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Mindfulness-based stress reduction for women diagnosed with breast cancer (Review)

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[Intervention Review]

Mindfulness-based stress reduction for women diagnosed with breast cancer

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ABSTRACT

Background

Breast cancer is the most common cancer in women. Diagnosis and treatment may drastically affect quality of life, causing symptoms such as sleep disorders, depression and anxiety. Mindfulness-based stress reduction (MBSR) is a programme that aims to reduce stress by developing mindfulness, meaning a non-judgmental, accepting moment-by-moment awareness. MBSR seems to benefit patients with mood disorders and chronic pain, and it may also benefit women with breast cancer.

Objectives

To assess the effects of mindfulness-based stress reduction (MBSR) in women diagnosed with breast cancer.

Search methods

In April 2018, we conducted a comprehensive electronic search for studies of MBSR in women with breast cancer, in the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, Embase, and two trial registries (World Health Organization's International Clinical Trials Registry Platform (WHO ICTRP) and ClinicalTrials.gov). We also handsearched relevant conference proceedings.

Selection criteria

Randomised clinical trials (RCTs) comparing MBSR versus no intervention in women with breast cancer.

Data collection and analysis

We used standard methodological procedures expected by Cochrane. Using a standardised data form, the review authors extracted data in duplicate on methodological quality, participants, interventions and outcomes of interest (quality of life, fatigue, depression, anxiety, quality of sleep, overall survival and adverse events). For outcomes assessed with the same instrument, we used the mean difference (MD) as a summary statistic for meta-analysis; for those assessed with different instruments, we used the standardised mean difference (SMD). The effect of MBSR was assessed in the short term (end of intervention), medium term (up to 6 months after intervention) and long term (up to 24 months after intervention).

Main results

Fourteen RCTs fulfilled our inclusion criteria, with most studies reporting that they included women with early breast cancer. Ten RCTs involving 1571 participants were eligible for meta-analysis, while four studies involving 185 participants did not report usable results.

Queries to the authors of these four studies were unsuccessful. All studies were at high risk of performance and detection bias since participants could not be blinded, and only 3 of 14 studies were at low risk of selection bias. Eight of 10 studies included in the meta-analysis recruited participants with early breast cancer (the remaining 2 trials did not restrict inclusion to a certain cancer type). Most trials considered only women who had completed cancer treatment.

MBSR may improve quality of life slightly at the end of the intervention (based on low-certainty evidence from three studies with a total of 339 participants) but may result in little to no difference up to 6 months (based on low-certainty evidence from three studies involving 428 participants). Long-term data on quality of life (up to two years after completing MBSR) were available for one study in 97 participants (MD 0.00 on questionnaire FACT-B, 95% CI −5.82 to 5.82; low-certainty evidence).

In the short term, MBSR probably reduces fatigue (SMD −0.50, 95% CI −0.86 to −0.14; moderate-certainty evidence; 5 studies; 693 participants). It also probably slightly reduces anxiety (SMD −0.29, 95% CI −0.50 to −0.08; moderate-certainty evidence; 6 studies; 749 participants), and it reduces depression (SMD −0.54, 95% CI −0.86 to −0.22; high-certainty evidence; 6 studies; 745 participants). It probably slightly improves quality of sleep (SMD −0.38, 95% CI −0.79 to 0.04; moderate-certainty evidence; 4 studies; 475 participants). However, these confidence intervals (except for short-term depression) are compatible with both an improvement and little to no difference.

In the medium term, MBSR probably results in little to no difference in medium-term fatigue (SMD −0.31, 95% CI −0.84 to 0.23; moderate-certainty evidence; 4 studies; 607 participants). The intervention probably slightly reduces anxiety (SMD −0.28, 95% CI −0.49 to −0.07; moderate-certainty evidence; 7 studies; 1094 participants), depression (SMD −0.32, 95% CI −0.58 to −0.06; moderate-certainty evidence; 7 studies; 1097 participants) and slightly improves quality of sleep (SMD −0.27, 95% CI −0.63 to 0.08; moderate-certainty evidence; 4 studies; 654 participants). However, these confidence intervals are compatible with both an improvement and little to no difference.

In the long term, moderate-certainty evidence shows that MBSR probably results in little to no difference in anxiety (SMD −0.09, 95% CI −0.35 to 0.16; 2 studies; 360 participants) or depression (SMD −0.17, 95% CI −0.40 to 0.05; 2 studies; 352 participants). No long-term data were available for fatigue or quality of sleep.

No study reported data on survival or adverse events.

Authors' conclusions

MBSR may improve quality of life slightly at the end of the intervention but may result in little to no difference later on. MBSR probably slightly reduces anxiety, depression and slightly improves quality of sleep at both the end of the intervention and up to six months later. A beneficial effect on fatigue was apparent at the end of the intervention but not up to six months later. Up to two years after the intervention, MBSR probably results in little to no difference in anxiety and depression; there were no data available for fatigue or quality of sleep.

PLAIN LANGUAGE SUMMARY

Mindfulness-based stress reduction for women with breast cancer

What is the aim of this review?

The aim of this Cochrane Review was to determine whether mindfulness-based stress reduction (MBSR) benefits women with breast cancer. Cochrane researchers collected and analysed all relevant studies to answer this question and found 14 studies, most of which included women with early breast cancer.

Key messages

The women's health was monitored at different time points: straight after completing MBSR, up to six months after completing MBSR and up to two years after MBSR.

MBSR may slightly improve quality of life at the end of the intervention but result in little to no difference in women's overall well-being (quality of life) later on. MBSR probably reduces anxiety and depression, and probably improves quality of sleep at both the end of MBSR and up to six months later. Women reported being less tired just after completing MBSR but not up to 6 months later. There was no information available on survival or adverse events.

What was studied in the review?

Women with breast cancer mostly experience diagnosis and treatment as a severe and life-threatening situation that may drastically affect their quality of life, causing symptoms such as sleep disorders, depression, anxiety and fatigue. Previous research shows that MBSR seems to benefit patients with lung cancer, mood disorders or chronic pain, so it may also benefit women with breast cancer.

MBSR is an eight-week programme that aims to reduce stress by developing mindfulness, meaning that one practises moment-by-moment awareness in a non-judgmental and accepting way. We wanted to study whether MBSR benefits women with breast cancer with regard to quality of life, anxiety, depression, fatigue and quality of sleep. We also looked at its influence on survival and adverse events related to cancer therapy.

We searched for studies that compared MBSR versus no treatment, and we studied the results at the end of the intervention, up to six months after the intervention and up to 2 years after the intervention.

What are the main results of this review?

The review authors found 14 relevant studies including mostly women with early breast cancer. Most studies considered women who had completed cancer treatment. We could analyse only the results of 10 studies including 1571 participants; the other four studies did not report (usable) results; queries to the authors were unsuccessful. Of the 10 studies analysed, 6 were from the USA, 3 from Europe, and 1 from China.

The review shows MBSR may improve quality of life slightly at the end of the intervention but may result in little to no difference up to six months or up to two years after completing MBSR. At the end of the intervention, MBSR reduces depression, probably slightly reduces fatigue and anxiety, and probably improves quality of sleep. Up to six months later, MBSR probably slightly reduces anxiety and slightly improves quality of sleep, and it slightly reduces depression. There was a benefit on fatigue at the end of the intervention but not up to six months later. However, for all beneficial effects except for short-term depression, the results we found could be due to chance. Up to two years after the intervention, MBSR probably results in little to no difference in anxiety, depression and quality of life. No long-term data were available for fatigue or quality of sleep. No study reported data on survival or adverse events.

How up-to-date is this review?

The authors searched for studies published up to April 2018.

Summary of findings for the main comparison. MBSR versus usual care for women diagnosed with breast cancer

MBSR versus usual care for women diagnosed with breast cancer

Patient or population: women diagnosed with breast cancer
Setting: medium term
Intervention: MBSR
Comparison: usual care

Outcomes	Anticipated absolute effects* (95% CI)		№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with usual care	Risk with MBSR			
Quality of life	—	—	428 (3 RCTs)	⊕⊕⊙⊙ Low[a,b,c]	Quality of life was assessed in 6 additional studies (including 542 participants). Due to these concerns about missing data, we did not perform a meta-analysis but applied vote counting (see McKenzie 2018): 1 study suggests a beneficial effect of MBSR, while the 2 other studies suggest neither benefit nor harm.
Overall survival	Not reported				
Fatigue assessed with 2 different questionnaires Higher scores represent more fatigue Follow-up: range 3-5 months	The fatigue score in the intervention group was on average 0.31 SDs lower (0.84 lower to 0.23 higher) than in the usual care groups		607 (4 RCTs)	⊕⊕⊕⊙ Moderate[c,d]	As a rule of thumb, an SMD of 0.2 is considered a small effect, 0.5 a moderate effect, and 0.8 a large effect.
Anxiety assessed with 6 different questionnaires Higher scores represent more anxiety Follow-up: range 3-6 months	The anxiety score in the intervention group was on average 0.28 SDs lower (0.49 lower to 0.07 lower) than in the usual care groups		1094 (7 RCTs)	⊕⊕⊕⊙ Moderate[c,e]	As a rule of thumb, an SMD of 0.2 is considered a small effect, 0.5 a moderate effect, and 0.8 a large effect.
Depression assessed with 5 different questionnaires Higher scores represent more depression	The depression score in the intervention group was on average 0.32 SDs lower (0.58 lower to 0.06 lower) than in the usual care groups		1097 (7 RCTs)	⊕⊕⊕⊙ Moderate[c,e]	As a rule of thumb, an SMD of 0.2 is considered a small effect, 0.5 a moderate effect, and 0.8 a large effect.

Follow-up: range 3-6 months				
Quality of sleep assessed with 3 different questionnaires Higher scores represent worse quality of sleep Follow-up: range 3-6 months	The quality of sleep score in the intervention group was on average 0.27 SDs lower (0.63 lower to 0.08 higher) than in the usual care groups	654 (4 RCTs)	⊕⊕⊕⊖ Moderate[c,e]	As a rule of thumb, an SMD of 0.2 is considered a small effect, 0.5 a moderate effect, and 0.8 a large effect.
Adverse events	Not reported			

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparator group and the __relative effect__ of the intervention (and its 95% CI).
CI: confidence interval; **MBSR**: mindfulness-based stress reduction; **RCT**: randomised controlled trial; SD: standard deviation; **SMD**: standardised mean difference.

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.

[a]Data on quality of life measured in six additional studies but no results available for meta-analysis.
[b] Studies were unblinded.
[c]Sample size < 400 (less then the minimum optimal information size (OIS) recommended for continuous outcomes).
[d]95% CI includes both an appreciable benefit and an appreciable harm.
[e]95% CI includes both an effect not relevant to participants and an appreciable benefit.

BACKGROUND

Description of the condition

Breast cancer is the most common cancer in women. There are 1.6 million new cases per year worldwide (Ferlay 2013). Incidence rates vary, with the lowest rates in less developed regions and nearly four-fold higher rates in more developed regions, from 27 per 100,000 in Middle Africa and Eastern Asia to 96 per 100,000 in Western Europe (Ferlay 2013). According to the World Health Organization (WHO), worldwide more than 508,000 women died from breast cancer in 2011 (WHO 2014). In the USA, the American Cancer Society 2014 estimated there would be 232,670 new diagnoses and about 40,000 breast cancer deaths in 2014. The five-year relative survival for women diagnosed with breast cancer in the USA in 2009 was 89.5% (Howlader 2013).

Breast cancer treatment depends on the tumour type and staging, and it consists of local therapy such as surgery and radiation, or of systemic therapy such as chemotherapy, hormone therapy, targeted therapy, or a combination of these treatments. Breast cancer staging (0 to IV) is classified into the following TNM categories: primary tumour, Tx to T4; with or without lymph nodes, Nx to N3b; with or without metastasis, Mx to M1. Stage I is the least advanced, and stage IV the most advanced, whereas 0 stands for non-invasive cancer (National Cancer Institute 2014).

Most women experience breast cancer diagnosis and treatment as a severe and life-threatening situation, and it can drastically affect their quality of life (QoL), causing psychological distress and symptoms such as sleep disorders, depression and anxiety (Faller 2013). German practice guidelines for breast cancer highly recommend providing psychosocial and psycho-oncological supportive care, such as relaxation training and psycho-educational interventions in addition to standard therapy and after treatment (GGPO 2014). There is evidence from several randomised controlled trials (RCTs) showing an improvement in QoL and quality of sleep following the use of mindfulness-based stress reduction (MBSR) practices (Andersen 2013; Hoffman 2012). The most common coexisting symptom of all cancers, including breast cancer, is fatigue due to anaemia, cancer treatments or depression (Matthews 2014; Mitchell 2011; National Cancer Comprehensive Network 2014; Tan 2014).

Description of the intervention

MBSR was developed in the USA in the 1970s by Prof Jon Kabat-Zinn (Kabat-Zinn 1990). MBSR is a programme that reduces stress by developing mindfulness, meaning a non-judgmental, accepting moment-by-moment awareness. The intervention is free of any cultural, religious and ideological factors, but it is associated with the Buddhist origins of mindfulness. The MBSR programme is usually performed in groups of up to 20 participants and consists of eight weekly sessions (two-hour classes) and a one-day retreat (six hours' mindful exercises) between sessions six and seven. Additionally, daily home assignments for about 45 minutes using a mindfulness practice CD are completed throughout the programme. There are three main formal practical exercises: body scan (mindful body perception), gentle yoga exercises and traditional sitting meditation. Furthermore, there is a focus on informal exercises (i.e. mindfulness in the daily routine, in dealing with stress, pain, depression, anxiety or disease). People learn to adapt an alternative lifestyle by repeatedly performing the formal and informal exercises. After completion of the programme, participants are asked to continue with the daily exercise by integrating it into their everyday routine.

Since Kabat-Zinn founded the Center for Mindfulness in Medicine in 1995 and the Mindfulness-Based Stress Reduction Clinic in 1979 at the University of Massachusetts (USA), MBSR has been successfully used in many hospitals and widely practised in complementary medicine, mainly in the field of cancer diseases (Ludwig 2008).

How the intervention might work

Kabat-Zinn's research goals are to integrate mindfulness into medicine (Kabat-Zinn 1990). He mainly focuses on mind-body interactions for healing, clinical applications of mindfulness meditation training for people with chronic pain or stress-related disorders, or both. He acknowledged the importance of the effects of MBSR on the brain and the immune system, and observed how the brain processes emotions, particularly under stress. The effect of this programme is scientifically based on findings in the field of psychology and stress research and has been successfully applied in the healthcare sector and in educational and social facilities worldwide (Hölzel 2011; Meibert 2011). According to Hölzel 2011, there is a relationship between MBSR and changes in grey matter concentration in brain regions that regulate emotion, self-referential processing, learning and memory processes. Several studies indicate the beneficial relationship between stress reduction and QoL associated with simultaneous improvement in the immune system following MBSR practice (Carlson 2013; Hoffman 2012; Lengacher 2009).

