancer Society; the Psychosocial Research Committee (Grant number R13-A640-09-S3) and the CAM Research Committee (Grant number UP7001), University of Copenhagen; Multidisciplinary CAMresearch (Grant number 603-44-204/SD), Danish Cancer Research Foundation (Grant number 50-08- 2008) and the Danish Cancer Society Research Centre.

Yates 2005

Study characteristics

Methods	Design: RCT Setting: three major metropolitan hospitals, Australia

Yates 2005 *(Continued)*

	Duration of intervention: 3 weeks
Participants	N = 110 (intervention 53, control 57) and 1 excluded from analysis for ineligibility Inclusion criteria: • > 18 years • Commencing chemotherapy for stage I or II breast cancer • Women were admitted to the study if they had an Eastern Cooperative Oncology Group performance rating of one or two • Haemoglobin level at least 11.6 g/mL at recruitment
Interventions	• Intervention: patient received individual fatigue education and support program delivered on clinic and by phone over 3 (10- to 20-) minute sessions 1 week apart. The first session was 20 minutes in length and delivered face-to-face. The second and third sessions were conducted by phone 1 week apart and were 10 minutes in length • Control: general cancer educational sessions equivalent in number and timing to sessions provided to intervention. The control sessions were delivered in one face-to-face session, followed by two phone sessions at 1-week intervals
Outcomes	• QoL: European Organisation for Research- and Treatment of Cancer QoL questionnaire C30 • Psychological well-being (anxiety and depression): Hospital Anxiety and Depression scale • Assessment done at baseline T1, T2, T3, T4
Notes	• Because patients receiving chemotherapy face a range of unfamiliar, highly stressful experiences, especially at their first treatment visit, the first control or intervention session was conducted at the second treatment visit to minimise the effect of high initial levels of anxiety on the patient's ability to participate in the intervention • Follow-up assessment was conducted on the day of each subsequent treatment cycle to minimise the confounding effects of treatment • Because there were similar numbers of patients who had received radiotherapy in both the intervention and control groups, any treatment-related differences between groups were expected to be similar

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The patient was then randomly assigned to intervention or control conditions through a central telephone system using computer-generated random numbers" Comment: this was judged as at a low risk of bias
Allocation concealment (selection bias)	Unclear risk	Quote: "Group allocation was concealed from research assistants involved in recruitment and the baseline and follow-up assessments" Comment: the method used to conceal the allocation sequence was not reported to permit a clear judgment
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "Group allocation was concealed from research assistants involved in recruitment and the baseline and follow-up assessments"

Yates 2005 *(Continued)*

		Comment: the method used to blind the outcome assessment was not reported to permit a clear judgement
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only one excluded from analysis due to ineligibility Number of participants who completed follow-up 1 (50 intervention and 54 in control); follow-up 2 (50 intervention and 50 control) and follow-up 3 (49 intervention and 48 control) Intention-to-treat analysis was done Comment: low dropout rates and ITT analysis suggested a low risk of bias
Selective reporting (reporting bias)	Unclear risk	No data presented for secondary outcomes (QoL and psychological well-being) because there was no significant effect of the intervention for cancer self-efficacy, quality of life, or psychological well-being Comment: this was judged as at an unclear risk of bias
Other bias	Low risk	Quote: "The authors indicated no potential conflicts of interest." Comment: this was judged as at a low risk of bias

Zahedian 2021

Study characteristics	
Methods	RCT
Participants	Depressed patients with breast cancer Inclusion criteria: (a) adults 20–70 years of age, (b) being treated for a diagnosis of breast cancer, (c) mild to moderate depression score by the Beck Depressive Inventory and (d) the ability to attend sessions. Exclusion criteria: absence from treatment sessions, death, and severe psychological or physiological conditions coinciding with the period of psychotherapy.
Interventions	Intervention: meta-cognitive therapy. One weekly group session for 8 weeks Control: treatment as usual
Outcomes	Depression by Beck Depressive Inventory Measured at baseline (T0), immediately after (T1), and one month after the intervention (T2) using the Beck Depressive Inventory (BDI). The score ranges from at least zero to at most 63. Cognitive strategies by Cognitive emotion regulation questionnaire Metacognitive beliefs by Meta cognitions questionnaire
Notes	

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	A computer-generated random number sequence (https:// www. randomizer. org/) was used by means of a simple allocation strategy

Zahedian 2021 *(Continued)*

Allocation concealment (selection bias)	Low risk	A statistician not involved in the study performed the randomisation.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Neither the therapist nor the participants can be blinded to the delivered treatment. Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not reported Comment: there was insufficient information to permit a clear judgement of risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	There were no dropouts in either arm
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Funded by the Research Deputy of Bushehr University of Medical Sciences [Grant Numbers 1401/71/20/DP].

Zhang 2017

Study characteristics	
Methods	Design: RCT Country: China Setting: outpatient Method of randomisation: lottery Method of allocation: independent statistics staff Outcome assessor blinding: by a research assistant who was blinded to the group assignment and independent from the MBSR delivery.
Participants	N = 60 (intervention 30, control 30) Inclusion criteria: (i) were diagnosed with Stages I–III breast cancer, (ii) were aged 18 years or older, (iii) were within 2–6 months after the completion of surgery, and (iv) had no other major disabling medical or mental disorder Exclusion criteria: patients who had participated in a similar intervention were excluded.
Interventions	Intervention group: mindfulness-based stress reduction Frequency: 8 weeks Duration: 2 to 4 hours Control group: usual care received the MBSR intervention (if desired) after the study
Outcomes	Stress measured by Perceived Stress Scale of Chinese version (CPSS)

Zhang 2017 *(Continued)*

	Anxiety measured by State Trait Anxiety Inventory (STAI) Assessed at three times (before intervention-T1, after intervention-T2 and follow up at 3 months-T3).
Notes	Funding: supported by Heilongjiang Education Department Project of China

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised by using the lottery by statistics staff who were independent of the study. The participants were blinded to their random assignment until the end of this session.
Allocation concealment (selection bias)	Low risk	Randomised by using the lottery by statistics staff who were independent of the study. The participants were blinded to their random assignment until the end of this session.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not possible in this type of intervention Comment: the effect of lack of blinding on outcome in this type of intervention was unclear
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The anonymous data were collected by a research assistant who was blinded to the group assignment and independent of the MBSR delivery.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Two dropped from the intervention arm. The unbalanced drop out and per protocol analysis pose unclear risk of bias.
Selective reporting (reporting bias)	Low risk	The results reported coincide with the outcomes of interest reported in the trial design
Other bias	Low risk	Supported by Heilongjiang Education Department Project of China

ABS: Affects Balance Scale; **BAI:** Beck Anxiety Inventory not specified;**BC:** breast cancer; **BDI:** Beck Depression Inventory; **BSI:** Brief Symptom Inventory; **CARES-SF:** Cancer Rehabilitation Evaluation System - Short Form; **CBI:** Cancer Behaviour Inventory; **CBT:** Cognitive Behavioural Therapy; **CES-D:** Center for Epidemiological Study - Depression; **CED-S:** Center for Epidemiological Scale; **CNS:** Central Nervous System; CR: cognitive rehabilitation; **CSQ:** Coping Strategies Questionnaire; **ECG:** electrocardiogram**; ECOG:** Eastern Cooperative Oncology Group; **FACT:** Functional Assessment of Cancer Therapy;**HADS;** Hospital Anxiety and Depression Scale; **IES**: Impact of Event Scale;**ITT:** Intention-to-Treat; **LSSI:** Lipp Stress Symptoms Inventory for adults;**MAC:** Mental Adjustment to Cancer**; MATT:** Memory and Attention Adaption Training;**MBSR:** Mindfulness-Based Stress Reduction; **MHI:** Mental Health Inventory; **POMS:** Profile of Mood States;**QoL:** Quality of Life; **RCT:** Randomised Controlled Trial; **RE:** Relationship Enhancement;**RVT:** Relaxation and Visualisation Therapy;**STAI:** State Trait Anxiety Inventory; **TAU:** Treatment as usual; **VAS:** visual Analogue Scale.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Admiraal 2017	Intervention was web-based and not delivered by professionals in the field.
Allard 2006	The intervention was merely a means of directing women towards coping strategies that were effective and not considered a psychological intervention according to our definition

Study	Reason for exclusion
Badger 1999	The intervention was not psychological according to the definition in this review. The outcome measurement scale was not validated
Badger 2013	Stage IV metastatic disease was included and the intervention was aimed at education and social support
Bjorneklett 2012	The intervention was not psychological according to the definition in this review
Braden 2000	We could not retrieve information on disease stage
Burton 1991	Not an RCT
Carlson 2013	The study included 3 participants with stage IV disease with no secondary analysis by stage.
Carlson 2016	The study included 3 participants with stage IV disease with no secondary analysis by stage.
Chan 2014	Included all cancer patients and there was no subanalysis for participants with breast cancer
Charalambous 2016	Participants were diagnosed with breast or prostate cancer and there is no separate group analysis for each.
Chen 2015	Design is pre-test-post-test, quasiexperimental design
Cherrier	Participants were cancer patients and there is no subanalysis for breast cancer group.
Crane-Okada 2012	The intervention was peer counselling and this does not fit the definition of psychological intervention in this review
Cruess 2001	Data were a subset of the original article by Antoni 2001
Cunningham 1998	Included women with metastatic breast cancer
David 2011	Included women with metastatic disease
Dodds 2015	Feasibility pilot study
Edelman 1999	Included women with metastatic breast cancer
Elias 2015	Intervention is based on relaxation and spirituality
Esplen 2018a	The intervention was focused around body image and sexual functioning.
Esplen 2018b	The study included women with family history of breast cancer
Ferguson 2016	The parent study Ferguson 2012 was included
Freeman 2008	Included women with metastatic breast cancer
Freeman 2015	Included women with stage IV disease with no secondary analysis by stage
Gaston-Johansson 2000	Only women undergoing autologous brain stem transplantation (ABMT) were included
Gaston-Johansson 2013	Included stage II, III, or IV breast cancer, scheduled for high-dose chemotherapy and ahematopoietic stem cell transplantation. No subanalysis by stage was included.