Why it is important to do this review

There is an increasing recognition of MBSR interventions as a way to decrease distress and increase psychological health, but more systematic reviews of RCTs are needed to verify these results. This systematic review summarises and meta-analyses the evidence on MBSR in women with breast cancer. We assessed the quality of the evidence in terms of QoL, overall survival (OS), fatigue, depression and quality of sleep. Improvements in early diagnosis and treatment of breast cancer have prolonged survival, but this might also lead to specific psychological issues and problems for long-term breast cancer survivors (Faller 2013; Ploos 2013). Consequently, there has to be more emphasis on the short- and long-term impact on patients' QoL.

OBJECTIVES

To assess the effects of mindfulness-based stress reduction (MBSR) in women diagnosed with breast cancer.

METHODS

Criteria for considering studies for this review

Types of studies

We considered RCTs only.

Types of participants

We included all women (aged 18 years or over) with a confirmed diagnosis of breast cancer. We considered all types of tumours and all stages according to the current TNM categories (primary tumour, Tx to T4; with or without lymph nodes, Nx to N3b; with or without

metastasis, Mx to M1), including women with a diagnosis of early breast cancer and women with a diagnosis of metastatic breast cancer.

Types of interventions

The experimental intervention included MBSR plus anticancer therapy (MBSR was considered relevant both during and after active therapy). Some deviations to the Kabat-Zinn MBSR programme were allowed: not all components described in the Background section needed to be implemented. Studies were eligible when: their intervention did not include a one-day retreat, the participants were offered at least six of the eight foreseen weekly group sessions, and there were fewer requirements for home assignment than in the original programme designed by Kabat-Zinn.

We excluded further types of mindfulness-based therapies such as mindfulness-based cognitive therapy, dialectical behaviour therapy, acceptance and commitment therapy, mindful exercise and mindfulness-based art therapy.

The control intervention was usual care (anticancer therapy alone).

Participants in both groups must have been scheduled to receive identical anticancer and supportive therapy.

If we identified three-arm studies, we included the MBSR and the usual supportive care-arm only, according to the inclusion criteria.

Types of outcome measures

Primary outcomes

- Quality of life (QoL) measured with reliable and validated instruments such as the Functional Assessment of Cancer Therapy-General (FACT-G; King 2014), the 36-item Short Form Health Survey (SF-36; Ware 1992), or disease-specific questionnaires such as the English European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire-Core 30 (QLQ-C30; Lundy 2014).

Secondary outcomes

- Overall survival (OS) defined as the time interval from randomisation until death from any cause or last follow-up; the hazard ratio (HR) was considered to be the most appropriate measure of treatment effect
- Fatigue, if measured with reliable and validated instruments such as the Brief Fatigue Inventory (BFI; Mendoza 1999)
- Anxiety, if measured with reliable and validated instruments such as the Spielberger State-Trait Anxiety Inventory (STAI; Julian 2011)
- Depression, if measured with reliable and validated instruments such as the Centers for Epidemiological Studies - Depression (CES-D; Hann 1999)
- Quality of sleep, if measured with reliable and validated instruments such as the Pittsburgh Sleep Quality Index (PSQI; Buysse 1989)
- Adverse events, classified as Common Terminology Criteria for Adverse Events (CTCAE) grade 3 or higher (CTEP 2014)

Search methods for identification of studies

Electronic searches

We adapted the search strategies as suggested in the *Cochrane Handbook for Systematic Reviews of Interventions* (Lefebvre 2011). We searched the following databases.

- The Cochrane Breast Cancer Group's (CBCG's) Specialised Register (18 February 2015). Details of the search strategies used by the Group for identifying studies and the procedure used to code references are outlined in the Group's module (www.mrw.interscience.wiley.com/cochrane/clabout/articles/BREASTCA/frame.html). We extracted trials with the key words 'breast neoplasms', 'breast near cancer', 'breast near neoplasm', 'breast near carcinoma', 'breast near tumour', 'mind-body therapies', 'body-mind', 'mind-body near', 'mindfulness based stress reduction', 'mindfulness based', 'mbsr', 'meditation', 'relaxation therapy' and 'relaxation* near', and we considered them for inclusion in the review.
- Cochrane Central Register of Controlled Trials (CENTRAL; 2018, Issue 3) in the Cochrane Library (searched 10 April 2018). See Appendix 1 and Appendix 2.
- MEDLINE via OvidSP (2008 to 10 April 2018). For RCTs, we limited the search to results from 2008 onwards to coincide with the years where references had not been uploaded into the CBCG's Specialised Register. See Appendix 3 and Appendix 4.
- Embase (via embase.com; 2008 to 18 February 2015). For RCTs, we limited the search to results from 2008 onwards to coincide with the years where references had not been uploaded into the CBCG's Specialised Register. See Appendix 5.
- The WHO International Clinical Trials Registry Platform (ICTRP) search portal for all prospectively registered and ongoing trials in 10 April 2018 (apps.who.int/trialsearch/Default.aspx). See Appendix 6.
- Clinicaltrials.gov (clinicaltrials.gov/) in 10 April 2018. See Appendix 7.

Searching other resources

We handsearched references of all identified trials, relevant review articles and current treatment guidelines for further literature. We did not contact experts in the field to identify unpublished trials.

We searched the proceedings of relevant conferences of the following societies for the years not included in CENTRAL (from January 2005 to 2017).

- American Society of Clinical Oncology (ASCO).
- European Society for Medical Oncology (ESMO).
- San Antonio Breast Cancer Symposium (SABCS).
- European Congress for Integrative Medicine (ECIM).
- International Research Congress on Integrative Medicine and Health (IRCIMH).

Data collection and analysis

Selection of studies

Two review authors (LS, NS) independently screened the abstracts yielded from the search strategies to assess eligibility for this review. In the case of a disagreement, we obtained the full-text

publication. As we always reached a consensus, we did not need to ask a third review author (MR) to arbitrate (Higgins 2011a).

We documented the study selection process in a flow chart as recommended in the PRISMA statement, showing the total numbers of retrieved references and the number of included and excluded studies (Moher 2009).

We included both full-text and abstract publications if sufficient information was available on study design, characteristics of participants, interventions and outcomes.

Data extraction and management

Two review authors (LS, NS) extracted data as specified in Cochrane guidelines. We contacted authors of particular studies for auxiliary information (Higgins 2011b). We used a standardised data extraction form containing the following items.

- General information: author, title, source, publication date, country, language, duplicate publications.
- Risk of bias: allocation concealment, blinding (participants, personnel, outcome assessors), incomplete outcome data, selective outcome reporting, other sources of bias.
- Study characteristics: trial design, aims, setting and dates, source of participants, inclusion/exclusion criteria, comparability of groups, subgroup analysis, statistical methods, power calculations, treatment cross-overs, compliance with assigned treatment, length of follow-up, time point of randomisation.
- Participant characteristics: underlying disease, stage of disease, histological subtype, additional diagnoses, age, sex, ethnicity, number of participants recruited/allocated/evaluated, participants lost to follow-up; type of treatment (multi-agent chemotherapy (intensity of regimen, number of cycles)), additional radiotherapy.
- Interventions: type, duration and intensity of meditation intervention, usual care, duration of follow-up.
- Outcomes: QoL, OS, fatigue, anxiety, depression, quality of sleep, adverse events.

Assessment of risk of bias in included studies

Two review authors (LS, NS) independently assessed the risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011c).

- Sequence generation.
- Allocation concealment.
- Blinding of participants and personnel.
- Blinding of outcome assessment.
- Incomplete outcome data.
- Selective outcome reporting.
- Other sources of bias.

We made a judgment for every criterion, using one of three categories.

- 'Low risk': if the study adequately fulfils the criterion (i.e. the study is at a low risk of bias for the given criterion).
- 'High risk': if the study does not fulfil the criterion (i.e. the study is at high risk of bias for the given criterion).
- 'Unclear': if the study report does not provide sufficient information to allow for a judgment of 'Yes' or 'No' or if the risk of bias is unknown for one of the criteria listed above.

Measures of treatment effect

For time-to-event outcomes (e.g. OS) we planned to consider HRs if they were available from published data, otherwise we planned to extract HRs according to Parmar 1998 and Tierney 2007. We planned to extract log HRs and corresponding 95% confidence intervals (CI), and, if unavailable, we planned to extract P values and the number of events and calculate the log HR. If neither were reported, we planned to analyse survival curves and extract the number of events and censored participants from these curves. However, no data on overall survival were reported.

For binary outcomes (such as adverse events), we planned to calculate risk ratios (RR) with 95% CIs for each trial. However, no data on adverse events were reported.

If possible, we analysed data from ordinal scales as continuous data (e.g. QoL, fatigue, depression, quality of sleep, anxiety) using mean differences (MD) according to Chapter 7 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). If different scales were used to report questionnaire data, we used standardised mean differences (SMDs) to determine effect sizes. We considered an SMD of 0.2 as a small effect, 0.5 as a moderate effect, and 0.8 as a large effect.

We planned to evaluate baseline and end-of-treatment data, if available, at one month, two months, three months, six months and one year after the end of treatment. Since most studies presented end-of-treatment instead of change data, we analysed the end-of-treatment data (based on the assumption that baseline data are comparable for randomised treatment groups). Change data were presented in an additional sensitivity analysis, if available. We decided post hoc to restrict the analyses to three separate time points.

- Short-term analysis (end of intervention).
- Medium-term analysis (up to 6 months after baseline).
- Long-term analysis (more than 12 months after baseline).

Studies were eligible for pooling in each separate analysis, i.e. up to three time points per study were considered. For each study, the latest measure available for the respective analysis was chosen.

We did not pre-specify whether we preferred to use adjusted or unadjusted outcome data in our data extraction and analyses. If both unadjusted and adjusted data were available, we considered the unadjusted data to avoid including effects based on different adjustment approaches, thus ensuring a uniform approach across studies. This (post hoc) decision was based on the assumption that randomisation makes for balanced groups.

Unit of analysis issues

We did not encounter any unit of analysis issues.

Dealing with missing data

We contacted the original investigators to request missing data. If our queries were unsuccessful and standard deviations (SDs) were missing, we calculated them from standard errors, confidence intervals and t values. In some cases, we were able to extract the

respective SD from another systematic review (Haller 2017). We addressed the potential impact of missing data on the findings of the review in both the Results and Discussion section.

Assessment of heterogeneity

We evaluated heterogeneity of treatment effects using a Chi^2 test with a significance level of $P < 0.1$. We used the I^2 statistic as an approximate guide to interpret the magnitude of heterogeneity (I^2 greater than 30%: moderate heterogeneity, I^2 greater than 75%: considerable heterogeneity; Deeks 2011). Due to a lack of data, we were unable to explore potential causes of heterogeneity by subgroup analysis.

Assessment of reporting biases

In meta-analyses with at least 10 trials, we planned to explore potential publication bias by generating a funnel plot and to statistically test it via linear regression (Sterne 2011). We would have considered a P value of less than 0.1 as being significant for this test. However, we were unable to explore potential publication bias since we did not include at least 10 trials in any meta-analysis. For future updates, we will be aware that funnel plot asymmetry has limitations according to Chapter 10 of the *Cochrane Handbook for Systematic Reviews of Intervention* (Sterne 2011). We considered that study reports may selectively present results; moreover, duplicate publication of results can be difficult to identify, and the availability of study information may be subject to time-lag bias.

Data synthesis

We performed analyses according to Cochrane recommendations and used Review Manager 5 (RevMan 5) for analysis (Deeks 2011; RevMan 2014). Since the studies included were clinically heterogeneous, and the intervention was implemented differently in each study, we decided post hoc to use the random-effects model for meta-analysis. We used the fixed-effect model envisaged in the protocol in a sensitivity analysis for the primary outcome (quality of life) only. We created a 'Summary of findings' table on absolute risks in each group with the help of GRADE (Schuenemann 2011), summarising the evidence for QoL, OS (no data available), fatigue, anxiety, depression, quality of sleep and adverse events (no data available). We decided to present the medium-term data in this 'Summary of findings' table.

During the review, we also decided to apply vote counting to describe the available results in case we were unable to undertake a meta-analysis due to concerns about missing data (McKenzie 2018). For vote counting, we judged an effect as showing benefit if the standardised effect size suggested a beneficial effect and the confidence interval was not compatible with a harmful effect. We judged an effect as showing harm if the standardised effect size suggested a harmful effect and the confidence interval was not compatible with a beneficial effect.

Subgroup analysis and investigation of heterogeneity

We planned to perform subgroup analyses using the following characteristics.

- Age (under 40 years; 40 years and over; under 60 years; 60 years and over).
- Stages (early breast cancer versus metastatic breast cancer).
- Type of breast cancer.
- MBSR during or after active therapy.
- Concomitant therapies (chemotherapy, radiotherapy).

However, due to the paucity of data and an unclear subgroup allocation (see Table 1), we were unable to conduct any of the planned subgroup analyses.

Sensitivity analysis

We considered performing sensitivity analyses using the following characteristics.

- Sequence generation (low versus high risk of bias).
- Fixed-effect modelling.
- Estimations from imputation of missing data.

However, we were unable to conduct the first two sensitivity analyses as planned: we rated no studies as being at high risk of bias with regard to sequence generation and therefore compared studies at low risk with those at unclear risk.

The sensitivity analysis for fixed-effect model was conducted for the primary outcome (quality of life) only, since we decided during the review to use the random-effects model for meta-analysis (see Differences between protocol and review).

In an additional post hoc sensitivity analysis, we checked whether the trials included only data with less than 30% attrition and less than 15 percentage points' difference in missing participants between groups.

If studies presented change data in addition to or instead of end-of-treatment data, we presented the change values in a further post hoc sensitivity analysis. As suggested in Higgins 2018, we calculated change SDs from P values but did not impute them.

RESULTS

Description of studies

Results of the search

Our searches yielded a total of 1233 potentially relevant citations from the electronic searches, and 22 conference proceedings and 7 registered trials. After deduplication, we screened titles and abstracts of 678 records and the full text (or abstract or trial registry entry) of 66 records. Of these, 36 references for 14 trials (presented as 22 full-text publications and 14 abstracts) were eligible for inclusion in this review. We excluded 19 records. We classified one record as a study awaiting classification, since neither a publication nor an abstract was available (Choi 2012). The other 10 records reported ongoing trials (1810 participants). All but two foresee trial completion within two years of the time of writing; the two exceptions did not report a completion date.