Study	Reason for exclusion
Germino 2013	Intervention is self-delivered and CD based
Gil 2005	The outcome was a description of the coping strategy and was not measured by a validated tool
Goodwin 2003	Included women with metastatic breast cancer
Greer 1992	Included participants with any type of cancer
Groarke 2013	Participants included women diagnosed with stage IV breast cancer (metastasis)
Haj Sadeghi 2018	Pilot study, uncorrected proof, not clear if metastatic patients were included or not.
Halkett 2013	The intervention was mainly educational and informative and did not fit the intervention criteria in this review
Hamama-Raz 2016	The groups were not randomly allocated but self selected. The outcome is an intermediate outcome as opposed to coping skills or psychological outcomes
Hamidian 2019	Quasi experimental design, outcome is posttraumatic stress growth, and the original study from which this is stemming was included (Hamidian 2018)
Heiney 2003	Not an RCT; only a description of the intervention
Heiney 2012	Outcome was social well-being
Helgeson 2001	The intervention was purely educational
Henderson 2013	The parent study has been included Henderson 2012. This study contains analysis of a subset of particpants (those who underwent radiotherapy) thus teh original study was included
Hirai 2012	Not an RCT
Hopko 2011	Included women at stage 4 (metastatic) disease
Hosaka 1996	Included women with metastasis
Hoskins 2001	A pilot study and too small to have meaningful statistics and methodology to be adapted
Hsiao 2012	Included women with metastatic disease and the intervention did not fulfil the inclusion criteria in this review
Hummel 2017	Intervention is Internet based and focused on sexual dysfunction.
Jalambadani	Not ranRCT.
Johns 2016	Included both breast and colorectal cancer survivors with no subgroup analysis
Jones 2013	Intervention is mainly educational
Kenne Sarenmalm	This is a protocol
Klinkhammer-Schalke 2012	The intervention was not psychological according to the definition used in this review
Kvale 2016	The intervention is not considered a psychological, cognitive behavioural intervention according to our definition

Study	Reason for exclusion
Kwok 2011	The intervention was education and informative, and did not fit the criteria in this review
Lai 2019	Intervention is not CBT according to our definition. It consisted of one nurse consultation and 2 telephone calls and was based on providing information to the patients
Lechner 2014	Included stage IV patients and no sub-analysis by disease stage was done
Lee 2013	The intervention was not psychological and was not led by a professional, mostly dyadic-based educational and support group
Lengacher 2009	This intervention was not psychological but a form of meditation or yoga - it did not fit our criteria
Lengacher 2014	The parent and subsequent larger studies were included (Lengacher 2009; Lengacher 2016)
Lengacher 2019	The outcome is salivary cortisol and IL-6. Further, the parent study (Lengacher 2016) has already been included.
Leon-Pizarro 2007	Participants included women with breast cancer or gynaecological cancer
Lepore 2014	Intervention was Internet based, focused on social support and not led by professionals in the field.
Lev 2000	The main problem with this study was that the data were poorly reported so that they could not be included unless further details were given by the authors. Most of the results were qualitative
Manne 2017	This is a secondary analysis of the parent study which was included (Manne 2016)
Manos 2009	This was not an RCT. The women who agreed to participate were in the intervention group while those who refused were the control group. Group allocation was based entirely on the patient's wish
Masoumi 2017	Not RCT. Quasi experimental pre test and post test design.
Matthews 2014	The intervention was addressing specifically insomnia which is not one of the outcomes identified a priori in this review
McGregor 2004	This study was designed to test the effects of the Cognitive Behaviour Stress Management (CBSM) intervention on immune function among a subset of women (N = 29) from the larger trial (Antoni 2001) which was included in this review
McKiernan 2010	A CCT and not an RCT
Montgomery 2017	Intervention is complex and is composed of multi interventions. Data were not extractable for each.
Monti 2013	Included women with stage IV metastatic disease
Naumann 2012	Intervention was mostly supportive and exercise based
Paez 2007	Included women with metastatic and non-metastatic disease
Park 2017	Quasi experimental design. Outcome is cognitive ability which does not match our inclusion criteria
Pintado 2017	Outcomes (body image) don’t match our inclusion criteria

Study	Reason for exclusion
Poorkiani 2010	Intervention was not psychological and instead involved physiotherapy and education
Pouy 2018	Not RCT, quasi-experimental study design
Qiu 2013	The study included patients with stage IV disease
Qiu 2018	The parent study was included Ren 2019
Ramos 2018	Outcomes do not match our inclusion criteria
Rissanen 2014	Outcome (fatigue) does not match our inclusion criteria
Rissanen 2015	Study outcome focus is on mode of delivery group or individual attendance for stress management.
Rosberger 2002	The outcome was coping style as opposed to QoL or psychological morbidity
Rosen 2018	The study included patients with stage IV metastatic disease and there was no secondary analysis by stage
Rottmann 2012	The intervention was educational and informative and did not fit the criteria in this review
Samarel 1997	The intervention did not fit the eligibility criteria of this review
Samarel 2002	The intervention was mainly social and educational
Sandgren 2000	The intervention was derived from a psychological intervention that had been shown to be effective, but it was sufficiently modified in the study that it was no longer deemed as an acceptable psychological intervention
Sandler 2017	The study included patients with breast and colon cancer with no secondary analysis as per cancer type
Sherman 2012	Intervention and outcomes did not fit the definitions and criteria in this review
Shrock 1999	Not an RCT
Sidani 1995	Included women with metastatic and recurrent disease
Stoerkel 2018	Excluded because the intervention was delivered through MP3 player and not professional led.
Taeidi 2018	Uncorrected proof. Intervention is problem solving. Not clear if stage IV was included or not.
Taub 2019	This is a secondary analysis of a study which has already been included (Gudenkauf 2015)
Thornton 2009	Participants were part of the sample in the parent study (Andersen 2004) which was included in this review
Van de Wal 2017	Included breast, prostate and colon cancer with no secondary analysis by cancer site
Vaziri 2017	Study design is not RCT. It is quasi experimental pre test post test design with small sample size (16 patients).
Ventura 2017	Intervention is computer based (CD) and mainly educational and is based on evaluation of an approach

Study	Reason for exclusion
Victoria Cerezo 2014	Emotional intelligence, resilience and affectivity are outcomes that were not identified a priori in this review.
Walker 1999	The intervention involved self administered tapes
Weissflog 2015	Fatigue was the primary outcome.
Wu 2018	Included patients with stage IV disease with no secondary analysis according to stage.
Wurtzen 2015	The parent study Wurtzen 2013 has been included
Yan 2001	The outcome did not fit the study criteria
Ye 2016	Intervention was delivered by breast cancer survivors and not professionals in the field.
Zachariae 2018	Intervention is focused on insomnia and is Internet-based. Outcomes are sleep quality and fatigue which are not consistent with the outcomes we identified a priori.
Zhou 2015	Intervention is music therapy and muscle relaxation

CBT: cognitive behaviourble therapy: **CCT:** controlled clinical trial; **QoL:** quality of life; **RCT:** randomised controlled trial.

DATA AND ANALYSES

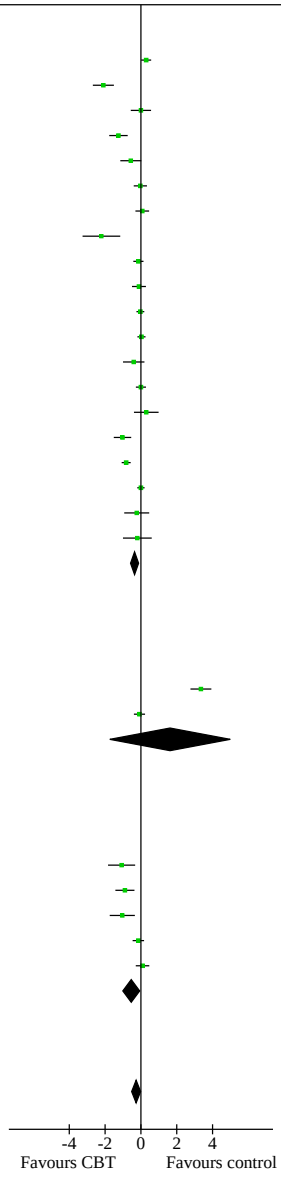
Comparison 1. CBT versus control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Standardised mean difference in the change from baseline in depression	27	3321	Std. Mean Difference (IV, Random, 95% CI)	-0.27 [-0.52, -0.02]
1.1.1 Group delivered intervention (less than or equal 20 hrs)	20	2660	Std. Mean Difference (IV, Random, 95% CI)	-0.35 [-0.58, -0.13]
1.1.2 Group delivered intervention (more than 20 hrs)	2	270	Std. Mean Difference (IV, Random, 95% CI)	1.63 [-1.74, 4.99]
1.1.3 Individually delivered intervention(less than 20 hrs)	5	391	Std. Mean Difference (IV, Random, 95% CI)	-0.54 [-1.01, -0.07]
1.2 Standardised mean difference in the change from baseline mean change in anxiety	22	2702	Std. Mean Difference (IV, Random, 95% CI)	-0.43 [-0.68, -0.17]
1.2.1 Group delivered intervention (less than 20 hrs)	18	2186	Std. Mean Difference (IV, Random, 95% CI)	-0.27 [-0.46, -0.07]
1.2.2 Group delivered intervention (more than 20 hrs)	2	270	Std. Mean Difference (IV, Random, 95% CI)	-1.69 [-5.17, 1.78]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.2.3 Individually delivered intervention (less than 20 hrs)	2	246	Std. Mean Difference (IV, Random, 95% CI)	-0.51 [-0.99, -0.04]
1.3 Standardised mean difference in the change from baseline mood disturbance	13	2276	Std. Mean Difference (IV, Random, 95% CI)	-0.18 [-0.31, -0.04]
1.3.1 Group delivered intervention (less than 20 hrs)	10	1457	Std. Mean Difference (IV, Random, 95% CI)	-0.18 [-0.37, -0.00]
1.3.2 Group delivered intervention (more than 20 hrs)	1	159	Std. Mean Difference (IV, Random, 95% CI)	-0.01 [-0.32, 0.30]
1.3.3 Individually delivered intervention (less than 20 hrs)	2	660	Std. Mean Difference (IV, Random, 95% CI)	-0.19 [-0.34, -0.04]
1.4 Standardised mean difference in quality of life	20	1747	Std. Mean Difference (IV, Random, 95% CI)	0.78 [0.32, 1.24]
1.4.1 Group intervention less than or equal 20 hours	16	1390	Std. Mean Difference (IV, Random, 95% CI)	0.74 [0.26, 1.22]
1.4.2 Individual intervention	3	246	Std. Mean Difference (IV, Random, 95% CI)	0.09 [-0.57, 0.76]
1.4.3 Group intervention more than 20 hours	1	111	Std. Mean Difference (IV, Random, 95% CI)	3.35 [2.77, 3.93]
1.5 Stress (group intervention)	8	564	Std. Mean Difference (IV, Random, 95% CI)	-0.34 [-0.55, -0.12]
1.6 Standardised mean difference in the change from baseline coping	7	633	Std. Mean Difference (IV, Random, 95% CI)	-0.24 [-0.60, 0.12]
1.6.1 Group delivered intervention	6	597	Std. Mean Difference (IV, Random, 95% CI)	-0.05 [-0.26, 0.17]
1.6.2 Individually delivered intervention	1	36	Std. Mean Difference (IV, Random, 95% CI)	-1.76 [-2.54, -0.98]
1.7 Overall survival (group delivered intervention)	2	530	Hazard Ratio (IV, Random, 95% CI)	0.76 [0.25, 2.32]

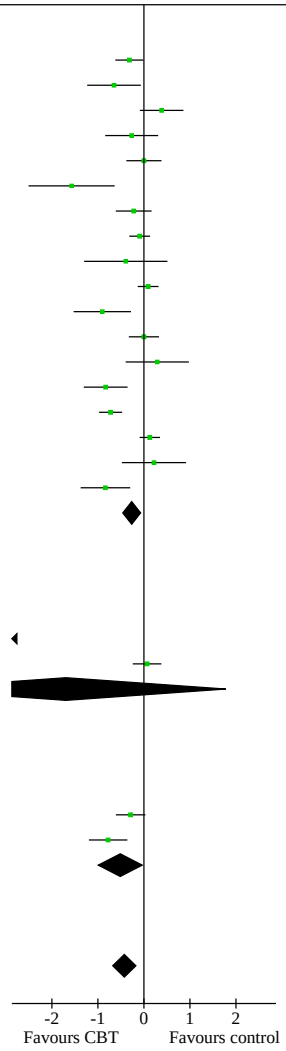
Analysis 1.1. Comparison 1: CBT versus control, Outcome 1: Standardised mean difference in the change from baseline in depression

Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
1.1.1 Group delivered intervention (less than or equal 20 hrs)								
Ashing 2014	17.2	10.5	100	14.1	10.6	99	4.1%	0.29 [0.01 , 0.57]
Bower 2015	14.2	1.7	39	17.9	1.8	32	3.5%	-2.10 [-2.68 , -1.51]
Fukui 2000	2.7	2.3	25	2.7	2.1	23	3.6%	0.00 [-0.57 , 0.57]
Garssen 2013	34	9.8	34	49.1	13.6	36	3.7%	-1.25 [-1.77 , -0.74]
Gonzalez-Hernandez 2018	5.4	5.2	22	8.6	5.87	25	3.5%	-0.57 [-1.15 , 0.02]
Gudenkauf 2015	1.7	0.64	55	1.72	0.6	58	4.0%	-0.03 [-0.40 , 0.34]
Ho 2016	5	4.3	49	4.7	3.6	57	3.9%	0.08 [-0.31 , 0.46]
Jang 2016	51.6	8.3	12	71.5	9.1	12	2.5%	-2.21 [-3.26 , -1.15]
Janusek 2019	10.31	10.15	96	11.79	10.89	96	4.1%	-0.14 [-0.42 , 0.14]
Kim 2013	5.8	3.1	51	6.2	4.1	51	3.9%	-0.11 [-0.50 , 0.28]
Lengacher 2016	8.7	6.3	167	8.9	6.8	155	4.2%	-0.03 [-0.25 , 0.19]
Manne 2016	7.3	3.6	151	7.2	2.9	151	4.2%	0.03 [-0.20 , 0.26]
Mirmahmoodi 2020	17.18	9.46	22	21.59	11.97	22	3.5%	-0.40 [-1.00 , 0.20]
Nicolaisen 2018	2.6	3	101	2.6	2.9	94	4.1%	0.00 [-0.28 , 0.28]
Nunes 2007	12.6	6.4	20	10.6	6.7	14	3.3%	0.30 [-0.39 , 0.99]
Park 2020	2.94	2.98	38	6.69	4.17	36	3.7%	-1.03 [-1.52 , -0.54]
Ren 2019	4.4	3.9	98	7.9	4.4	196	4.2%	-0.82 [-1.07 , -0.57]
Schou Bredal 2014	2.4	2.6	185	2.4	2.9	182	4.2%	0.00 [-0.20 , 0.20]
Trindade 2020	3.6	3.01	15	4.53	4.49	17	3.2%	-0.23 [-0.93 , 0.46]
Zahedian 2021	12.83	88.21	12	25.75	8.22	12	3.0%	-0.20 [-1.00 , 0.60]
Subtotal (95% CI)			**1292**			**1368**	**74.4%**	**-0.35 [-0.58 , -0.13]**
Heterogeneity: Tau² = 0.20; Chi² = 136.34, df = 19 (P < 0.00001); I² = 86%								
Test for overall effect: Z = 3.11 (P = 0.002)								
1.1.2 Group delivered intervention (more than 20 hrs)								
Henderson 2012	8.8	0.3	53	7.6	0.4	58	3.5%	3.35 [2.77 , 3.93]
Merckaert 2017	3.8	3.8	82	4.1	3.6	77	4.1%	-0.08 [-0.39 , 0.23]
Subtotal (95% CI)			**135**			**135**	**7.6%**	**1.63 [-1.74 , 4.99]**
Heterogeneity: Tau² = 5.83; Chi² = 103.46, df = 1 (P < 0.00001); I² = 99%								
Test for overall effect: Z = 0.95 (P = 0.34)								
1.1.3 Individually delivered intervention(less than 20 hrs)								
Desautels 2018	4.1	3	25	7.3	2.65	11	3.1%	-1.08 [-1.84 , -0.32]
Kim 2018	6.1	2.6	30	9.1	3.9	30	3.6%	-0.89 [-1.43 , -0.36]
Marchioro 1996	4.83	1.82	18	8.17	4.05	18	3.2%	-1.04 [-1.74 , -0.34]
Napoles 2015	0.38	0.48	76	0.46	0.62	75	4.1%	-0.14 [-0.46 , 0.18]
Yates 2005	0	2.35	53	-0.2	2.06	55	4.0%	0.09 [-0.29 , 0.47]
Subtotal (95% CI)			**202**			**189**	**18.0%**	**-0.54 [-1.01 , -0.07]**
Heterogeneity: Tau² = 0.21; Chi² = 18.06, df = 4 (P = 0.001); I² = 78%								
Test for overall effect: Z = 2.26 (P = 0.02)								
Total (95% CI)			**1629**			**1692**	**100.0%**	**-0.27 [-0.52 , -0.02]**
Heterogeneity: Tau² = 0.37; Chi² = 296.97, df = 26 (P < 0.00001); I² = 91%								
Test for overall effect: Z = 2.10 (P = 0.04)								
Test for subgroup differences: Chi² = 1.86, df = 2 (P = 0.39), I² = 0%								