The PRISMA flow diagram displays the screening process (Figure 1; Moher 2009).

Figure 1. Study flow diagram.

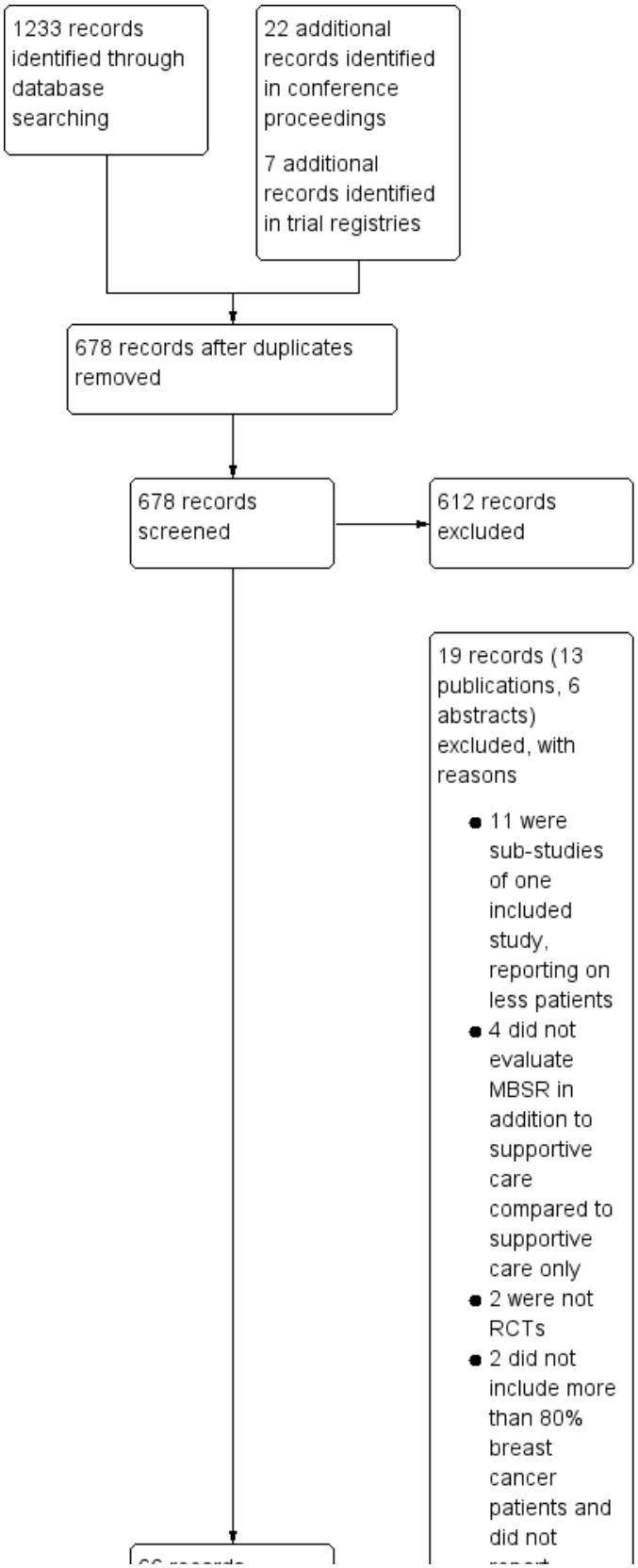
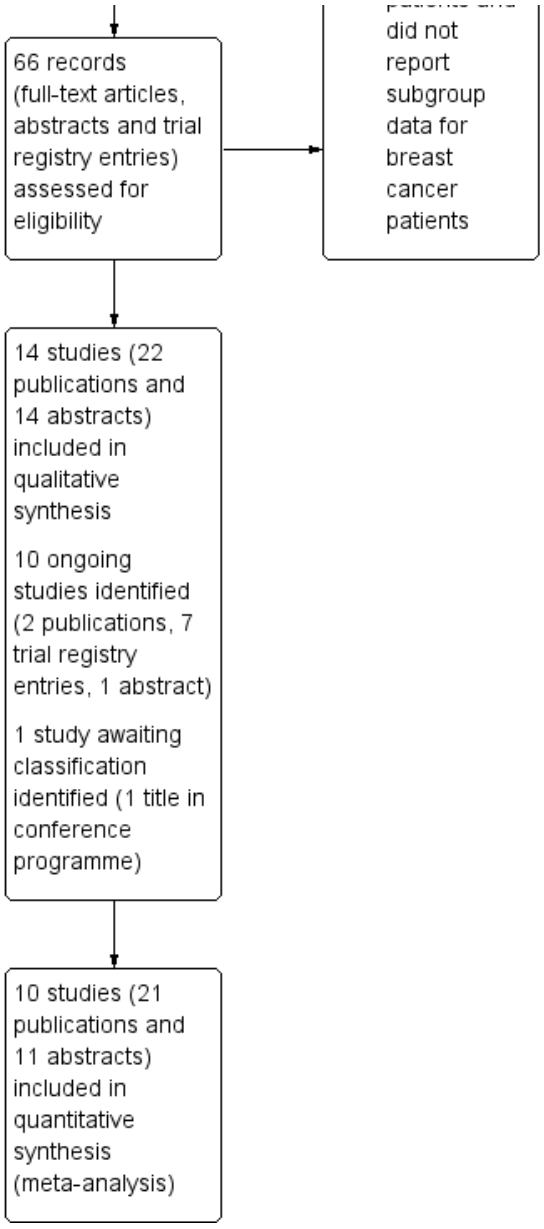


Figure 1. (Continued)



Included studies

Fourteen trials published in 36 publications fulfilled our inclusion criteria. The meta-analysis included 10 studies in 1571 participants (Bower 2015; Henderson 2013; Hoffman 2012; Johns 2014; Kenne 2017; Lengacher 2009; Lengacher 2014; Lerman 2012;Wurtzen 2015; Zhang 2017), while the results of four studies were not amenable to quantitative analysis (Johnson 2015; Koumarianou 2014; Shapiro 2003; Zaidi 2015). Attempts to contact their authors were unsuccessful, so the meta-analyses do not include data from 185 participants. These four studies collected data on quality of life, and one study each additionally measured depression, anxiety and sleep (see Characteristics of included studies).

Of the studies included in the meta-analysis, six took place in the USA and one each in China, Denmark, Sweden and the UK. All studies took place between 2008 and 2014, except for three that did not report the study period. The number of included participants ranged from 35 in Johns 2014 to 336 in Wurtzen 2015. Each study stated the funding source (mostly foundations and independent funders, like the National Institute of Health; see Characteristics of included studies). Further information on these studies appears in the Characteristics of included studies section, and detailed information on the study populations can be found in Table 2.

Participants

Eight of the ten trials included in the meta-analysis recruited participants with non-metastatic breast cancer only (stages ranging from 0 to III). Two trials did not restrict participation to a certain cancer type; however, Lerman 2012 provided separate data for the breast cancer patients, and the proportion of breast cancer patients in Johns 2014 exceeded 80%.

The mean age ranged from 46 years to 59 years (Lengacher 2009 gave percentages only for three age categories).

Participants in six trials were eligible only after completion of cancer treatment, while three trials allowed concurrent treatment – although less than 80% actually received it (Henderson 2013; Wurtzen 2015; Zhang 2017). For Lerman 2012, it was unclear whether participants with concurrent treatment were eligible or not.

Four studies reported mean time since diagnosis, which ranged from seven months to 4.1 years (Bower 2015; Hoffman 2012; Lerman 2012; Wurtzen 2015). Participants included in Henderson 2013 had been diagnosed within the previous two years.

In seven trials, more than two-thirds of participants had received at least some college education. Hoffman 2012 did not report baseline education status; however, almost three-quarters of included participants were graded as the highest social grade 'AB' (higher and intermediate occupational position). More than two-thirds of included participants in Kenne 2017 had received at least some additional education after secondary school. This was in stark contrast to participant education status in Zhang 2017, where a maximum 30% of participants had attended college. It is unclear why most participants included in the studies were highly educated, since no study listed this as an inclusion criterion. Less educated participants may have chosen not to engage in this activity or may have attended other clinics.

Interventions

Four trials implemented the standard MBSR intervention as described in the Description of the intervention (Hoffman 2012; Lerman 2012; Wurtzen 2015; Zhang 2017). The remaining six studies deviated to some degree: Henderson 2013 did not state the target time for home practice, and three additional monthly two-hour sessions were part of the intervention. Bower 2015, Johns 2014, Lengacher 2009 and Lengacher 2014 held fewer than eight classes, did not offer a one-day retreat and required shorter home practice. Kenne 2017 also did not include a one-day retreat and envisaged shorter home practice.

Outcomes

Primary outcome measure

Quality of life

Nine studies assessed short-term quality of life (Hoffman 2012; Johns 2014; Johnson 2015; Koumarianou 2014; Lengacher 2009; Lengacher 2014; Lerman 2012; Shapiro 2003; Zaidi 2015). The questionnaires used were SF-36, FACT-B and EORTC (QLQ-C30 and BR23). However, only data from three studies with 339 participants were available for meta-analysis (Hoffman 2012; Lengacher 2009; Lerman 2012; see Effects of interventions).

Eight studies assessed medium-term quality of life (Henderson 2013; Hoffman 2012; Johns 2014; Johnson 2015; Kenne 2017; Lengacher 2014; Shapiro 2003; Zaidi 2015). The questionnaires used were SF-36 and FACT-B. However, only data from three studies with 428 participants were available for meta-analysis (Henderson 2013; Hoffman 2012; Kenne 2017; see Effects of interventions).

Henderson 2013 provided long-term data (FACT-B) at 24 months from baseline.

Secondary outcome measures

Overall survival

None of the trials reported overall survival.

Fatigue

For the short-term analysis, data from five studies were available for meta-analysis (Bower 2015; Hoffman 2012; Johns 2014; Lengacher 2009; Lengacher 2014). The questionnaires used were FSI (subscale severity or not reported), POMS (domain fatigue/inertia) and the revised Symptom Checklist (SCL)-90-R (subscale fatigue). Trialists reported the results either at the end of the intervention or at 8 to 12 weeks from baseline (Table 3).

Four studies using two different questionnaires (FSI (subscale severity) and POMS (domain fatigue/inertia)) were included in the medium-term analysis (Bower 2015; Hoffman 2012; Johns 2014; Lengacher 2014). The results were reported at one to three months after the intervention (Table 3).

No long-term data were available for fatigue.

Anxiety

For the short-term analysis, data from six studies were available for meta-analysis (Hoffman 2012; Johns 2014; Lengacher 2009; Lengacher 2014; Lerman 2012; Zhang 2017). The trials used four different questionnaires: General Anxiety Disorder 7 (GAD-7), POMS (subcale tension/anxiety), SCL-90-R (subscale anxiety) and STAI (state scale), reporting results either at the end of the intervention or at 8 to 12 weeks from baseline (Table 3).

The medium-term analysis included seven studies (Henderson 2013; Hoffman 2012; Johns 2014; Kenne 2017; Lengacher 2014; Wurtzen 2015; Zhang 2017). They used six different questionnaires: the Beck Anxiety Inventory (BAI), GAD-7, the Hospital Anxiety and Depression Scale (HADS; dimension anxiety), POMS (subcale tension/anxiety), STAI (state scale) and SCL-90-R (subscale anxiety), reporting results at three to six months from baseline (Table 3).

Henderson 2013 (BAI at 24 months from baseline) and Wurtzen 2015 (SCL-90-R (subscale anxiety) at 12 months from baseline) provided long-term data.

Depression

For the short-term analysis, data from six studies were available for meta-analysis (Bower 2015; Hoffman 2012; Johns 2014; Lengacher 2009; Lengacher 2014; Lerman 2012). They used four different questionnaires: CES-D, the Personal Health Questionnaire Depression Scale (PHQ-8), POMS (subscale depression/dejection) and SCL-90-R (subscale depression). The results were reported either at the end of the intervention or at 8 to 12 weeks from baseline (Table 3).

Seven studies were included in the medium-term analysis (Bower 2015; Henderson 2013; Hoffman 2012; Johns 2014; Kenne 2017; Lengacher 2014; Wurtzen 2015), using six different questionnaires: the Beck Depression Inventory (BDI), CES-D, HADS (dimension depression), POMS (subcale depression/dejection), PHQ-8 and SCL-90-R (subscale depression). The results were reported between three and six months from baseline (Table 3).

Henderson 2013 (BDI at 24 months from baseline) and Wurtzen 2015 (CES-D at 12 months from baseline) provided long-term data.

Quality of sleep

For the short-term analysis, data from four studies were available for meta-analysis (Bower 2015; Johns 2014; Lengacher 2009; Lengacher 2014). The questionnaires used were the Insomnia Severity Index (ISI), PSQI and SCL-90-R (subscale disturbed sleep). The results were reported at the end of the intervention (Table 3).

Four studies were included in the medium-term analysis (Bower 2015; Johns 2014; Lengacher 2014; Wurtzen 2015). Three different questionnaires were used (ISI, Medical Outcomes Study Sleep Scale (MOSS; sleep problem index II) and PSQI), and the results were reported at three to six months from baseline.

No long-term data were available for quality of sleep.

Adverse events

None of the trials reported adverse events.

Conflicts of interest

For all studies included, the authors indicated no potential conflicts of interest.