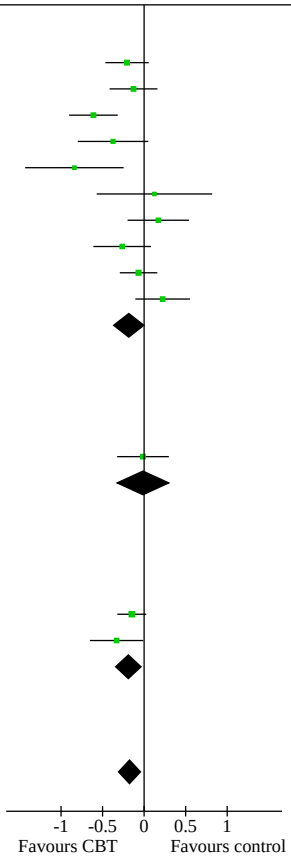
Analysis 1.2. Comparison 1: CBT versus control, Outcome 2: Standardised mean difference in the change from baseline mean change in anxiety

Study or Subgroup	Intervention Mean	Intervention SD	Intervention Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
1.2.1 Group delivered intervention (less than 20 hrs)								
Dolbeault 2009	42.25	10.04	81	45.46	10.17	87	5.1%	-0.32 [-0.62 , -0.01]
Fukui 2000	6.4	3.1	25	9.2	5.2	23	4.2%	-0.65 [-1.23 , -0.07]
Garssen 2013	37.8	2.2	34	37	1.9	36	4.6%	0.39 [-0.09 , 0.86]
Gonzalez-Hernandez 2018	6.09	5.38	22	7.56	5.49	25	4.3%	-0.27 [-0.84 , 0.31]
Ho 2016	6.6	4.4	49	6.6	3.7	57	4.9%	0.00 [-0.38 , 0.38]
Jang 2016	44.67	14.37	12	64.67	9.77	12	3.1%	-1.57 [-2.51 , -0.64]
Kim 2013	5.51	3.12	51	6.28	3.73	51	4.8%	-0.22 [-0.61 , 0.17]
Lengacher 2016	31.82	12.1	155	32.99	13.4	148	5.2%	-0.09 [-0.32 , 0.13]
Loprinzi 2011	33.3	11.7	12	39	16.7	8	3.2%	-0.39 [-1.30 , 0.51]
Manne 2016	17.8	7.1	151	17.2	6	151	5.2%	0.09 [-0.13 , 0.32]
Mirmahmoodi 2020	23.5	11.35	22	35	13.52	22	4.1%	-0.90 [-1.53 , -0.28]
Nicolaisen 2018	5.2	4.1	82	5.2	3.3	63	5.0%	0.00 [-0.33 , 0.33]
Nunes 2007	37.05	8.26	20	34.91	5.3	14	3.9%	0.29 [-0.40 , 0.98]
Park 2020	3.83	3.04	38	6.64	3.64	36	4.6%	-0.83 [-1.31 , -0.36]
Ren 2019	5	3.3	98	7.9	4.3	196	5.2%	-0.72 [-0.97 , -0.47]
Schou Bredal 2014	5.4	3.9	161	4.9	3.9	154	5.3%	0.13 [-0.09 , 0.35]
Trindade 2020	4.2	3.43	15	3.41	3.57	17	3.9%	0.22 [-0.48 , 0.92]
Zhang 2017	87.14	4.15	28	90.73	4.31	30	4.4%	-0.84 [-1.38 , -0.30]
Subtotal (95% CI)			**1056**			**1130**	**81.0%**	**-0.27 [-0.46 , -0.07]**
Heterogeneity: Tau² = 0.12; Chi² = 72.58, df = 17 (P < 0.00001); I² = 77%								
Test for overall effect: Z = 2.69 (P = 0.007)								
1.2.2 Group delivered intervention (more than 20 hrs)								
Henderson 2012	13.9	0.6	53	16	0.6	58	4.2%	-3.48 [-4.07 , -2.88]
Merckaert 2017	7.6	4.3	82	7.3	4.5	77	5.1%	0.07 [-0.24 , 0.38]
Subtotal (95% CI)			**135**			**135**	**9.2%**	**-1.69 [-5.17 , 1.78]**
Heterogeneity: Tau² = 6.22; Chi² = 106.67, df = 1 (P < 0.00001); I² = 99%								
Test for overall effect: Z = 0.96 (P = 0.34)								
1.2.3 Individually delivered intervention (less than 20 hrs)								
Napoles 2015	0.39	0.53	76	0.58	0.76	75	5.0%	-0.29 [-0.61 , 0.03]
Yates 2005	-4.7	2.95	48	-2.5	2.65	47	4.8%	-0.78 [-1.20 , -0.36]
Subtotal (95% CI)			**124**			**122**	**9.8%**	**-0.51 [-0.99 , -0.04]**
Heterogeneity: Tau² = 0.08; Chi² = 3.31, df = 1 (P = 0.07); I² = 70%								
Test for overall effect: Z = 2.11 (P = 0.03)								
Total (95% CI)			**1315**			**1387**	**100.0%**	**-0.43 [-0.68 , -0.17]**
Heterogeneity: Tau² = 0.30; Chi² = 197.61, df = 21 (P < 0.00001); I² = 89%								
Test for overall effect: Z = 3.32 (P = 0.0009)								
Test for subgroup differences: Chi² = 1.51, df = 2 (P = 0.47), I² = 0%								



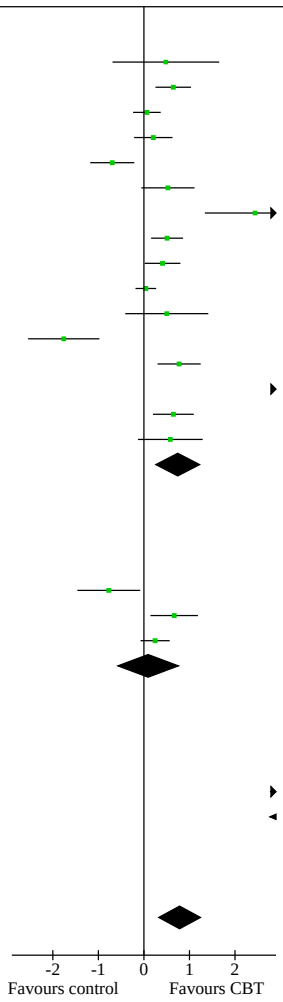
Analysis 1.3. Comparison 1: CBT versus control, Outcome 3: Standardised mean difference in the change from baseline mood disturbance

Study or Subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
1.3.1 Group delivered intervention (less than 20 hrs)								
Andersen 2004	-12.58	23.19	114	-8.11	19.96	113	9.5%	-0.21 [-0.47 , 0.06]
Boesen 2011	-8.5	12	89	-7	11.5	97	8.8%	-0.13 [-0.42 , 0.16]
Dolbeault 2009	-20.37	22.07	92	-6.46	23.31	96	8.6%	-0.61 [-0.90 , -0.32]
Fillion 2008	-0.68	2.58	44	0.43	3.27	43	5.9%	-0.37 [-0.80 , 0.05]
Fukui 2000	-8.8	12.76	25	3.7	16.46	23	3.7%	-0.84 [-1.43 , -0.25]
Graves 2003	8.33	25.23	15	5.14	24.77	17	2.9%	0.12 [-0.57 , 0.82]
Gudenkauf 2015	1.07	0.91	55	0.92	0.84	58	6.9%	0.17 [-0.20 , 0.54]
Johannsen 2016	16.1	6.4	67	17.8	6.4	62	7.4%	-0.26 [-0.61 , 0.08]
Manne 2016	19.3	20.5	151	20.6	18.2	151	10.4%	-0.07 [-0.29 , 0.16]
Nicolaisen 2018	20	15.4	82	16.7	13.7	63	7.8%	0.22 [-0.11 , 0.55]
Subtotal (95% CI)			**734**			**723**	**71.9%**	**-0.18 [-0.37 , -0.00]**
Heterogeneity: Tau² = 0.05; Chi² = 25.14, df = 9 (P = 0.003); I² = 64%								
Test for overall effect: Z = 1.99 (P = 0.05)								
1.3.2 Group delivered intervention (more than 20 hrs)								
Merckaert 2017	11.3	7.3	82	11.4	7.2	77	8.2%	-0.01 [-0.32 , 0.30]
Subtotal (95% CI)			**82**			**77**	**8.2%**	**-0.01 [-0.32 , 0.30]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.09 (P = 0.93)								
1.3.3 Individually delivered intervention (less than 20 hrs)								
Mishel 2005	-0.07	0.32	244	-0.02	0.35	265	11.9%	-0.15 [-0.32 , 0.03]
Napoles 2015	3.87	5.79	76	6.27	8.42	75	8.0%	-0.33 [-0.65 , -0.01]
Subtotal (95% CI)			**320**			**340**	**19.9%**	**-0.19 [-0.34 , -0.04]**
Heterogeneity: Tau² = 0.00; Chi² = 0.96, df = 1 (P = 0.33); I² = 0%								
Test for overall effect: Z = 2.43 (P = 0.01)								
Total (95% CI)			**1136**			**1140**	**100.0%**	**-0.18 [-0.31 , -0.04]**
Heterogeneity: Tau² = 0.03; Chi² = 27.12, df = 12 (P = 0.007); I² = 56%								
Test for overall effect: Z = 2.60 (P = 0.009)								
Test for subgroup differences: Chi² = 1.06, df = 2 (P = 0.59), I² = 0%								