Excluded studies

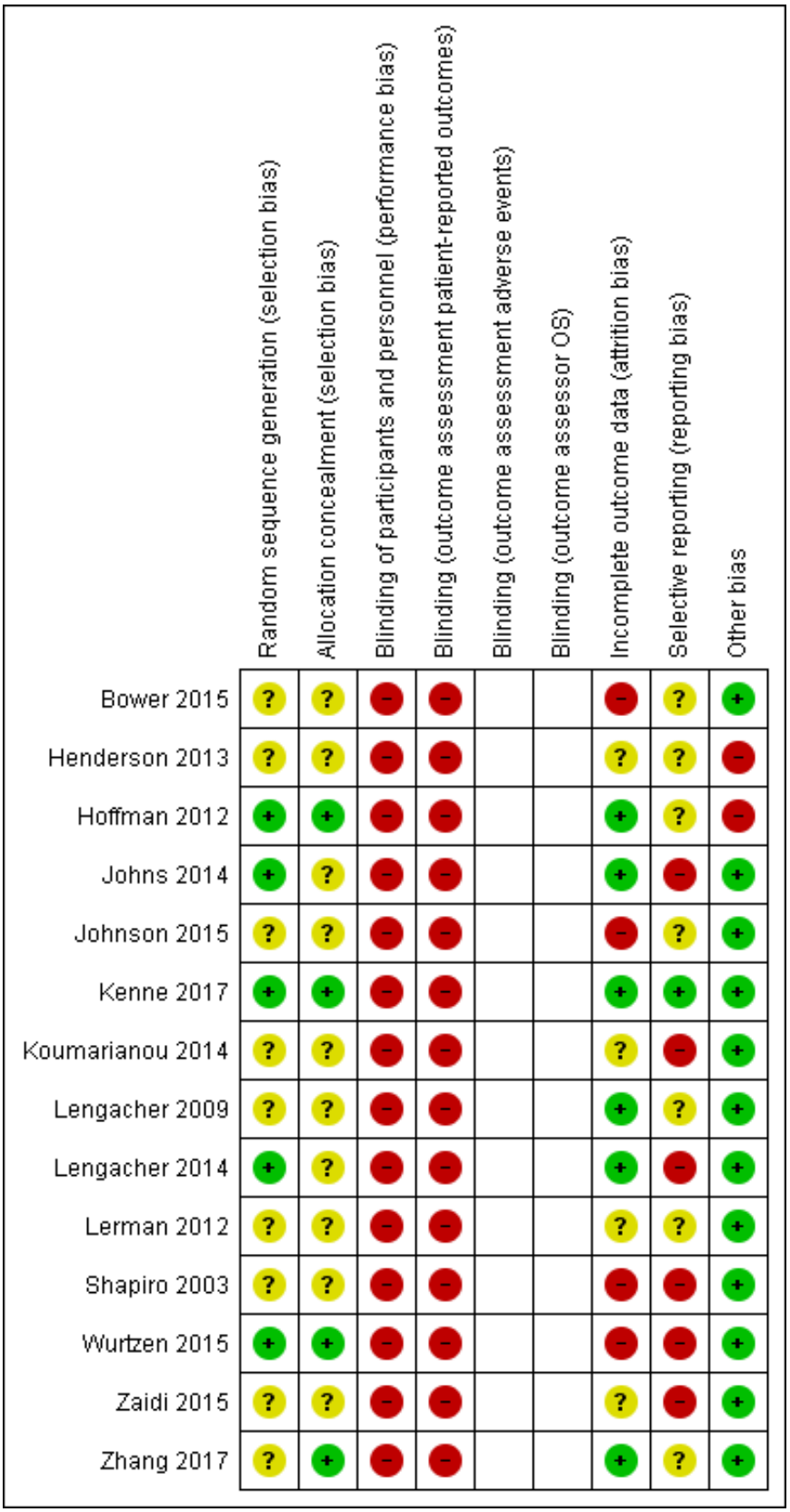
We excluded eight studies. Lengacher 2012 reported sub-studies of an included trial, Lengacher 2014, describing considerably fewer participants than in the parent study. The studies by Carlson 2013 and Carlson 2015 were excluded since the control intervention consisted of a one-day stress management course and therefore does not correspond to our control intervention. Less than 80% of participants in Branstrom 2012 had breast cancer. The study author of Carmody 2011 clarified that a history of breast cancer was an exclusion criterion for that trial. Two studies by Rhamani were excluded since they were both described as quasi-experimental and as randomised and we therefore judged them as non-randomised (Rahmani 2014; Rahmani 2015). Finally, we excluded Johannsen 2016 because the study investigated the effects of a mindfulness-based cognitive therapy, which does not correspond to our intervention.

Risk of bias in included studies

Allocation

Three studies were at low risk of selection bias (Hoffman 2012; Kenne 2017; Wurtzen 2015). Two studies reported adequate methods of sequence generation but did not report allocation concealment in sufficient detail (Johns 2014; Lengacher 2014). For Zhang 2017, the information on sequence generation was deemed insufficient, but allocation concealment was judged to be adequate. Eight studies did not report methods of sequence generation or allocation concealment in sufficient detail (Bower 2015; Henderson 2013; Johnson 2015; Koumarianou 2014; Lengacher 2009; Lerman 2012; Shapiro 2003; Zaidi 2015). For a summarised presentation see Figure 2.

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



Blinding

In the context of the studies included, participants could not be blinded. Since the only data available were patient-reported outcomes, we considered all studies to be at high risk of performance and detection bias. For a summarised presentation see Figure 2.

Incomplete outcome data

The risk of attrition bias was low in six studies (Hoffman 2012; Johns 2014; Kenne 2017; Lengacher 2009; Lengacher 2014; Zhang 2017), and it was high in four (Bower 2015; Johnson 2015; Shapiro 2003; Wurtzen 2015). The remaining five studies did not adequately describe loss to follow-up and were at unclear risk of bias (Henderson 2013; Koumarianou 2014; Lerman 2012; Zaidi 2015). For a summarised presentation see Figure 2.

Selective reporting

When studies did not have publications on study design or study protocols available, we rated them as being at unclear risk of bias unless we observed outcome discrepancies between the Methods and Results sections. The risk of reporting bias was low in Kenne 2017 because reported outcomes were consistent with a publication on study design. It was high in six studies, since results were not usable for meta-analysis (Johns 2014; Koumarianou 2014; Lengacher 2014; Shapiro 2003; Wurtzen 2015; Zaidi 2015). For a summarised presentation see Figure 2.

Other potential sources of bias

Two studies were at risk of other potential biases: In addition to the standard MBSR intervention, participants in Henderson 2013 received three monthly two-hour sessions following completion of the MBSR. Participants in Hoffman 2012 received an average of 30 hours of 'The London Haven' support before study entry. For a summarised presentation see Figure 2.

Effects of interventions

See: **Summary of findings for the main comparison** MBSR versus usual care for women diagnosed with breast cancer

Unless specified otherwise, results from all sensitivity analyses (see Sensitivity analysis) yielded the same results as the standard data analysis.

Ten studies in 1571 participants were included in the meta-analysis (Bower 2015; Henderson 2013; Hoffman 2012; Johns 2014; Kenne 2017; Lengacher 2009; Lengacher 2014; Lerman 2012; Wurtzen 2015; Zhang 2017), while four studies collected data on quality of life but either presented no results or did not report results usable for quantitative analysis (Johnson 2015; Koumarianou 2014; Shapiro 2003; Zaidi 2015). These four studies included 185 participants (see Characteristics of included studies).

Quality of life

Short-term results (end of intervention)

Three studies reporting data from 339 participants provided results for short-term quality of life (Hoffman 2012; Lengacher 2009; Lerman 2012). Johns 2014 and Lengacher 2014 (357 total participants) also assessed this outcome but only partially reported results, while Johnson 2015, Koumarianou 2014, Shapiro 2003 and Zaidi 2015 assessed the outcome but either did not report results or presented results in a way not usable for quantitative analysis (see Characteristics of included studies). These four studies would have contributed another 185 additional participants to the meta-analysis. The potential impact of these missing results is unclear. Due to these concerns about missing data, we did not perform a meta-analysis but chose to apply vote counting: all three studies suggest a beneficial effect of MBSR. The corresponding results are reported in the Data and analyses section (Analysis 1.1; higher values correspond to higher quality of life (improvement)). Due to the missing data (suggesting potential publication bias) and imprecision, we judged the certainty of the evidence to be low. The result is confirmed by the analysis of change data (Analysis 14.1).

Medium-term results (up to six months after baseline)

Three studies reporting data from 428 participants provided results for medium-term quality of life (Henderson 2013; Hoffman 2012; Kenne 2017). Johns 2014 and Lengacher 2014 (total 357 participants) also assessed medium-term quality of life but only partially reported it. Johnson 2015, Shapiro 2003 and Zaidi 2015 assessed the outcome but either did not report results or presented results in a way that was not usable for quantitative analysis (see Characteristics of included studies). These three studies would have contributed another 120 additional participants to the meta-analysis. The potential impact of these missing results is unclear. Due to these concerns about missing data, we did not perform a meta-analysis but chose to apply vote counting (see McKenzie 2018): one study suggests a beneficial effect of MBSR, while the two other studies suggest neither benefit nor harm. The corresponding results are reported in the Data and analyses section (Analysis 2.1; higher values correspond to higher quality of life (improvement)). Due to the missing data (suggesting potential publication bias) and imprecision, we judged the certainty of the evidence to be low.

Long-term results (more than 12 months after baseline)

Neither Johns 2014, Lengacher 2014 nor the four studies not reporting usable data on quality of life followed participants in the long term (Johnson 2015; Koumarianou 2014; Shapiro 2003; Zaidi 2015; see Characteristics of included studies). Thus, no long-term data on quality of life are available. The evidence suggests that MBSR does not improve long-term quality of life (MD 0.00 on questionnaire FACT-B, 95% CI −5.82 to 5.82; 1 study; 97 participants; Analysis 3.1; higher values correspond to higher quality of life (improvement)); we rated the certainty of the evidence as low due to imprecision.

Overall survival

None of the trials reported overall survival.

Fatigue

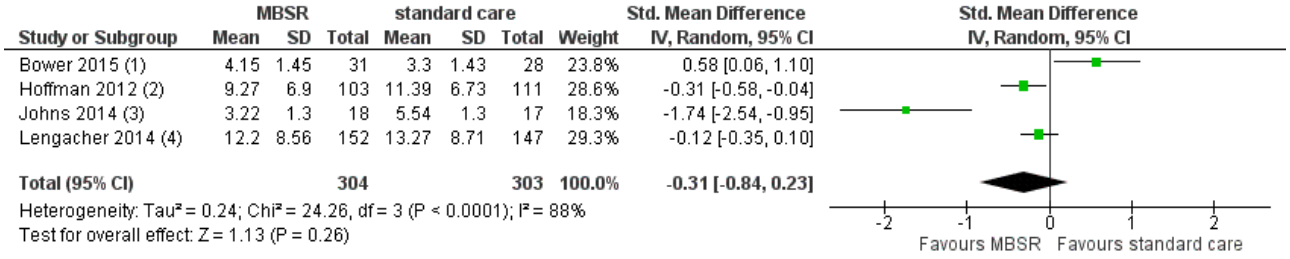
Short-term results (end of intervention)

MBSR probably reduces short-term fatigue (SMD −0.50, 95% CI −0.86 to −0.14; Analysis 1.2; higher values correspond to more fatigue (deterioration)). However, the confidence interval is compatible with both an improvement and little to no difference. This was based on five studies including 693 participants (moderate-certainty data due to imprecision).

Medium-term results (up to 6 months after baseline)

When looking at the medium-term data on fatigue, MBSR probably results in little to no difference (SMD −0.31, 95% CI −0.84 to 0.23; Figure 3; Analysis 2.2; higher values correspond to more fatigue (deterioration)). The confidence interval is compatible with both an improvement and a deterioration in fatigue. This was based on moderate-certainty data from four studies including 607 participants (see Summary of findings for the main comparison). A sensitivity analysis including only studies at low risk of bias with regard to sequence generation suggested a moderate beneficial effect but did not rule out that MBSR results in little to no difference (SMD −0.56, 95% CI −1.10 to −0.01; Analysis 5.2).

Figure 3. Forest plot of comparison: 2 MBSR vs standard care (medium-term), outcome: 2.2 fatigue.



Footnotes
(1) FSI (subscale severity) at 3 months after intervention; SDs from Haller 2017
(2) POMS (domain fatigue/inertia) at week 12 to 14 from baseline
(3) FSI (subscale severity) at 1 month after intervention (rated on 0-10 scale according to publication); SD calculated in RevMan
(4) FSI (subscale severity) at week 12 from baseline

Long-term results (more than 12 months after baseline)

No long-term data were available for fatigue.

Anxiety

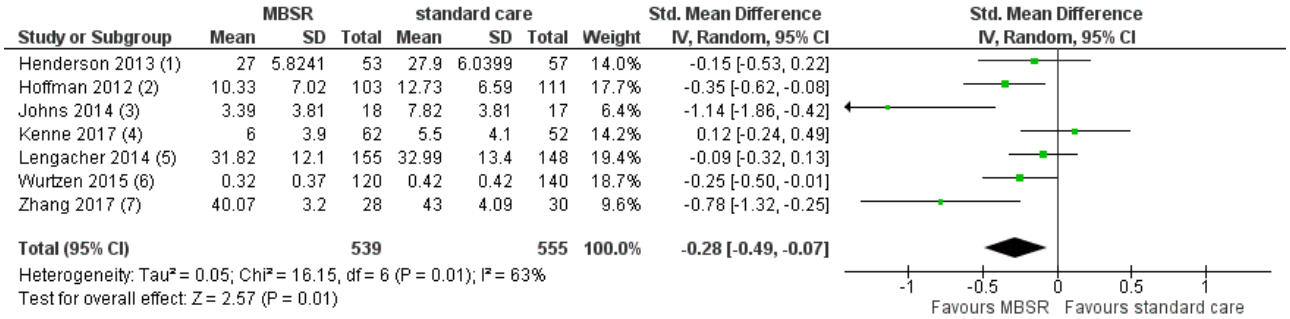
Short-term results (end of intervention)

In the short-term, MBSR probably reduces anxiety slightly (SMD −0.29, 95% CI −0.50 to −0.08, see Analysis 1.3; higher values correspond to more anxiety (deterioration)). However, the confidence interval is compatible with both a slight improvement and little to no difference. This was based on moderate-certainty data due to imprecision (six studies with 749 participants). In contrast, the analysis of change data (based on a single study) suggests MBSR results in little to no difference (Analysis 14.2).

Medium-term results (up to 6 months after baseline)

When looking at the medium-term data, MBSR probably reduces anxiety slightly (SMD −0.28, 95% CI −0.49 to −0.07; Figure 4; Analysis 2.3; higher values correspond to more anxiety (deterioration)). However, the confidence interval is compatible with both a slight improvement and little to no difference. This was based on moderate-certainty data from seven studies in 1094 participants (see Summary of findings for the main comparison).

Figure 4. Forest plot of comparison: 2 MBSR vs standard care (medium-term), outcome: 2.3 anxiety.



Footnotes
(1) BAI at 4 months from baseline; SD calculated in RevMan
(2) POMS (subcale tension/anxiety) at weeks 12 to 14 from baseline
(3) GAD-7 at 1 month after intervention; SD calculated in RevMan
(4) HADS (dimension anxiety) at 1 month after invention
(5) STAI (state subscale) at week 12 from baseline
(6) SCL-90-R subscale anxiety at 6 months from baseline; SD from Haller 2017
(7) STAI (state subscale) at 3 months after intervention

Long-term results (more than 12 months after baseline)

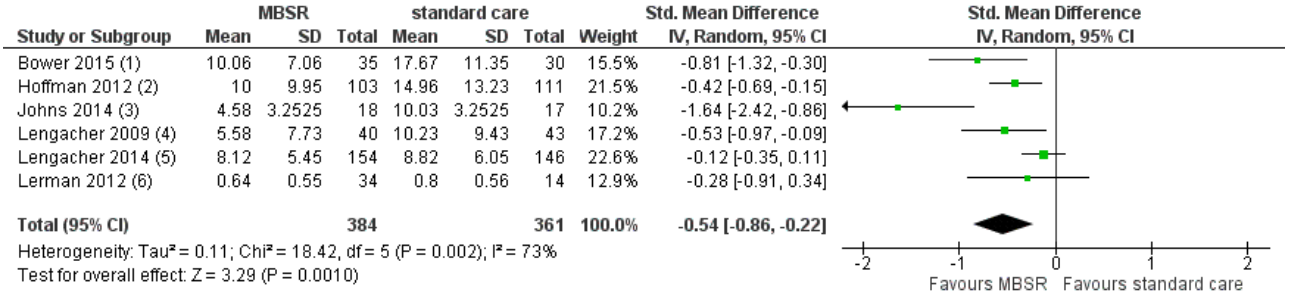
The long-term analysis suggests that MBSR probably results in little to no difference in anxiety (SMD −0.09, 95% CI −0.35 to 0.16; see Analysis 3.2; higher values correspond to more anxiety (deterioration)). However, the confidence interval is compatible with both a slight improvement and little to no difference. This was based on moderate-certainty data due to imprecision (two studies with 360 participants). In contrast, the analysis of change data based on a single study suggests that MBSR results in little to no difference in long-term anxiety (Analysis 15.1).

Depression

Short-term results (end of intervention)

MBSR reduces short-term depression (SMD −0.54, 95% CI −0.86 to −0.22; Figure 5 Analysis 1.4; higher values correspond to more depression (deterioration)). This was based on high-certainty data from six studies with 745 participants. The result is confirmed by the analysis of change data based on a single study (Analysis 14.3). Sensitivity analyses including only studiesat low risk of bias for sequence generation (SMD −0.57, 95% CI −1.11 to −0.04; see Analysis 4.4) and including only studies that did not use imputation for missing data (SMD −0.60, 95% CI −1.05 to −0.16; Analysis 11.4) did not conclusively rule out that MBSR makes little to no difference to short-term depression.

Figure 5. Forest plot of comparison: 1 MBSR vs standard care (short-term), outcome: 1.4 depression.

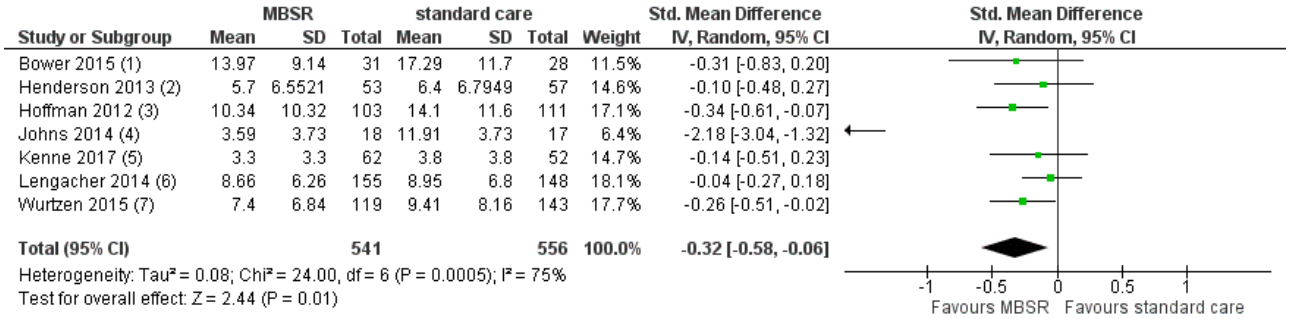


Footnotes
(1) CES-D at end of intervention
(2) POMS (subcale depression/dejection) at week 8 to 12 from baseline
(3) PHQ-8 at end of intervention; SD calculated in RevMan
(4) CES-D at end of intervention; data provided by the authors upon request
(5) CES-D at end of intervention
(6) SCL-90 (subscale depression) at end of intervention; data provided by the authors upon request

Medium-term results (up to 6 months after baseline)

When looking at the medium-term data, MBSR probably reduces depression slightly (SMD −0.32, 95% CI −0.58 to −0.06; Figure 6 Analysis 2.4; higher values correspond to more depression (deterioration)). However, the confidence interval is compatible with both an improvement and little to no difference. This was based on moderate-certainty data from seven studies with 1097 participants (see Summary of findings for the main comparison). A sensitivity analysis combining studies with an unclear risk of bias due to sequence generation suggested that MBSR may make little to no difference in depression, but it did not rule out a slight improvement (SMD −0.18, 95% CI −0.48 to 0.13; see Analysis 8.4).

Figure 6. Forest plot of comparison: 2 MBSR vs standard care (medium-term), outcome: 2.4 depression.



Footnotes
(1) CES-D at 3 months after intervention
(2) BDI at 4 months from baseline; SD calculated in RevMan
(3) POMS (subcale depression/dejection) at weeks 12 to 14 from baseline
(4) PHQ-8 at 1 month after intervention; SD calculated in RevMan
(5) HADS (dimension depression) 1 month after intervention
(6) CES-D at week 12 from baseline
(7) CES-D at 6 months from baseline; SDs from Haller 2017

Long-term results (more than 12 months after baseline)

The long-term analysis suggests that MBSR probably results in little to no difference in depression (SMD −0.17, 95% CI −0.40 to 0.05; Analysis 3.3; higher values correspond to more depression (deterioration)). However, the confidence interval is compatible with both a slight improvement and little to no difference. We rated the evidence as being of moderate certainty due to imprecision (2 studies with 352 participants). The result is confirmed by the analysis of change data based on a single study (Analysis 15.2).

Quality of sleep

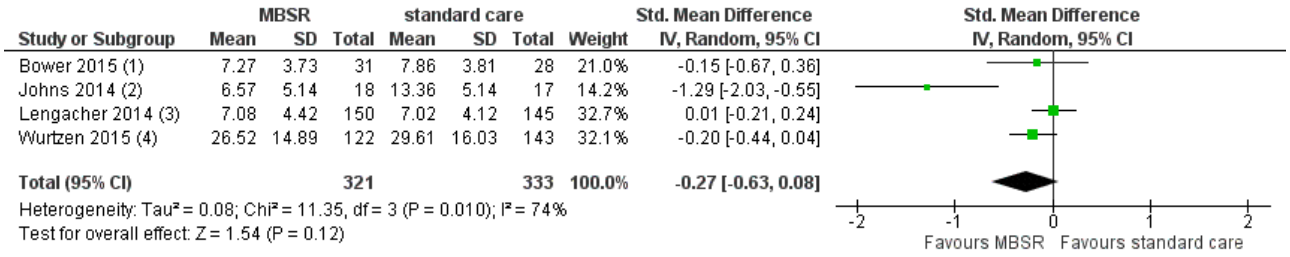
Short-term results (end of intervention)

In the short-term, MBSR probably slightly increases quality of sleep (SMD −0.38, 95% CI −0.79 to 0.04; see Analysis 1.5; higher values correspond to lower quality of sleep (deterioration)). However, the confidence interval is compatible with both a slight improvement and little to no difference. This was based on moderate certainty data due to imprecision (four studies with 475 participants). The result is confirmed by the analysis of change data based on a single study (Analysis 14.4). A sensitivity analysis including two studies at low risk of bias for sequence generation suggested that MBSR may make little to no difference in quality of sleep (SMD −0.57, 95% CI −1.66 to 0.53; see Analysis 4.5).

Medium-term results (up to 6 months after baseline)

When looking at the medium-term data, MBSR probably slightly increases quality of sleep (SMD −0.27, 95% CI −0.63 to 0.08, see Figure 7 and Analysis 2.5; higher values correspond to lower quality of sleep (deterioration)). However, the confidence interval is compatible with both an improvement and little to no difference. This was based on moderate-certainty data from four studies with 654 participants (see Summary of findings for the main comparison).

Figure 7. Forest plot of comparison: 2 MBSR vs standard care (medium-term), outcome: 2.5 quality of sleep.



Footnotes
(1) PSQI at 3 months after intervention; SDs from Haller 2017
(2) ISI at 1 month after intervention; SD calculated in RevMan
(3) PSQI at week 12 from baseline
(4) MOSS (sleep problem index II) at 6 months from baseline; SDs from Haller 2017 (query to authors unsuccessful)

Long-term results (more than 12 months after baseline)

No long-term data were available for quality of sleep.

Adverse events

None of the trials reported adverse events.

DISCUSSION

Summary of main results

MBSR may improve quality of life slightly in the short term but may result in little to no difference later on (medium-term and long-term analysis). We found evidence that MBSR probably reduces both short-term and medium-term anxiety, depression and short-term fatigue, and that it probably improves quality of sleep (moderate-certainty evidence). However, the confidence intervals are compatible with both an improvement and little to no difference (except for short-term depression). In the long term, MBSR probably results in little to no difference in anxiety and depression (moderate-certainty evidence). No study reported data on survival or adverse events.

Overall completeness and applicability of evidence

Of a total of 14 included studies, 4 did not report results usable for quantitative analysis (queries to authors were unsuccessful). These four studies would have contributed 185 additional participants to the meta-analysis (1571 were actually included). All of these studies assessed quality of life, while one study (Koumarianou 2014) additionally assessed sleep and another study additionally assessed depression and anxiety (Shapiro 2003). The potential impact of these missing results on the meta-analysis - especially for quality of life - is unclear.

The trials included in this review were carried out in the USA, Europe and China. Only four trials implemented the standard MBSR intervention as envisaged by Kabat-Zinn (see Description of the intervention), while the remaining six studies deviated to some degree, for example by not offering a one-day retreat. All trials included participants with early breast cancer and most participants received at least some college education. We found no studies investigating participants receiving both MBSR and concurrent treatment.

The results of this review are applicable to different MBSR practices. However, the participants included in the studies were quite homogeneous. Thus, it is uncertain whether the results of this review can be applied to patients with metastatic breast cancer, patients receiving concurrent therapy other than endocrine therapy or patients with lower education status.

We found no data on serious adverse events, making it difficult to balance the benefits and harms for MBSR. In addition, no survival data have yet been published. However, survival data for Kenne 2017 are expected in 2019.

Baseline data on additional psychological therapies or medication were reported only for some studies. Thus, we could not evaluate a potential co-intervention bias.

Quality of the evidence

All studies were at high risk of performance and detection bias, since participants could not be blinded. We rated only 3 of 14 studies as being at low risk of selection bias. Six studies were at high risk of reporting bias.

Using the GRADE methodology, the certainty of evidence for all outcomes (except for short-term depression and quality of life) was moderate due to imprecision. For short-term depression, the data were of high certainty. The certainty of short-term and medium-term quality of life was low due to imprecision and risk of bias (publication bias). For long-term quality of life, we judged the certainty of the evidence as low due to serious imprecision.

Potential biases in the review process

We did not analyse publication bias using funnel plots because no comparison had the required minimum of 10 studies. Although we carried out extensive searches for studies and contacted authors of identified studies to obtain unpublished information as well as to clarify published data, we cannot rule out the possibility of publication bias.

During the review, we decided to analyse the data in three separate comparisons (short-, medium- and long-term data). Since all studies differed in the time points reported and due to concerns about multiplicity issues, we believe this approach was appropriate. However, the cutoffs for analysis could have been chosen differently, for instance by defining short-term data as 'one month after intervention' instead of 'end of intervention'. Different time cutoffs might lead to different results.

If trials used different scales to report questionnaire data, we used standardised mean differences (SMD) to determine effect sizes. However, there is some uncertainty whether cutoffs (low, medium, high effect) correspond directly to clinical effects or whether this relation is less pronounced (Leucht 2012).

Agreements and disagreements with other studies or reviews

Three current systematic reviews have evaluated the effect of MBSR on women with breast cancer.

A 2017 review by Haller 2017 included 10 studies, 2 of which were not considered relevant for this review (Johannsen 2016 applied mindfulness-based cognitive therapy, and Carlson 2013 compared MBSR with a stress-management day). The present Cochrane Review additionally included Johns 2014 and Kenne 2017. Haller 2017 also analysed short-, medium- and long-term data but used different time cutoffs for short-term data (closest to 2 months after the start of the intervention) and long-term data (closest to 12 months after the start of the intervention). They report significant effects for short-term quality of life and for long-term anxiety but not for medium-term fatigue or quality of sleep. The average effects were all below the threshold of minimal clinically important differences.

Huang 2016a considered non-randomised studies as well as RCTs and did not conduct separate analyses per follow-up interval. Analysing eight studies quantitatively, the authors found significant improvements for depression, anxiety and quality of life. The authors did not state whether effects were below or above minimal clinically important differences.

A 2016 review by Zhang 2016 included seven studies and did not conduct separate analyses per follow-up interval. The authors found positive effects of MBSR for anxiety, depression and fatigue. The authors did not state whether the effects were below or above minimal clinically important differences.

AUTHORS' CONCLUSIONS

Implications for practice

MBSR may be considered a supportive intervention for improving short-term and medium-term depression, anxiety and quality of sleep as well as short-term fatigue in women with non-metastatic breast cancer who have completed curative cancer treatment. However, doubts about the actual effects exist, since all confidence intervals – except for short-term depression – were compatible with both a (slight) improvement and little or no difference. Moreover, we were unable to determine the effect on quality of life due to missing data. Data on harms were not reported, but it is reasonable to expect no major harmful outcome. No data were available for survival either.

Participants with no college education were greatly underrepresented in the trials, suggesting that the choice to use MBSR may depend to a large extent on the personal preference of patients. Availability may be an additional barrier to the implementation of MBSR in practice.

Implications for research

All evidence in this review (except for short-term depression) is of moderate or low certainty due to imprecision. Thus, an update of this review incorporating the four studies that did not report usable results (185 participants), as well as the 10 ongoing trials identified in this review (with an additional 1810 participants, see Results of the search), may lead to more precise results and ultimately to a more reliable body of evidence.

Four ongoing studies are investigating MBSR as an online intervention. In an update, these may have to be assessed separately since 'standard' MBSR takes place in a group setting, providing social support. However, an online mindfulness programme may be a valuable option for patients, for example from rural areas, who are not able to participate in weekly group sessions.

Only four trials implemented the standard MBSR intervention as envisaged by Kabat-Zinn, while the remaining six studies deviated to some degree, for example by not offering a one-day retreat. It is unclear whether a more intensive (e.g. number of group sessions attended, having participated in the one-day retreat) mindfulness programme leads to a stronger effect.