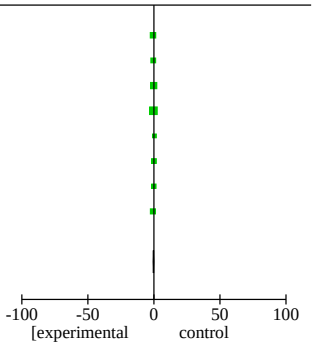
Analysis 1.4. Comparison 1: CBT versus control, Outcome 4: Standardised mean difference in quality of life

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
1.4.1 Group intervention less than or equal 20 hours								
Baucom 2009	3.22	0.34	7	2.89	0.91	5	4.1%	0.48 [-0.69 , 1.65]
Beutel 2013	58.4	24	52	42.7	24.4	54	5.3%	0.64 [0.25 , 1.03]
Dolbeault 2009	4.88	1.11	81	4.81	1.03	87	5.4%	0.07 [-0.24 , 0.37]
Fillion 2008	46.76	9.24	43	44.64	11.05	44	5.3%	0.21 [-0.22 , 0.63]
Garssen 2013	72.9	3.8	34	75.5	3.6	36	5.2%	-0.70 [-1.18 , -0.21]
Gonzalez-Hernandez 2018	71.73	15.45	22	62.8	17.63	25	5.1%	0.53 [-0.06 , 1.11]
Jang 2016	81.31	12.46	12	40.17	19.37	12	4.2%	2.44 [1.34 , 3.54]
Johannsen 2016	56.2	20.6	67	45.1	22.8	62	5.4%	0.51 [0.16 , 0.86]
Kim 2013	70.29	18.31	51	62.02	21.69	51	5.3%	0.41 [0.02 , 0.80]
Lengacher 2016	68.76	21.5	153	67.85	21.99	146	5.5%	0.04 [-0.19 , 0.27]
Loprinzi 2011	44.5	3.5	12	42.2	5.5	8	4.6%	0.50 [-0.41 , 1.41]
Marchioro 1996	41.17	6.91	18	60.28	13.33	18	4.8%	-1.76 [-2.54 , -0.98]
Park 2020	85.41	16.08	38	71.9	18.5	36	5.2%	0.77 [0.30 , 1.25]
Pettiford 2017	17.12	2.62	47	-6.08	2.36	56	3.8%	9.28 [7.93 , 10.63]
Tabrizi 2016	65.5	16.7	41	53.8	19.1	40	5.3%	0.65 [0.20 , 1.09]
Trindade 2020	67.22	11.12	15	58.33	17.62	17	4.9%	0.58 [-0.13 , 1.29]
Subtotal (95% CI)			**693**			**697**	**79.4%**	**0.74 [0.26 , 1.22]**
Heterogeneity: Tau² = 0.85; Chi² = 247.27, df = 15 (P < 0.00001); I² = 94%								
Test for overall effect: Z = 3.02 (P = 0.002)								
1.4.2 Individual intervention								
Ferguson 2012	5.37	1.22	17	6.4	1.38	18	4.9%	-0.77 [-1.46 , -0.08]
Kim 2018	64.4	15.6	30	51.4	22.4	30	5.2%	0.66 [0.14 , 1.19]
Napoles 2015	80.64	13.64	76	77.02	15.62	75	5.4%	0.25 [-0.07 , 0.57]
Subtotal (95% CI)			**123**			**123**	**15.5%**	**0.09 [-0.57 , 0.76]**
Heterogeneity: Tau² = 0.28; Chi² = 10.74, df = 2 (P = 0.005); I² = 81%								
Test for overall effect: Z = 0.27 (P = 0.79)								
1.4.3 Group intervention more than 20 hours								
Henderson 2012	8.8	0.3	53	7.6	0.4	58	5.1%	3.35 [2.77 , 3.93]
Subtotal (95% CI)			**53**			**58**	**5.1%**	**3.35 [2.77 , 3.93]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 11.26 (P < 0.00001)								
Total (95% CI)			**869**			**878**	**100.0%**	**0.78 [0.32 , 1.24]**
Heterogeneity: Tau² = 0.99; Chi² = 360.78, df = 19 (P < 0.00001); I² = 95%								
Test for overall effect: Z = 3.35 (P = 0.0008)								
Test for subgroup differences: Chi² = 64.99, df = 2 (P < 0.00001), I² = 96.9%								



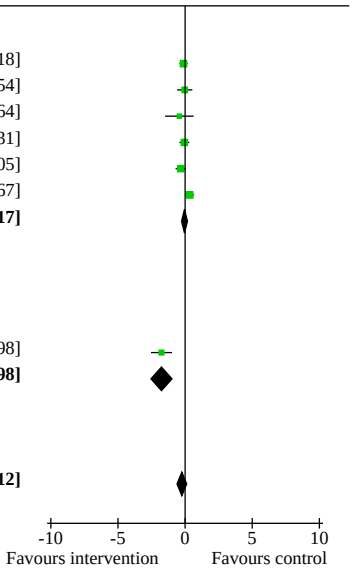
Analysis 1.5. Comparison 1: CBT versus control, Outcome 5: Stress (group intervention)

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Bower 2015	17.42	1.09	39	18.21	1.16	32	13.5%	-0.70 [-1.18 , -0.21]
Gonzalez-Hernandez 2018	5.95	4.5	22	8.16	4.05	25	10.3%	-0.51 [-1.09 , 0.07]
Ho 2016	17.5	4.1	51	18.4	5.5	49	17.5%	-0.18 [-0.58 , 0.21]
Janusek 2019	13.76	7.59	96	16.67	8.27	96	24.2%	-0.37 [-0.65 , -0.08]
Loprinzi 2011	18.9	7.9	12	15.4	8.5	8	5.0%	0.41 [-0.49 , 1.32]
Mirmahmoodi 2020	28.09	4.82	22	28.04	2.28	22	10.1%	0.01 [-0.58 , 0.60]
Trindade 2020	5.4	3.25	15	5.53	3.61	17	7.8%	-0.04 [-0.73 , 0.66]
Zhang 2017	31.54	3.75	28	34.27	3.36	30	11.7%	-0.76 [-1.29 , -0.22]
Total (95% CI)			**285**			**279**	**100.0%**	**-0.34 [-0.55 , -0.12]**
Heterogeneity: Tau² = 0.03; Chi² = 10.15, df = 7 (P = 0.18); I² = 31%								
Test for overall effect: Z = 3.07 (P = 0.002)								
Test for subgroup differences: Not applicable								



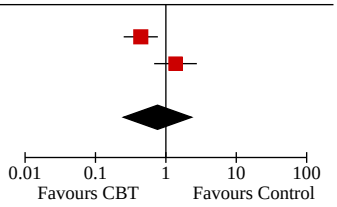
Analysis 1.6. Comparison 1: CBT versus control, Outcome 6: Standardised mean difference in the change from baseline coping

Study or Subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
1.6.1 Group delivered intervention								
Dolbeault 2009	17.8	5.1	81	18.46	5.9	87	17.9%	-0.12 [-0.42 , 0.18]
Fukui 2000	50.5	8	25	50.7	6.1	23	13.6%	-0.03 [-0.59 , 0.54]
Graves 2003	27.14	10.71	7	31.86	9.97	7	7.3%	-0.43 [-1.49 , 0.64]
Gudenkauf 2015	3.35	0.69	55	3.39	0.64	58	16.8%	-0.06 [-0.43 , 0.31]
Ho 2016	48.1	12.9	51	52.1	11.5	57	16.6%	-0.33 [-0.71 , 0.05]
Nicolaisen 2018	50.1	4	82	48.8	3.4	64	17.5%	0.34 [0.02 , 0.67]
Subtotal (95% CI)			**301**			**296**	**89.6%**	**-0.05 [-0.26 , 0.17]**
Heterogeneity: Tau² = 0.03; Chi² = 8.19, df = 5 (P = 0.15); I² = 39%								
Test for overall effect: Z = 0.41 (P = 0.68)								
1.6.2 Individually delivered intervention								
Marchioro 1996	41.17	6.91	18	60.28	13.33	18	10.4%	-1.76 [-2.54 , -0.98]
Subtotal (95% CI)			**18**			**18**	**10.4%**	**-1.76 [-2.54 , -0.98]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 4.41 (P < 0.0001)								
Total (95% CI)			**319**			**314**	**100.0%**	**-0.24 [-0.60 , 0.12]**
Heterogeneity: Tau² = 0.16; Chi² = 26.14, df = 6 (P = 0.0002); I² = 77%								
Test for overall effect: Z = 1.33 (P = 0.18)								
Test for subgroup differences: Chi² = 17.11, df = 1 (P < 0.0001), I² = 94.2%								



Analysis 1.7. Comparison 1: CBT versus control, Outcome 7: Overall survival (group delivered intervention)

Study or Subgroup	log[Hazard Ratio]	SE	Experimental Total	Control Total	Weight	Hazard Ratio IV, Random, 95% CI
Andersen 2004	-0.821	0.285	114	113	51.8%	0.44 [0.25 , 0.77]
Kissane 2003	0.315	0.356	154	149	48.2%	1.37 [0.68 , 2.75]
Total (95% CI)			**268**	**262**	**100.0%**	**0.76 [0.25 , 2.32]**
Heterogeneity: Tau² = 0.54; Chi² = 6.21, df = 1 (P = 0.01); I² = 84%						
Test for overall effect: Z = 0.48 (P = 0.63)						
Test for subgroup differences: Not applicable						