Since two ongoing studies include women "currently under at least one adjuvant therapy" (Huang 2016b) or "undergoing radiotherapy" (NCT02900326), their results may provide information on the effectiveness of MBSR for women during active therapy (see Characteristics of ongoing studies). However, there is still a need to conduct trials on MBSR for women with metastatic breast cancer, since six of the ongoing trials exclude women with metastatic breast cancer from participating (for four trials, no information on breast cancer status as an inclusion criterion was available).

Further studies of MBSR should address all important outcomes. Ideally, they should measure patient-reported outcomes using the same questionnaires at standardised time points. It would also be important to report baseline data on psychological treatment and use of medication to be able to investigate a potential co-intervention bias.

Further research is needed to determine minimally important differences specific to breast cancer for questionnaires; for this review, we could identify only three (Table 4).

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Bower 2015

Methods	RCT Follow-up: 3 months
Participants	Inclusion criteria: • diagnosis with stage 0, I, II or III breast cancer at or before 50 years • completed local and/or adjuvant cancer therapy (except hormone therapy) at least 3 months previously • up to 10 years after cancer treatment Exclusion criteria: • breast cancer recurrence, metastasis, or another cancer diagnosis (excluding non-melanoma skin cancer) • active, uncontrolled medical illness that could impact inflammation

Bower 2015 *(Continued)*

	Sample size:
	• N = 71 randomised
	  ○ MBSR: N = 39
	  ○ UC: N = 32
	Country:
	• USA (1 centre)

Interventions	(1) MBSR group (N = 39 randomised) • 6 weekly, 2-h group sessions including presentations of theoretical materials on mindfulness; experiential practice of meditation and gentle movement exercises (e.g. mindful walking); and a psychoeducational component for cancer survivors • Participants were instructed to practice mindfulness techniques on a daily basis, beginning with 5 min daily and increasing to 20 min daily (2) Wait-list control group (N = 32 randomised) • after completing the 3-month follow-up assessments, participants were offered participation in MBSR
Outcomes	Outcomes relevant to this review: • fatigue (Fatigue Symptom Inventory, FSI) • depression (Center for Epidemiological Studies - Depression, CES-D) • quality of sleep (Pittsburg Sleep Quality Index, PSQI) Outcomes were assessed at: • baseline • within 1 or 2 weeks after the intervention • 3 months after the intervention
Funding	"This work was supported by Susan G. Komen for the Cure and by a Komen Scholar Grant to Dr. Ganz. Dr. Crespi was supported in part by grant CA 16042 from the National Institutes of Health. Dr. Crosswell was supported by the National Institute of General Medical Sciences (T32GM084903), the National Institute on Aging (T32AG033533), and the UCLA Career Development Program in Population-Based Cancer Prevention and Control Research (R25T, NCI/NIH Cancer Education and Career Development Program). We also acknowledge the Petit Foundation for support."
Declarations of interest	The authors made no disclosures.
Notes	The trial took place between March 2011 and October 2012.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Given class scheduling considerations, participants were 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 had completed the baseline assessment, they were randomised (4:3) to the intervention group or the wait-list control group"
Allocation concealment (selection bias)	Unclear risk	Quote: "Randomized condition assignments were kept in sealed envelopes in the research office"

Bower 2015 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding in this context is not feasible
Blinding (outcome assessment patient-reported outcomes)	High risk	Blinding in this context is not feasible
Incomplete outcome data (attrition bias) All outcomes	High risk	> 10% of participants randomised are missing both for short-term and medium-term data (no data imputation)
Selective reporting (reporting bias)	Unclear risk	No publication on study design available
Other bias	Low risk	None identified

Henderson 2013

Methods	RCT Follow-up: 2 years

Participants	Inclusion criteria:
	
	• adult women (age 20-65 years)
	• newly diagnosed (within past 2 years) stage I or II breast cancer
	• Eastern Cooperative Oncology Group Performance Status 0,1 or 2
	
	Exclusion criteria:
	
	• previous diagnosis of cancer in the past 5 years (except non-melanoma skin cancer)
	
	Sample size:
	
	• N = 180 randomised, n = 163 analysed (randomisation per arm not reported)
	  ◦ MBSR (n = 53 analysed)
	  ◦ NEP (n= 52 analysed)
	  ◦ UC (n = 58 analysed)
	
	Country:
	
	• USA (4 centres)

Interventions	(1) MBSR group (n = 53 assessed)
	
	• introductory meeting
	• 8-week standard MBSR intervention
	  ◦ 7 weekly 2.5 to 3.5-h sessions and
	  ◦ 1, 7.5 h silent retreat in the 6th week
	• 3 monthly 2-h sessions following completion of the MBSR, focused on support, sharing and practice.
	
	(2) UC (usual care) group (n = 58 assessed)
	
	• no formal intervention, but allowed to participate in activities of their choice other than MBSR and NEP
	• monthly phone calls for support

Henderson 2013 *(Continued)*

	(3) NEP (nutrition and education programme) group (n = 52 assessed)
Outcomes	Outcomes relevant to this review: • cancer specific QoL (Functional Assessment of Cancer Therapy, breast cancer version, FACT-B) • depression (Beck Depression Inventory, BDI) • anxiety (Beck Anxiety Inventory, BAI) • general distress (Symptom Checklist 90 Revised, SCL-90-R) Outcomes were assessed at: • baseline • 4 months (end of intervention) • 12 months and • 24 months.
Funding	The BRIDGES study was funded by a grant from the US Army Medical Research and Material Command. One author was supported by the National Cancer Institute.
Declarations of interest	The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of the article.
Notes	Study dates not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information regarding sequence generation
Allocation concealment (selection bias)	Unclear risk	No information regarding allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding in this context is not feasible
Blinding (outcome assessment patient-reported outcomes)	High risk	Blinding in this context is not feasible
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Data available for 163 of 180 randomised participants (< 10% of participants missing); however, no information is given as to which intervention group the dropouts had been assigned to
Selective reporting (reporting bias)	Unclear risk	No publication on study design available
Other bias	High risk	In addition to 'standard' MBSR intervention, participants received 3 monthly 2-h sessions following completion of the MBSR.

Hoffman 2012

Methods	RCT

Hoffman 2012 *(Continued)*

	Follow-up: 14 weeks

Participants	Inclusion criteria:
	• adult women (age 18 to 80 years)
	• stage 0 to III breast cancer
	• within 2 months to 2 years after completion of surgery, chemotherapy and/or radiotherapy
	Exclusion criteria:
	• substance misuse, suicidal thoughts, current psychosis
	Sample size:
	• N = 229 randomised, n = 214 analysed
	  ◦ MBSR group (N = 114, n = 103)
	  ◦ wait-list group (N = 115, n = 111)
	Country:
	• UK (1 centre)

Interventions	(1) MBSR (n = 103 analysed) • 8 weekly classes of 2 h • one 6-h day of mindfulness in week 6 • body scan, gentle and appropriate lying and standing yoga-based stretches, sitting meditation, group discussions, didactic teaching and home practice • home practice was delivered by 4 CDs of formal mindfulness practices and a manual (participants were asked to practice for 40-45 min for 6 or 7 days a week) (2) Wait-listed control (n = 111 analysed) • no special intervention
Outcomes	Outcomes relevant to this review: • mood (subscales depression, anxiety, fatigue; Profile of Mood States, POMS) • cancer specific QoL (FACT-B and FACT-ES) Outcomes were assessed at: • baseline (T1) • weeks 8 to 12 (T2) and • weeks 12 to 14 (T3)
Funding	Quote: "Supported by the Girdlers' Company through the Florence Nightingale Foundation, Harvey White, MD, and The Haven."
Declarations of interest	The authors indicated no potential conflicts of interest.
Notes	Study dates are not clearly reported. Quote: "The study setting was atypical of widely available support services. Generalizability was limited to women with stage 0 to III breast cancer who seek psychological services."

Risk of bias

Bias	Authors' judgement	Support for judgement

Hoffman 2012 *(Continued)*

Random sequence generation (selection bias)	Low risk	Computer-generated randomisation
Allocation concealment (selection bias)	Low risk	Quote: "Random assignment was performed by operations director of the organization, who was independent from the study, by using an externally computer-generated randomisation program on blocks of four, which ensured allocation concealment because no clinician/researcher could anticipate or direct the allocation of participants."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding is not feasible in this context
Blinding (outcome assessment patient-reported outcomes)	High risk	Blinding is not feasible in this context
Incomplete outcome data (attrition bias) All outcomes	Low risk	Values imputed by LOCF < 15%; reasons for dropout clearly stated
Selective reporting (reporting bias)	Unclear risk	No publication on study design available
Other bias	High risk	Participants received an average of 30 h of 'The London Haven' support before study entry.

Johns 2014

Methods	RCT Follow-up: 6 months

Participants	Inclusion criteria:
	
	• age ≥ 18 years
	• cancer diagnosis
	• reported experiencing persistent cancer-related fatigue (CRF) for the previous 8 weeks or longer
	• reported clinically significant CRF at the time of eligibility screening. Clinically significant CRF was defined by a cutoff mean score of ≥ 4 across the 3-item FSI
	
	Exclusion criteria:
	
	• cancer treatment (other than endocrine treatment for breast cancer) in the prior 3 months
	• enrolled in hospice care
	• severe hearing impairment
	• severe depression (questionnaire PHQ-8 score ≥ 20)
	• previously participated in a mindfulness meditation class
	
	Sample size:
	
	• N = 35 randomised
	  ○ MBSR: N = 18
	  ○ wait-list: N =17
	
	Country:

Johns 2014 *(Continued)*

	• USA
Interventions	(1) MBSR (N = 18) • mindful practices of the body scan, gentle Hatha yoga, walking meditation, sitting meditation, and compassion meditation • the programme was adapted for the cancer context; adaptations included 2-h classes, 7 classes instead of 8, no retreat, brief psycho-education related to CRF, and shorter guided home practices (20 min) • recordings of guided mediations were created by facilitator for home practice (2) Wait-listed control group (N = 17) • wait-list participants were offered the 7-week MBSR course following completion of the T3 assessment
Outcomes	Outcomes relevant to this review: • quality of life (SF-36)[a] • fatigue (FSI) • depression (PHQ-8) • anxiety (General Anxiety Disorder, GAD-7) • quality of sleep (ISI) Outcomes were assessed at • baseline (T1) • end of intervention MBSR (T2) • 1 month follow-up MBSR (T3) • end of intervention for waitlisted controls (T4) • 6 months after completing respective MBSR course for all participants (T5)
Funding	Quote: "The research reported in this publication was supported by grants from the Walther Cancer Foundation, Inc., and the National Cancer Institute."
Declarations of interest	Quote: "The authors have no conflicts of interest to report"
Notes	Recruitment period: spring 2010 [a]Results were reported for item vitality only (query to author unsuccessful)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The randomisation sequence was generated by coin toss in blocks of four by the principal investigator."
Allocation concealment (selection bias)	Unclear risk	Quote: "Research assistants and participants were blinded to the randomisation sequence using sequentially numbered and sealed envelopes." (It is not mentioned that the envelopes were opaque)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding in this context is not feasible

Johns 2014 *(Continued)*

Blinding (outcome assessment patient-reported outcomes)	High risk	Blinding in this context is not feasible. However, participants were randomised after completing baseline questionnaires and therefore blinded at baseline.
Incomplete outcome data (attrition bias) All outcomes	Low risk	CONSORT diagram available: no dropouts after allocation reported
Selective reporting (reporting bias)	High risk	Data on quality of life only partially reported; no publication on study design available
Other bias	Low risk	None identified

Johnson 2015

Methods	RCT Follow-up: 1 year
Participants	Inclusion criteria: • women with stage IV breast cancer and bone metastases undergoing radiotherapy • due to very low accrual rates, the inclusion criteria were broadened to include non-metastatic participants with any kind of cancer-related pain Exclusion criteria: not specified Country: • Canada
Interventions	(1) MBSR group (N = 5 randomised) • 6 1-h individual sessions (2) Usual care (N = 2 randomised) (3) Acupuncture (N = 5 randomised)
Outcomes	Outcomes relevant to this review: • quality of life (questionnaire not specified) [a] • mood (questionnaire not specified)[a] Outcomes were assessed at baseline, week 3, week 6, 4-month and 1-year follow-up
Funding	Not reported
Declarations of interest	Not reported
Notes	The trial took place between February 2007 and June 2011. [a]Only 2 participants completed all assessment time points. No results were reported

Risk of bias

Bias	Authors' judgement	Support for judgement

Johnson 2015 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	No information given
Allocation concealment (selection bias)	Unclear risk	No information given
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding is not feasible in this context
Blinding (outcome assessment patient-reported outcomes)	High risk	Blinding is not feasible in this context
Incomplete outcome data (attrition bias) All outcomes	High risk	Only 2 of 12 participants completed the trial (no results reported)
Selective reporting (reporting bias)	Unclear risk	No information given
Other bias	Low risk	None identified

Kenne 2017

Methods	RCT Follow-up: 3 months (results reported at 3 months: further follow-up is planned for up to 5 years)

Participants	Inclusion criteria:
	
	• early stage breast cancer
	• after completion of adjuvant chemotherapy, with or without radiation therapy/endocrine therapy
	• eligible participants were contacted at the first follow-up appointment for participants receiving hormonal therapy or at the last treatment for participants undergoing chemotherapy
	
	Exclusion criteria
	
	• additional advanced illness at diagnosis
	• ongoing major depression
	• ongoing trastuzumab therapy
	• previous use of MBSR or other mind-body programmes (including yoga)
	
	Sample size:
	
	• N = 177 randomised
	  ◦ MBSR: N = 66 randomised (4 dropouts)
	  ◦ control: N = 54 randomised (2 dropouts)
	
	Country:
	
	• Sweden (2 centres)

Interventions	(1) MBSR group (N = 66 randomised)

Kenne 2017 *(Continued)*

	• standardised, 2-h course once a week for 8 weeks led by a certified MBSR instructor focusing on the participants' experiences of mindfulness, and including gentle meditation and yoga training • participants were given homework assignments consisting of 20 min session, 6 days/week • participants received information material including an introduction to mindfulness training, a CD, a diary and the training programme (2) Usual care (N = 54 randomised) • usual care according to the national and local guidelines recommendations (3) Active control (N = 57 randomised) • self-instructing MBSR programme
Outcomes	Outcomes relevant to this review: • quality of life (International Breast Cancer Study Group Quality of Life Core Questionnaire (IBCSG QoL), SF-36) • anxiety (Hospital Anxiety and Depression Scale, HADS) • depression (HADS) • survival: not reported, data are expected for 2019 Outcomes were assessed at: • baseline • 1 month after intervention
Funding	Quote: "This research was supported by grants from: the Swedish Cancer Society; the Health & Medical Care Committee of the Regional Executive Board, Västra Götaland; the Research Funds Skaraborg Hospital; and the Skaraborg Research Committee."
Declarations of interest	The authors indicated no potential conflicts of interest.
Notes	Study dates not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was computerized and conducted in blocks of 9, 12, and 15, varied randomly."
Allocation concealment (selection bias)	Low risk	Quote: "Assignment codes were kept in sequentially numbered, opaque, sealed envelopes" "At the time of allocation, the research nurse will pick the sequential envelope, write the participant's name and personal registration number on the envelope, and then open it."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding is not feasible in this context
Blinding (outcome assessment patient-reported outcomes)	High risk	Blinding is not feasible in this context
Incomplete outcome data (attrition bias)	Low risk	<10% of participants randomised are missing (no data imputation); however, "two patients were excluded as they did not complete the intervention"

Kenne 2017 *(Continued)*

All outcomes		
Selective reporting (reporting bias)	Low risk	Publication on study design available
Other bias	Low risk	None identified

Koumarianou 2014

Methods	RCT Follow-up: 8 weeks
Participants	Inclusion criteria: • newly diagnosed breast cancer patients with early stage disease Exclusion criteria: no information given Country: • Greece
Interventions	(1) MBSR group (N = 35 randomised) • 8 week programme • including diaphragmatic breathing, progressive muscle relaxation and guided imagery (2) no intervention (N = 30 randomised)
Outcomes	Outcomes relevant to this review: • quality of life (questionnaire not specified)[a] • sleep quality (questionnaire not specified)[a] Outcomes were assessed at the beginning and the end of the study.
Funding	Not reported
Declarations of interest	Not reported
Notes	[a]Results as reported cannot be used for meta-analysis (query to author unsuccessful)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No information given
Allocation concealment (selection bias)	Unclear risk	No information given
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding is not feasible in this context.

Koumarianou 2014 *(Continued)*

Blinding (outcome assessment patient-reported outcomes)	High risk	Blinding is not feasible in this context.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information given
Selective reporting (reporting bias)	High risk	Only abstract available (data reported not usable for meta-analysis), query to authors unsuccessful
Other bias	Low risk	None identified

Lengacher 2009

Methods	RCT Follow-up: 6 weeks

Participants	Inclusion criteria:
	
	• women aged ≥ 21 years
	• breast cancer diagnosis of stage 0 to III
	• surgery and adjuvant radiation and/or chemotherapy completed within the prior 18 months to study enrolment
	
	Exclusion criteria:
	
	• prophylactic mastectomy
	• breast cancer stage IV
	• severe psychiatric diagnosis
	• treatment for recurrent breast cancer
	
	Sample size:
	
	• N = 84 randomised, n = 82 analysed
	  ◦ MBSR (N = 41, n = 40 analysed)
	  ◦ UC (N = 34, n = 42 analysed)
	
	Country:
	
	• USA (1 centre)

Interventions	(1) MBSR:
	
	• 6 weekly 2-h sessions conducted by a psychologist certified in MBSR and standardised by following a training manual (class size: 4-8)
	• the intervention included
	  ◦ meditation practice (sitting meditation, body scan and walking meditation)
	  ◦ yoga
	  ◦ supportive group interaction and discussion
	  ◦ educational material related to relaxation, meditation, the mind-body connection
	• participants received a training manual and audiotapes to support home practice
	• participants were asked to formally meditate and perform yoga exercises for a minimum of 15-45 min per day, 6 days per week; they were also asked to informally practice 15-45 min per day
	
	(2) UC control-group (wait-listed)

Lengacher 2009 *(Continued)*

	• usual care • no meditation, yoga and/or MBSR during the study • wait-listed to receive MBSR (if desired) within 5 months of the postassessment
Outcomes	Outcomes relevant to this review: • state anxiety (State-Trait Anxiety Inventory, STAI) • depression (Center for Epidemiological Studies Depression Scale, CES-D) • quality of life (Medical Outcomes Studies Shortform General Health Survey, SF-36) Outcomes were assessed at: • baseline • within 2 weeks at the end of the 6-week intervention
Funding	Supported by the National Institute of Health, National Cancer Institute
Declarations of interest	None stated
Notes	Recruitment period: March 2006 to July 2007 According to John Kabat-Zinn the complete programme lasts 8 weeks. Therefore, with a period of 6 weeks this study is deviating from the standard duration. Participants received an incentive of USD 30 for data completion at each time point as well as USD 50 at the beginning and at the completion of the trial.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information given regarding sequence generation
Allocation concealment (selection bias)	Unclear risk	No information given regarding allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding in this context is not feasible
Blinding (outcome assessment patient-reported outcomes)	High risk	Blinded assessment for baseline data only, blinding in this context (for data at the end of the intervention) is not feasible
Incomplete outcome data (attrition bias) All outcomes	Low risk	< 10% of participants randomised are missing (no data imputation); reasons for dropout clearly stated
Selective reporting (reporting bias)	Unclear risk	No publication on study design available
Other bias	Low risk	None identified

Lengacher 2014

Methods	RCT Follow-up: 12 weeks

Participants	Inclusion criteria:
	
	• women
	• age ≥ 21 years
	• a previous breast cancer diagnosis of stage 0 to III
	• completed treatment from 2 weeks to 2 years prior to study enrolment
	
	Exclusion criteria:
	
	• breast cancer stage IV
	• severe mental disorder
	• breast cancer recurrence
	
	Sample size:
	
	• N = 322 randomised
	  ○ MBSR: N = 167 randomised, n = 152 analysed
	  ○ UC: N = 155 randomised, n = 147 analysed
	
	Country:
	
	• USA (1 centre)

Interventions	(1) MBSR intervention-group (N = 167 randomised)
	
	• 6, 2-h weekly sessions including
	  ○ training in formal meditation (sitting meditation, body scan, gentle Hatha yoga and walking meditation)
	  ○ informal techniques of integrating mindfulness into daily life activities
	  ○ supportive interaction among group members
	• participants were requested to formally and informally practice the meditative techniques for 15-45 min per day (a manual and CDs were provided to guide home practice)
	
	(2) UC control-group (N = 155 randomised)
	
	• standard post-treatment clinic visits
	• participants were asked to refrain from practicing meditation, yoga and MBSR during the study
	• participants were offered the MBSR intervention within 6 months after completion of the study

Outcomes	Outcomes relevant to this review: • quality of life (SF-36)[a] • fatigue (FSI) • anxiety (STAI) • depression (CES-D) • quality of sleep (PSQI) Outcomes were assessed at: • baseline • 6 weeks • 12 weeks
Funding	Quote: "Supported by the National Cancer Institute and in part by the Survey Methods Core Facility at the H. Lee Moffitt Cancer Center and Research Institute."

Lengacher 2014 *(Continued)*

Declarations of interest	Quote: "The authors have no conflicts to report."
Notes	Recruitment period: April 2009 to March 2013 Participants received an incentive of USD 30 for data completion at each time point. According to John Kabat-Zinn the complete programme lasts 8 weeks. Therefore, with a period of 6 weeks this study is deviating from the standard duration. [a]Data available for subscales pain, emotional well-being and general health only (therefore not usable)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "An SPSS macro ... was used to create a stratified block randomisation scheme"
Allocation concealment (selection bias)	Unclear risk	No information given regarding allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding in this context is not feasible
Blinding (outcome assessment patient-reported outcomes)	High risk	Blinding in this context is not feasible. However, participants were randomised after completing baseline questionnaires and therefore blinded at baseline.
Incomplete outcome data (attrition bias) All outcomes	Low risk	< 10% of participants randomised are missing (no data imputation)
Selective reporting (reporting bias)	High risk	Quality of life data only partially reported; no publication on study design available
Other bias	Low risk	None identified

Lerman 2012

Methods	RCT Follow-up: until end of intervention (6 weeks)
Participants	Inclusion criteria: • female cancer patients • age ≥ 18 years • planned or ongoing hormonal therapy/maintenance chemotherapy acceptable if treatment/disease was not expected to limit participation Exclusion criteria: • not completed cancer treatment • psychiatric symptoms that might impair group setting

Lerman 2012 *(Continued)*

	Participant demographics:
	• N = 77 randomised, n = 68 analysed
	  ○ MBSR: N = 53, n = 48 analysed (4 dropouts, 1 no data)
	  ○ control: N = 24, n = 20 analysed (1 dropout, 3 no data)
	Country:
	• USA (1 centre)

Interventions	(1) MBSR group (n = 34 breast cancer patients analysed) • 8-week programme • 2 h per week training in practicing meditation, yoga, mindful communication skills, mindful breast self-examination/awareness • 4 h weekend retreat during week 6 • participants requested to daily practice meditation and/or yoga for 45 min • workshop leader physician trained in MBSR or yoga • maximum class size was 15 (2) Control (wait-listed; n = 14 breast cancer patients analysed) • instructed not to use or practice meditation or yoga technique
Outcomes	Outcomes relevant to this review: • quality of life (EORTC QLQ-30, EORTC QLC-20 BR23) • depression (SCL-90-R, subscale depression) • anxiety (SCL-90-R, subscale anxiety) Outcomes were assessed at: • baseline • end of intervention
Funding	Quote: "This study was funded in part by the 2010 Oakland University–William Beaumont Hospital Multidisciplinary Research Award"
Declarations of interest	Quote: "The authors have no conflict of interest or commercial interests in the subject of study"
Notes	Recruitment period: September 2009 to August 2010

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "This single score was used to match and randomise patients to either the treatment or wait-listed control group" A query to the authors clarified that "the composite EORTC QLQ-30 score obtained from each subject prior to beginning the workshop series was used to rank (stratify) the subjects. Subjects in each stratum (i.e., with similar scores) were then randomly assigned to either the MBSR group or the wait-listed control group."
Allocation concealment (selection bias)	Unclear risk	No information given

Lerman 2012 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding in this context is not feasible
Blinding (outcome assessment patient-reported outcomes)	High risk	Blinding in this context is not feasible
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	5 participants from MBSR group and 4 participants from control group were lost to follow-up (with reasons given). It is unclear how many of those were breast cancer patients.
Selective reporting (reporting bias)	Unclear risk	No publication on study design available
Other bias	Low risk	None identified

Shapiro 2003

Methods	RCT Follow-up: 9 months postintervention
Participants	Inclusion criteria: • female • age 18–80 • have a history of stage II breast cancer • currently in remission • within 2-year post-treatment Exclusion criteria: none stated Participant demographics: • N = 63 randomised • number of months post-treatment: range 2 to 25 months (mean = 13.4, SD = 6.9) • age: range 38 to 77 years (mean = 57, SD = 9.7) Country: • USA

Interventions	(1) MBSR intervention
	
	• consisting of 6 weekly 2-h sessions and 1, 6-h silent retreat
	• participants received training in the following meditative practices (adapted from Kabat-Zinn)
	  ◦ sitting meditation
	  ◦ body scan
	  ◦ Hatha yoga
	• didactic material was presented on the psychological and physiological effects of stress
	
	(2) usual care
	
	• no formal or structured intervention or instruction

Shapiro 2003 *(Continued)*

	• participants should 'freely choose' which stress management techniques to engage in each week (e.g. talking to a friend,exercise, and taking a warm bath) • participants received a workbook including support resources available in the community, poetry, and a diary for journaling
Outcomes	Outcomes relevant to this review: • depression (BDI[a]) • anxiety (STAI)[a] • quality of life (FACT-B)[a] • Profile of Mood States Scale (POMS)[a] Outcomes were assessed at: • baseline • end of intervention • 3 months post-intervention • 9 months post-intervention
Funding	National Institute of Health, National Cancer Institute, Bethesda, MD (grant number: 1 RO3 CA83342-01)
Declarations of interest	The authors indicated no potential conflicts of interest.
Notes	[a]No means or SD are reported (query to author unsuccessful)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information provided
Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding is not feasible in this context
Blinding (outcome assessment patient-reported outcomes)	High risk	Blinding is not feasible in this context
Incomplete outcome data (attrition bias) All outcomes	High risk	49 participants (78%) completed the 9-month follow-up assessment; no reasons for discontinuation given
Selective reporting (reporting bias)	High risk	Data reported not usable for meta-analysis, query to author unsuccessful
Other bias	Low risk	None identified

Wurtzen 2015

Methods	RCT Follow-up: 12 months

Participants	Inclusion criteria:
	
	• women aged 18-75 years
	• breast cancer diagnosis of stage I to III within previous 3 to 18 months
	• undergone surgery for their cancer at Herlev and Ringsted hospitals
	
	Exclusion criteria:
	
	• diagnosis of another cancer within previous 10 years
	• current major psychiatric disease
	
	Sample size:
	
	• N = 336 randomised
	  ◦ MBSR: N = 168 (n = 35 lost to follow-up)
	  ◦ control: N = 168 (n = 18 lost to follow-up)
	
	Country:
	
	• Denmark (2 centres)

Interventions	(1) MBSR intervention-group (N = 168) • 8 weekly 2-h sessions according to standardised MBSR manual ◦ psycho-education on stress responses, mindful meditation (body scan, sitting and walking meditation) and gentle yoga • 5-h silent retreat after week 7 • home practice daily for 45 min (participants were written material and CDs with meditation guides to support home training) (2) UC control group (N = 168) • usual care
Outcomes	Outcomes relevant to this review: • anxiety (SCL-90-R, subscale anxiety)[a] • depression (CES-D)[a] • sleep quality (Medical Outcome Study sleep scale, MOSS)[a] Results were reported at: • baseline • 2 months after start of intervention • 6 months after start of intervention • 12 months after start of intervention
Funding	"This work is funded by the Danish Cancer Society; the Psychosocial Research Committee and the CAM Research Committee, University of Copenhagen; Multidisciplinary CAM-Research, Danish Cancer Research Foundation and the Danish Cancer Society Research Centre."
Declarations of interest	No conflicts of interest declared
Notes	Intervention period: March 2008 to November 2009 [a]No SD reported; if possible, SDs were obtained from Haller 2017 (query to author was unsuccessful)

Wurtzen 2015 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "eligible patients were randomised ... by use of computer-generated sequences of 10 patients."
Allocation concealment (selection bias)	Low risk	Quote: "eligible patients were randomised (1:1) via web interface ... Participants were informed about the allocation result ... by telephone."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding in this context is not feasible
Blinding (outcome assessment patient-reported outcomes)	High risk	Blinding in this context is not feasible. However, participants were randomised after completing baseline questionnaires and therefore blinded at baseline.
Incomplete outcome data (attrition bias) All outcomes	High risk	> 10% of participants randomised are missing (no data imputation); reasons not given
Selective reporting (reporting bias)	High risk	Complete results only available by query to authors; no publication on study design available
Other bias	Low risk	None identified