ADDITIONAL TABLES

Table 1. Characteristics of studies that reported depression but were not included in the meta-analysis

Study	Tool	Intervention	Sample size	Country	Format of delivery	Dose of intervention	Result	Justification	Quality of study
Beutel 2013	HADs	Brief psychodynamic psychotherapy	N=158 (intervention 78, control 79)	Germany	Group	20 hours	Depression remission in 44% in intervention compared to 23% in control	Only one domain was rated as unclear risk of bias the remaining is low risk of bias	High quality
Dowlatabadi 2016	Beck Depression Inventory	Positive psychotherapy	N= 42 (intervention 21, Control 21)	Iran	Group	15 hours	Decreased depression in intervention from 20.93 ± 6.25 to 14.18 ± 5.47 in intervention compared to 19.23 ± 4.7 to 20.11 ± 5.08 in control	3 domains were rated as high risk of bias	low quality
Ercoli 2015	Beck Depression Inventory	cognitive rehabilitation	N 48= (intervention 32, control 16)	USA	Group	10 hours	both groups reported decrease in depression but not significant between the two arms	3 domains were judged as unclear RoB including random sequence generation	low quality
Wurtzen 2013	Center for Epidemiological Studies-Depression (CES-D) and Symptom Checklist-90-r	mindfulness-based stress reduction	N= 336 (intervention 168, Control 168)	Denmark	Group	16 hours	Depression decreased in the intervention group. participants with higher levels of anxiety and depression at baseline showed a significantly greater decrease in the intervention group	3 domains were judged as unclear RoB including random sequence generation	low quality
Ren 2019	Hamilton Depression Rating Scale (HAMD-17)	CBT intervention	N= 392 (98 CBT intervention, 98 self management intervention, 196 Control)	China	Group	nine sessions for 12 weeks	Depression score in the CBT group was significantly lower compared to that in the SCM and UC groups Besides, the effect of CBT was maintained after its termination (12 weeks).	Two RoB domains are rated as unclear risk	Moderate quality
Charalampopoulou 2020	DASS-21questionnaire	Pythagorean Self-Awareness	N=60 (30 intervention, 30 control)	Greece	Group	18 hours	Statistically significant improvements in favour of the PSAI group was noted for depression	4 unclear RoB domains including allocation concealment	Low quality

Table 1. Characteristics of studies that reported depression but were not included in the meta-analysis *(Continued)*

Antoni 2009	CES-D (Centre for Epidemiology Studies-Depression)	Cognitive-behavioral stress management intervention (CBSM)	N=100 (47 intervention, 53 control)	USA	Group	20 hours	Proportion of women in intervention with moderate depressive symptoms was lower at follow up than at baseline so intervention reduced depression at the clinically meaningful level	4 unclear RoB domains including allocation concealment	Low quality
Badger 2007	20-item Center for Epidemiological Studies Depression Scale (CES-D)	Telephone-delivered psychosocial interventions	N=96 and their partners (38 intervention, 37 control)	USA	Individual couple therapy	3 hours	Depression decreased in both groups (intervention and control)	Two RoB domains were rated as unclear risk	Moderate quality
Kissane 2003	Hospital depression scale	Cognitive-existential	N = 303 (154 intervention, 149 control)	Australia	Group	30 hours	Reductoin in depression in intervention but not significant	2 domains were rated as unclear RoB plus allocation concealment domain is high risk of bias	Low quality
Marcus 2010	Center for epidemiologic studies depression scale	Telephone counselling	N = 304 (152 Intervention, 152 control)	USA	Individual	12 hours	Reduction in depression in intervention but not significant	5 domains were rated as unclear RoB including random allocation and allocation concealment	Low quality
Narvaez 2008	Beck depression Inventory (BDI)	CBT intervention	N = 38 (19 intervention, 19 control)	Spain	Group	13.5 hours	Depression score improved in intervention	0nly one domain was rated as low RoB all the rest are either high or unclear RoB	Low quality
Ferguson 2012	Center for Epidemiological Studies-Depression (CES-D) and Symptom Checklist-90-r	Memory and Attention Adaptation Training (MAAT) is a brief cognitive behav-	N=40 (19 intervention and 21 control)	USA	Individual	2.5 hours	Reduction in depression in intervention but not significant	3 domains were judged as unclear RoB including allocation concealment	Low quality

Table 1. Characteristics of studies that reported depression but were not included in the meta-analysis *(Continued)*

		ioural thera-py (CBT)							

Table 2. Characteristics of studies that reported anxiety but were not included in the meta-analysis

Study	Tool	Intervention	Sample size	Country	Format of delivery	Dose of intervention	anxiety improved but not significant	Justification	Quality of study
Chan 2017	Beck Anxiety Inventory (BAI)	Psychoeducation based on CBT	N= 88 (intervention 45, Control 43)	Singapore	Group	13.5 hours	improved in intervention group	4 domains including allocation concealment were judged as unclear RoB	low
Kim 2018	Hospital Anxiety and Depression Scale	psychological intervention CBT	N= 60 (intervention 30, control 30)	South Korea	Individual	7 hours	Anxiety improved in intervention group	4 domains including allocation concealment were judged as unclear RoB	low
Wurtzen 2013	Symptom Checklist-90-r	mindfulness-based stress reduction	N= 336 (intervention 168, Control 168)	Denmark	Group	16 hours	Anxiety improved in intervention group	3 domains including allocation concealment were rated as unclear risk of bias	low
Charalampopoulou 2020	DASS-21questionnaire	Pythagorean Self-Awareness	N=60 (30 intervention, 30 control)	Greece	Group	18 hours	Anxiety improved in intervention group	4 domains including allocation concealment were judged as unclear RoB	Low
Antoni 2009	Hamilton rating scale for anxiety	Cognitive-behavioral stress management intervention (CBSM)	128 (97 provided data for anxiety measures)	USA	Group	20 hours	Anxiety decreased only in intervention group	3 domains including allocation concealment were rated as unclear risk of bias	low
Badger 2007	Generated anxiety index	telephone interpersonal counselling	96 (outcome measured on 71)	USA	Individual	3 hours	Significant improvement in anxiety in intervention group	Two RoB domains were rated as unclear risk	moderate
Kissane 2003	Hospital anxiety and depression scale	Cognitive-existential	N = 303 (154 intervention, 149 control)	Australia	Group	30 hours	Anxiety score improved in intervention	2 domains were rated as unclear RoB plus allocation concealment domain is high risk of bias	low

Table 2. Characteristics of studies that reported anxiety but were not included in the meta-analysis *(Continued)*

Narvaez 2008	State anxiety scale from the State-Trait Aanxiety Inventory (STAI)	CBT intervention	N = 38 (19 intervention, 19 control)	Spain	Group	13.5 hours	No significant change	0nly one domain was rated as low RoB all the rest are either high or unclear RoB	low
Ferguson 2012	State-Trait Anxiety Inventory STAI	Memory and Attention Adaptation Training (MAAT) is a brief cognitive behavioural therapy (CBT)	N=40 (19 intervention and 21 control)	USA	Individual	2.5 hours	No significant change	3 domains were rated as unclear RoB including allocation concealment	low

Table 3. Characteristics of studies that reported mood disturbances but were not included in the meta-analysis

Study	Tool	Intervention	Sample size	Country	Format of delivery	Dose of intervention	Result	Justification	Quality of study
Antoni 2001	POMS (only three subscales used, anxiety, depression and anger)	Cognitive-behavioral stress management	136 (outcome measured on 100)	USA	Group	20 hours	Reduction in mood disturbance score in intervention but not significant	4 domains were rated as unclear risk of bias	low quality
Classen 2008	POMS total score	Supportive expressive therapy	N = 353	USA	Group	18 hours	Reduction in mood disturbance score in intervention but not significant	2 domains were rated as high risk of bias and 4 as unclear risk of bias	low quality
Kissane 2003	Affective state by affect balance state	Cognitive-existential	N = 303 (154 intervention, 149 control)	Australia	Group	30 hours	Reduction in mood disturbance score in intervention but not significant	2 domains were rated as unclear RoB plus allocation concealment domain is high risk of bias	low quality
Manne 2007	General distress: by Mental Health in-	Couple focused group Social-cog-	N = 238 (120 intervention, 118 usual care)	USA	Couple groups	9 hours	Emotional expression, emotional processing improved in intervention	5 domains were rated as unclear RoB	low quality

Table 3. Characteristics of studies that reported mood disturbances but were not included in the meta-analysis *(Continued)*

	ventory (MHI) and Cancer specific distress: by Impact of Event Scale (IES)	nitive intervention							
Richardson 1997	POMS Brief	standard vs support vs imagery	N = 47 Standard care (15) versus support group (16) versus imagery (16)	USA	Group	6 hours	No difference between intervention and control	3 domains were rated as unclear RoB and one as high RoB	low quality
Vos 2004	POMS	Psychotherapy vs social support vs control	N = 69 completed study at T2 (34 intervention versus 35 control)	Netherlands	Group	30 hours	No difference between intervention and control	5 domains were rated as unclear RoB	low quality
Taylor 2003	POMS	Support group	N = 73 (40 intervention, 33 control)	USA	Group	16 hours	marginally significant Reduction in mood disturbance score	6 domains rated as unclear RoB	Low quality

Table 4. Characteristics of studies that reported QoL but were not included in the meta-analysis

Study	Tool	Intervention	Sample size	Country	Format of delivery	Dose of intervention	Result	Justification	Quality of study
Graves 2003	FACT B	Social cognitive intervention	N = 32 (15 intervention, 17 control)	USA	Group	12 hours	No significant effect on QoL	4 domains rated as unclear RoB and 1 domain as high RoB	low
Richardson 1997	FACT B	standard vs support vs imagery	N = 47 Standard care (15) versus support group (16) versus imagery (16)	USA	Group	6 hours	QoL improved	3 domains were rated as unclear RoB and one as high RoB	low quality
Simpson 2001	QoL index	CBT	N = 89 (46 intervention, 43 control)	Canada	Group	9 hours	QoL improved	5 domains rated as unclear RoB	Low

Table 4. Characteristics of studies that reported QoL but were not included in the meta-analysis *(Continued)*

Boesen	EORTC global Qol	psycho-education	N = 210 (intervention 102, control 103)	Denmark	Group	18 hours	No significant effect on QoL	3 domains rated as unclear RoB	low
Chan 2017	EORTC QLQ-C30 functional scale scores	Psychoeducation-based on CBT	N= 88 (intervention 45, Control 43)	Singapore	Group	13.5 hours	QoL improved in both groups but no significant difference across both arms	4 domains including allocation concealment were judged as unclear RoB	low
Charalampopoulou 2020	FACT-B	Pythagorean Self-Awareness	N=60 (30 intervention, 30 control)	Greece	Group	18 hours	QoL improved in intervention group	4 domains including allocation concealment were judged as unclear RoB	Low

Table 5. Characteristics of studies that included stress but were not included in the meta-analysis

Study	Tool	Intervention	Sample size	Country	Format of delivery	Dose of intervention	Result	Justification	Quality of study
Lengacher 2016	Perceived Stress Scale,	Mindfulness-Based Stress Reduction MBSR	N= 322 (intervention 155, control 167)	USA	Group	12 hours	reduction in stress in the intervention group	5 domains including allocation concealment and random allocation were rated as unclear RoB	low
Charalampopoulou 2020	Perceived Stress Scale	Pythagorean Self-Awareness	N=60 (30 intervention, 30 control)	Greece	Group	18hours	Statistically significant improvements in favour of the PSAI group was noted for stress	4 domains including allocation concealment were rated as unclear RoB	low quality
Andersen 2004	Impact of event scale	Biobehavioural	227 (outcome measured on 199)	USA	Group	27 hours	Stress reduced in women with high initial stress	2 domains were rated as unclear risk of bias	moderate
Cohen 2007	perceived stress	Cognitive behaviour therapy vs relaxation and guided im-	170 agreed to participate and 26 dropped so 114 is the final number	Israel	group	18 hours	Stress was reduced in the intervention group	2 domains were rated as high risk of bias including allocation concealment and random allocation	low quality

Table 5. Characteristics of studies that included stress but were not included in the meta-analysis *(Continued)*

		agery vs control							
Nunes 2007	Inventory of Stress Symptoms Lipp (ISSL)	Relaxation and guided Imagery	N = 34 (20 intervention, 14 control)	Brazil	group	12 hours	Stress was reduced in the intervention group	6 domains were rated as unclear risk of bias	low quality
Taylor 2003	Impact of event scale and mental health inventory	Support group	N = 73 (40 intervention, 33 control)	USA	Group	16 hours	marginally significant	6 domains rated as unclear RoB	Low quality

APPENDICES

Appendix 1. CENTRAL

#1 MeSH descriptor: [Breast Neoplasms] explode all trees
#2 (metastatic or advanced) and (breast cancer or breast neoplasm or breast carcinoma or breast tumour or breast tumor)
#3 #1 not #2
#4 MeSH descriptor: [Psychotherapy] explode all trees
#5 MeSH descriptor: [Psychotherapy, Group] explode all trees
#6 MeSH descriptor: [Social Support] explode all trees
#7 MeSH descriptor: [Cognitive Therapy] explode all trees
#8 MeSH descriptor: [Behavior Therapy] explode all trees
#9 MeSH descriptor: [Cognitive Therapy] explode all trees
#10 MeSH descriptor: [Counseling] explode all trees
#11 psychotherapeutic or CBT or acceptance and commitment therapy or psycho-educational intervention
#12 #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11
#13 #3 and #12

Appendix 2. MEDLINE

# ▲	Searches
1	randomised controlled trial.pt.
2	randomized controlled trial.pt.
3	controlled clinical trial.pt.
4	randomized.ab.
5	randomised.ab.
6	placebo.ab.
7	randomly.ab.
8	trial.ab.
9	groups.ab.
10	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9
11	exp Breast Neoplasms/
12	breast cancer.mp.
13	breast carcinoma.mp.
14	breast tumour.mp.
15	breast tumor.mp.
16	breast neoplasm.mp.
17	11 or 12 or 13 or 14 or 15 or 16

(Continued)

18	exp Psychotherapy/
19	Psychotherapy, Group/
20	exp Social Support/
21	exp Cognitive Therapy/
22	exp Behavior Therapy/
23	exp Counseling/
24	cognitive behavio?ral therapy.mp.
25	cognitive behavio?ral technique.mp.
26	psychotherapeutic.mp.
27	CBT.mp.
28	(acceptance and commitment therapy).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
29	psycho-educational intervention.mp.
30	18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29
31	10 and 17 and 30
32	Animals/
33	Humans/
34	32 not 33
35	31 not 34
36	limit 35 to yr="2008 -Current"

Appendix 3. Embase (via OvidSP)

1	(((random* or factorial* or crossover* or cross) and over*) or placebo* or (doubl* and blind*) or (singl* and blind*) or assign* or allocat* or volunteer* or 'crossover).mp
2	exp breast tumor/
3	exp breast cancer/
4	exp breast carcinoma/
5	breast neoplasm*.mp

(Continued)

6	breast tumour*.mp
7	or/2-6
8	exp psychotherapy/
9	group psychotherapy.mp
10	social support/
11	exp cognitive behavioral therapy/
12	cognitive behavioural therapy.mp
13	exp counseling/
14	psychotherapeutic*.mp
15	CBT.mp
16	psychoeducation/
17	psycho-educational intervention*.mp
18	(acceptance and commitment therapy).mp
19	or/8-18
20	and/1,7,19
21	human/
22	limit 21 to embase
23	20 and 22
24	Limit 23 to yr="2013 -Current"

Appendix 4. PsycINFO

# ▲	Searches
1	exp Clinical Trials/ or randomised controlled trial.mp.
2	randomized controlled trial.mp. or exp Clinical Trials/
3	exp Clinical Trials/ or controlled clinical trial.mp.
4	randomized.ab.
5	randomised.ab.

(Continued)

6	placebo.ab.
7	randomly.ab.
8	trial.ab.
9	groups.ab.
10	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9
11	exp Breast Neoplasms/
12	breast cancer.mp.
13	breast neoplasm.mp.
14	breast carcinoma.mp.
15	breast tumo?r.mp.
16	11 or 12 or 13 or 14 or 15
17	exp Psychotherapy/
18	exp Group Psychotherapy/
19	exp Social Support/
20	exp Cognitive Behavior Therapy/
21	exp Cognitive Therapy/
22	exp Counseling/
23	exp Psychotherapeutic Techniques/
24	psychotherapeutic.mp.
25	CBT.mp.
26	(acceptance and commitment therapy).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
27	exp Psychoeducation/
28	psycho-educational intervention.mp.
29	17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28
30	10 and 16 and 29
31	limit 30 to human

Appendix 5. CINAHL

Search ID#	Search Terms	Search Options
S24	S8 and S15 and S23	Limiters - Exclude MEDLINE records; Human Search modes - Boolean/Phrase
S23	S16 or S17 or S18 or S19 or S20 or S21 or S22	Search modes - Boolean/Phrase
S22	(MH "Counseling+") OR counsel#ing	Search modes - Boolean/Phrase
S21	social AND support	Search modes - Boolean/Phrase
S20	cognitive behavio#r* technique*	Search modes - Boolean/Phrase
S19	(MH "Behavior Therapy+") OR behavio#r* therap*	Search modes - Boolean/Phrase
S18	psychological intervention* OR (MH "Psychology, Educational+") OR (MH "Psychology, Clinical") OR (MH "Psychology, Applied+") OR (MH "Psychological Well-Being") OR (MH "Psychology, Social+") OR (MH "Stress, Psychological+") OR (MH "Psychology+") OR (MH "Psychological Techniques+")	Search modes - Boolean/Phrase
S17	(MH "Psychosocial Care (Saba CCC)+") OR (MH "Rehabilitation, Psychosocial+") OR (MH "Support, Psychosocial+") OR psychosocial intervention*	Search modes - Boolean/Phrase
S16	(MH "Psychotherapy+") OR psychotherapy OR (MH "Psychotherapy, Brief") OR (MH "Psychotherapy, Group+") OR (MH "Cognitive Therapy")	Search modes - Boolean/Phrase
S15	S9 NOT S14	Search modes - Boolean/Phrase
S14	S10 or S11 or S12 or S13	Search modes - Boolean/Phrase
S13	metastatic breast neoplas*	Search modes - Boolean/Phrase
S12	metastatic breast tumo#r*	Search modes - Boolean/Phrase
S11	metastatic breast carcinoma*	Search modes - Boolean/Phrase
S10	metastatic breast cancer*	Search modes - Boolean/Phrase
S9	(MH "Breast Neoplasms+") OR (MH "Carcinoma, Ductal, Breast") OR breast cancer*	Search modes - Boolean/Phrase
S8	S1 or S2 or S3 or S4 or S5 or S6 or S7	Search modes - Boolean/Phrase
S7	AB groups	Search modes - Boolean/Phrase
S6	AB trial	Search modes - Boolean/Phrase
S5	AB randomly	Search modes - Boolean/Phrase

(Continued)

S4	AB placebo	Search modes - Boolean/Phrase
S3	AB randomi*	Search modes - Boolean/Phrase
S2	(MH "Clinical Trials+") OR (MH "Clinical Trial Registry") OR (MH "Cochrane Library") OR controlled clinical trial OR (MH "Preventive Trials") OR (MH "Community Trials") OR (MH "Intervention Trials") OR (MH "Nonrandomized Trials") OR (MH "Therapeutic Trials") OR (MH "Case Control Studies+")	Search modes - Boolean/Phrase
S1	(MH "Clinical Trials+") OR (MH "Cochrane Library") OR (MH "Preventive Trials") OR (MH "Community Trials") OR (MH "Intervention Trials") OR (MH "Nonrandomized Trials") OR (MH "Therapeutic Trials") OR (MH "Case Control Studies+") OR randomi?ed controlled trial OR (MH "Clinical Trial Registry")	Search modes - Boolean/Phrase

Appendix 6. WHO ICTRP

Basic Searches:

1. breast cancer* NOT metastatic AND psychosocial intervention*
2. breast cancer* NOT advance* AND psychosocial intervention*
3. breast cancer* NOT metastatic AND cognitive behavioural technique*
4. breast cancer* NOT advance* AND cognitive behavioural technique*
5. breast cancer* NOT metastatic AND cognitive behavioral technique*
6. breast cancer* NOT advance* AND cognitive behavioral technique*
7. breast cancer* NOT metastatic AND psychotherap*
8. breast cancer* NOT advance* AND psychotherap*
9. breast cancer* NOT metastatic AND psycho-education* intervention*
10. breast cancer* NOT advance* AND psycho-education*intervention*
11. breast cancer* NOT metastatic AND counselling
12. breast cancer* NOT advance* AND counselling

Advanced Searches:

1. Title: psychological intervention* for women with non-metastatic breast cancer
Recruitment status: ALL

2. Condition: breast cancer* NOT (metastatic OR advance*)
Intervention: psychosocial intervention*
Recruitment status: ALL

3. Condition: breast cancer* NOT (metastatic OR advance*)
Intervention: cognitive behavioural technique*
Recruitment status: ALL

4. Condition: breast cancer* NOT (metastatic OR advance*)
Intervention: cognitive behavioral technique*
Recruitment status: ALL

5. Condition: breast cancer* NOT (metastatic OR advance*)
Intervention: behavioral technique*
Recruitment status: ALL

6. Condition: breast cancer* NOT (metastatic OR advance*)
Intervention: psychotherap*
Recruitment status: ALL

7. Condition: breast cancer* NOT (metastatic OR advance*)
Intervention: psycho-education intervention*

Recruitment status: ALL

8. Condition: breast cancer* NOT (metastatic OR advance*)
Intervention: counselling
Recruitment status: ALL

Appendix 7. ClinicalTrials.gov

Basic Searches:

1. breast cancer* NOT (metastastic OR advance*) AND (psychosocial intervention* OR cognitive behavioural technique*OR cognitive behavioral technique* OR psychotherap* OR psycho-education* intervention* OR counselling)
2. breast cancer* NOT (metastastic OR advance*) AND (cognitive behavioral therapy OR cognitive behavioural therapy)

Advanced Searches:

1. Title: psychological intervention* for women with non-metastatic breast cancer
Recruitment status: All studies
Recruitment: All studies
Study results: All studies
Study type: All studies

2. Condition: breast cancer* NOT (metastastic OR advance*)
Intervention: psychosocial intervention* OR cognitive behavioural technique*OR cognitive behavioral technique* OR psychotherap* OR psycho-education* intervention* OR counselling
Recruitment status: All studies
Recruitment: All studies
Study results: All studies
Study type: All studies

3. Condition: breast cancer* NOT (metastastic OR advance*)
Intervention: cognitive behavioral therapy OR cognitive behavioural therapy
Recruitment status: All studies
Recruitment: All studies
Study results: All studies
Study type: All studies

Appendix 8. CancerLit

1. breast cancer* NOT (metastastic OR advance*) AND (psychosocial intervention* OR cognitive behavioural technique*OR cognitive behavioral technique* OR psychotherap* OR psycho-education* intervention* OR counselling)
2. breast cancer* NOT (metastastic OR advance*) AND (cognitive behavioral therapy OR cognitive behavioural therapy)

Appendix 9. PsycLit

1. breast cancer* NOT (metastastic OR advance*) AND (psychosocial intervention* OR cognitive behavioural technique*OR cognitive behavioral technique* OR psychotherap* OR psycho-education* intervention* OR counselling)
2. breast cancer* NOT (metastastic OR advance*) AND (cognitive behavioral therapy OR cognitive behavioural therapy)

Appendix 10. Iranmedex

1. breast cancer* NOT (metastastic OR advance*) AND (psychosocial intervention* OR cognitive behavioural technique*OR cognitive behavioral technique* OR psychotherap* OR psycho-education* intervention* OR counselling)
2. breast cancer* NOT (metastastic OR advance*) AND (cognitive behavioral therapy OR cognitive behavioural therapy)

Appendix 11. IndMed

1. breast cancer* NOT (metastastic OR advance*) AND (psychosocial intervention* OR cognitive behavioural technique*OR cognitive behavioral technique* OR psychotherap* OR psycho-education* intervention* OR counselling)
2. breast cancer* NOT (metastastic OR advance*) AND (cognitive behavioral therapy OR cognitive behavioural therapy)

Appendix 12. Embase (via Embase.com)

1. random* OR factorial* OR crossover* OR cross AND over* OR placebo* OR (doubl* AND blind*) OR (singl* AND blind*) OR assign* OR allocat* OR volunteer* OR 'crossover
2. 'breast neoplasm'

3. 'breast cancer'/exp OR 'breast cancer'
4. 'breast carcinoma'/exp OR 'breast carcinoma'
5. 'breast tumour'
6. 'breast tumor'/exp OR 'breast tumor'
7. #2 OR #3 OR #4 OR #5 OR #6
8. 'psychotherapy'/exp OR psychotherapy
9. 'group psychotherapy'/exp OR 'group psychotherapy'
10. 'social support'/exp OR 'social support'
11. 'cognitive behavioural therapy'/exp OR 'cognitive behavioural therapy'
12. 'cognitive behavioral therapy'/exp OR 'cognitive behavioral therapy'
13. 'counseling'/exp OR counseling
14. psychotherapeutic
15. cbt
16. 'psycho-educational intervention'
17. 'acceptance and commitment therapy'
18. #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17
19. #1 AND #7 AND #18
20. #19 AND [humans]/lim AND [embase]/lim AND [2008-2013]/py

WHAT'S NEW

Date	Event	Description
16 March 2021	New citation required but conclusions have not changed	32 new studies included, adding 4058 participants
16 March 2021	New search has been performed	Search for new studies performed on 16 March 2021

HISTORY

Protocol first published: Issue 10, 2010
Review first published: Issue 5, 2015

CONTRIBUTIONS OF AUTHORS

Ghufran Jassim (GJ) is responsible for:

- organising the retrieval of papers;
- writing to authors of papers for additional information;
- screening search results; and
- entering any extracted data in RevMan.

Two review authors (GJ), Sally Doherty (SD)) are responsible for:

- screening retrieved papers against inclusion criteria;
- appraising the quality of papers;
- data collection for the review;
- extracting data from papers;
- screening data on unpublished studies;
- designing and writing the review.

David Whitford (DW) is responsible for:

- resolving ambiguities related to screening papers for eligibility;
- designing and writing the review.

Ali Khashan (AK) is responsible for:

- data extraction;
- writing the 'Effects of intervention' section;
- analysis and interpretation of data.

DECLARATIONS OF INTEREST

There are no financial conflicts of interest and the authors declare no association with any parties who may have vested interests in the results of this review.

SOURCES OF SUPPORT

Internal sources

- No sources of support provided

External sources

- No sources of support provided

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Mood disturbance was not determined a priori in the protocol but was added to the review because it was used interchangeably with depression in many studies.

The published protocol stated that the primary outcomes would be (and in this order): QoL, depression and anxiety, stress, distress, coping and adjustment, overall survival and adverse events. However, in the review, and based on the reviewer's comments and in light of the *Cochrane Handbook for Systematic Reviews of Interventions*, a preferable alternative order has been used that divides the outcomes into primary (which are the main psychological outcomes of interest and the sole purpose of this review in the order: depression, anxiety, stress, mood disturbance) and secondary outcomes (which are complementary but not essential: quality of life, coping, adjustment, and survival). The new order of outcomes gives more structure to the description of outcomes and focus on the main objective of this review, which is assessing the main and most prevalent psychological morbidities as primary outcomes.

INDEX TERMS

Medical Subject Headings (MeSH)

Anxiety Disorders [therapy]; *Breast Neoplasms [psychology] [therapy]; Depression [therapy]; *Psychosocial Intervention; Quality of Life; Randomized Controlled Trials as Topic

MeSH check words

Female; Humans