Zaidi 2015

Methods	RCT Follow-up: 12 months
Participants	Inclusion criteria: • women with breast cancer • after 6 weeks of radiotherapy Exclusion criteria: not known Sample size: 50 participants Country: • Pakistan
Interventions	(1) MBSR group (N = 25) • MBSR practice for 8 weeks as twice weekly practice (2) control group (N = 25)
Outcomes	Outcomes relevant to this review: • quality of life (questionnaire not specified, no results reported)

Zaidi 2015 *(Continued)*

	Results were assessed at: • end of treatment • 1 month • 3 months
Funding	Not known
Declarations of interest	Not known
Notes	Since author's email address could not be identified, a query to author could not be sent. Contact details: Afsar imam Zaidi; Cancer-Care Institute of Pakistan, Lahore, Pakistan

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information in abstract
Allocation concealment (selection bias)	Unclear risk	No information in abstract
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding not feasible in this context
Blinding (outcome assessment patient-reported outcomes)	High risk	Blinding not feasible in this context
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information in abstract
Selective reporting (reporting bias)	High risk	Data reported not usable for meta-analysis
Other bias	Low risk	None identified

Zhang 2017

Methods	RCT Follow-up: 3 months
Participants	Inclusion criteria: • females diagnosed with breast cancer of stage I-III • 18 years or older • within 2-6 months after completion of surgery • no other major disabling medical or mental disorder Exclusion criteria:

Zhang 2017 *(Continued)*

	• having participated in a similar intervention before
	
	Sample size:
	
	• N = 60 randomised, n = 58 analysed
	  ○ MBSR (N = 30, n = 28)
	  ○ UC (N = 30, n = 30)
	
	Country:
	
	• China (1 centre)

Interventions	MBSR intervention-group (N = 30): • 8-week programme based on MBSR developed by Kabat-Zinn (adjusted according to conditions) • weekly 2-h sessions conducted by a psychologist certified and qualified in mindfulness skills (6 groups with 4-6 participants) • classes consisted of 4 basic forms of meditation practice (body scan, walking meditation, gentle yoga, sitting meditation), group discussions and didactic teaching • week 6: 4-h silent intensive meditation practice • participants were provided with a homework manual and an audio download; they were asked to practice for 40-45 min for 6-7 days per week UC control-group (N = 30): • usual care • participants were asked to not use MBSR or other related techniques, such as meditation or yoga • if desired, participants received MBSR after completion of the study
Outcomes	Outcomes relevant to this review: • anxiety (STAI) Assessments were made at: • baseline • after the end of the 8-week intervention • 3 months later
Funding	The research was supported by the Heilongjiang Department Project of China.
Declarations of interest	No potential conflict of interest was reported by the authors.
Notes	Recruitment period: March to October 2014

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "participants were randomised ... by using the lottery by statistics staff who were independent from the study"
Allocation concealment (selection bias)	Low risk	Quote: "participants were randomised ... by using the lottery by statistics staff who were independent from the study", "participants were blinded to their random assignment until the end of this session"
Blinding of participants and personnel (performance bias)	High risk	Blinding in this context is not feasible

Zhang 2017 *(Continued)*
All outcomes

Blinding (outcome assessment patient-reported outcomes)	High risk	Blinded assessment for baseline data only, blinding in this context (for data at the end of the intervention) is not feasible.
Incomplete outcome data (attrition bias) All outcomes	Low risk	< 10% of participants randomised are missing (no data imputation); reasons clearly stated
Selective reporting (reporting bias)	Unclear risk	No publication on study design available
Other bias	Low risk	None identified

BAI: Beck Anxiety Inventory; **BDI**: Beck Depression Inventory; **CES-D**: Center for Epidemiological Studies - Depression; **EORTC QLQ/QLC/BR**: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire/Core/Breast Cancer Update; **FACT-B/ES**: Functional Assessment of Cancer Therapy, breast cancer version/endocrine-specific version; **CRF**: cancer-related fatigue; **FSI**: Fatigue Symptom Inventory; **GAD-7**: General Anxiety Disorder 7; **HADS**: Hospital Anxiety and Depression Scale; **ISI**: Insomnia Severity Index; **IBCSG QoL**: International Breast Cancer Study Group Quality of Life Core Questionnaire; **LOCF**: last observation carried forward; **MBSR**: mindfulness-based stress reduction; **MOSS**: Medical Outcome Study sleep scale; **NEP**: nutrition and education programme; **PHQ-8**: Personal Health Questionnaire Depression Scale; **POMS**: Profile of Mood States; **PSQI**: Pittsburg Sleep Quality Index; **QoL**: quality of life;**RCT**: randomised controlled trial; **SCL-90-R**: Symptom Checklist 90 Revised; **SF-36**: Shortform General Health Survey; **STAI**: State-Trait Anxiety Inventory; **UC**: usual care.

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

Study	Reason for exclusion
Branstrom 2012	Less than 80% of participants had breast cancer.
Carlson 2013	The control intervention consisted of either supportive-expressive group therapy or a 1-day stress management course and therefore does not correspond to our control intervention.
Carlson 2015	The control intervention consisted of either supportive-expressive group therapy or a 1-day stress management course and therefore does not correspond to our control intervention.
Carmody 2011	According to the study author, a history of breast cancer was an exclusion criterion for that trial.
Johannsen 2016	Study investigated the effects of a mindfulness-based cognitive therapy. This intervention does not correspond to our intervention.
Lengacher 2012	Sub-study (with considerably fewer participants) to the parent study Lengacher 2014
Rahmani 2014	Study is both described as "quasi-experimental" and as "randomised", so we judged it to be non-randomised.
Rahmani 2015	Study is both described as "quasi-experimental" and as "randomised", so we judged it to be non-randomised.

Characteristics of studies awaiting assessment *[ordered by study ID]*

Choi 2012

Methods	Not known
Participants	Not known
Interventions	Not known
Outcomes	Not known
Notes	No abstract available (query to author unsuccessful)

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

Huang 2016b

Trial name or title	The effectiveness of mindfulness-based stress reduction (MBSR) for survivors of breast cancer: study protocol for a randomised controlled trial
Methods	RCT Follow-up: 12 months Sample size: 418 breast cancer (BC) survivors will be recruited
Participants	Inclusion criteria: • female with a history of stage 0, I, II, or III BC • within 2 years from the date of BC diagnosis • currently under at least one adjuvant therapy • low-income household Exclusion criteria: • current treatment for recurrent BC • a history of schizophrenia or schizo-affective disorder • current alcohol or drug abuse Country: • China

Interventions	(1) MBSR intervention group:
	• 8-week MBSR programme based on Jon Kabat-Zinn's, adapted to the Chinese context
	  ◦ weekly 2-h standardised sessions by a psychologist certified and trained in MBSR (8-10 groups by the size of 20-30 participants)
	  ◦ training manual for home practice of various forms of meditations (sitting meditation, body scan, and walking meditation) and gentle yoga (participants were requested to formally meditate 6 days per week and to informally practice 15-30 min per day)
	  ◦ time for discussions and interactions during the weekly group sessions
	(2) UC group:
	• standard post-treatment clinic visits
	• participants were asked not to start mindfulness-based practice during the study period
	• MBSR intervention will be offered to each usual care subject after 6 months follow-up

Outcomes	Outcomes relevant to this review:

Huang 2016b *(Continued)*

	• depression (Self-rating Depression Scale, SDS) • anxiety (Self-rating Anxiety Scale, SAS) • quality of life (Quality of Life Index – cancer version III)
Starting date	As of April 2016, the trial had not begun, authors looked for financial support
Contact information	Jiayan Huang Key Laboratory of Health Technology Assessment Ministry of Health (Fudan University) 130, DongAn Road 200032 Shanghai China jyhuang@shmu.edu.cn
Notes	Clinical trial registry number: ChiCTRIOR-14005390

Lengacher 2017

Trial name or title	A three arm randomised controlled trial on the efficacy of mindfulness-based stress reduction treatment on cognitive impairment among breast cancer survivors
Methods	RCT Follow-up: not known Sample size: 330 participants
Participants	Inclusion criteria: • breast cancer survivors with stage I to III breast cancer who received chemotherapy or chemotherapy and radiation
Interventions	• 6-week MBSR(BC) programme • 6-week Breast Cancer Education Support programme • usual care
Outcomes	Outcomes listed: • objective neuropsychological and subjective cognitive measurements • cost utilisation data
Starting date	October 2015 (the trial is anticipated to end in 2020)
Contact information	Cecile Lengacher, University of South Florida
Notes	The project is supported by NIH grant (R01 CA199160-01) from the National Cancer Institute.

McGowan 2015

Trial name or title	Mindfulness-based stress reduction (MBSR) for individuals diagnosed with breast cancer: evaluation of an online MBSR (eMBSR) treatment program to relieve symptoms of psychological distress - a proposed randomised wait list control trial
Methods	RCT Follow-up: 3 months (via online questionnaires) Sample size: not reported
Participants	Inclusion criteria: • women diagnosed breast cancer Exclusion criteria: • men • no breast cancer diagnosis Country: • Australia
Interventions	(1) eMBSR intervention • therapist-supported self-study online version of MBSR (8-week group intervention based on mindful meditation and yoga) • easy-to-use multimedia treatment programme over the Internet to reach remote and rural participants • group support through online discussion board (2) wait-list (control)
Outcomes	Endpints relevant to this review: • psychological distress • well-being
Starting date	Not reported
Contact information	Dipti McGowa Griffith University, School of Applied Psychology, Brisbane, Queensland, Australia
Notes	Acknowledgement of funding: none

NCT02119481

Trial name or title	Effects of mindfulness meditation and stress management after breast cancer
Methods	RCT Follow-up: 24 months Sample size: 142 participants
Participants	Inclusion criteria: • breast cancer patient ≥ 18 years of age who have received the cancer diagnosis ≤ 2 years previously

NCT02119481 *(Continued)*

	• access and regular use of the Internet Exclusion criteria: • Previous severe psychiatric illness Country: • Sweden
Interventions	(1) Mindfulness-based stress reduction training • delivered in individual web-based sessions (2) Waiting-list control condition (3) Expressive writing condition
Outcomes	Outcomes relevant to this review: • sleep quality • all-cause mortality
Starting date	May 2014
Contact information	Richard Branstrom, Associate Professor, Karolinska Institutet
Notes	Estimated study completion date: June 2018

NCT02125006

Trial name or title	The effect of an inter-disciplinary program, Including MBSR, in breast cancer survivors with chronic neuropathic pain (InDepth)
Methods	RCT Follow-up: 5 months (3 months postintervention) Sample size: 118 participants
Participants	Inclusion criteria: • women • 18 years or older • completed treatment for breast cancer a minimum of 1 year prior to study enrolment • have been experiencing neuropathic pain following their cancer treatment for a minimum of 6 months • report pain intensity levels ≥4 (moderate to severe) Exclusion criteria: • metastatic disease or current evidence of cancer recurrence Country: • Canada
Interventions	(1) Interdisciplinary programme including MBSR • 8 weekly 2.5 h sessions and one 6 h session midway through the course

NCT02125006 *(Continued)*

	(2) Wait-listed control group • participants will be enrolled in the MBSR workshop 3 months after the corresponding intervention group completes the programme
Outcomes	Outcomes relevant to this review: • pain-related disability • neuropathic pain intensity • pain severity • mood states • depressive symptoms • quality of life
Starting date	October 2013
Contact information	Principal Investigator: Patricia Poulin, PhD Ottawa Hospital Research Institute
Notes	Estimated study completion date: March 2018

NCT02349217

Trial name or title	Mindfulness based couples therapy
Methods	RCT Follow-up: 8 weeks Sample size: 60 participants
Participants	Inclusion criteria: • stage 0-IIIA breast cancer survivors and their partner • female breast cancer survivors will be at least 2 months from receiving cancer treatment (surgery, adjuvant therapy or radiation) and within 3 years from completing cancer treatment, except for tamoxifen/aromatase inhibitors • couples co-habiting for at least 3 years with current partner who is willing to participate in study • 21 years of age or older Exclusion criteria: • male breast cancer survivors • diagnosis of diabetes, unless they are able to provide a letter from a physician who will continue to monitor the participant during the research study • anti-inflammatory medications (e.g. statins, cholesterol medication) • consume excessive amounts of alcohol (> 30 drinks/week) • major medical conditions involving the immune system such as autoimmune and/or inflammatory diseases • pressure readings ≥ 140/90 mm Hg, as defined by the 7th Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, will be deemed ineligible to participate and excluded from the study. They will be referred to their family physician or community services. Those ineligible based on their initial blood pressure reading are allowed to participate if they provide a letter from a physician who will continue to monitor the participant during the research study

NCT02349217 *(Continued)*

	• haemoglobin level < 10g/d • less than 21 years of age Country: • USA
Interventions	(1) Mindfulness Based Stress Reduction Intervention (MBRE) • participant and partner take part in an 8-week MBRE intervention course • MBRE course consists of meditation and yoga techniques and handouts (2) Usual care • participants receive self-help materials
Outcomes	Outcomes relevant to this review: • pain • fatigue • depression
Starting date	January 2015
Contact information	Principal Investigator: Cobi J Heijnen, PHD MD Anderson Cancer Center
Notes	Estimated study completion date: January 2020

NCT02601794

Trial name or title	A study of delivering a mindfulness app intervention to accompany supportive care among women with breast cancer (DIVAS)
Methods	RCT Follow-up: 12 weeks (end of intervention) Sample size: 112 participants
Participants	Inclusion criteria: • women • age ≥ 25 • breast cancer diagnosis within past 5 years Exclusion criteria: • unfamiliar with mobile phones/tablets, including ability to download and register mindfulness app • become unable to participate in a fully app and web-based intervention trial Country: • USA
Interventions	(1) App-based mindfulness training

NCT02601794 *(Continued)*

	• 12 week mindfulness training delivered remotely through mobile app (2) Wait-list control • no intervention provided during study period • 12 week mindfulness training will be delivered through mobile app once all study assessments have been completed
Outcomes	Endpoint relevant to this review: • quality of life (FACT-B)
Starting date	August 2015
Contact information	Pricipal investigator: Kristen Rosen, MPH University of Texas Health Science Center San Antonio
Notes	According to the principal investigator, the trial is completed and the manuscript reporting the main outcomes is currently under review (August 2017).

NCT02900326

Trial name or title	Mindfulness-based stress reduction (MBSR) program combined with endurance exercise training: a help in treatment for breast cancer?
Methods	RCT Follow-up: 8 weeks Sample size: 100 participants
Participants	Inclusion criteria: • breast cancer • finished with chemotherapy treatment • undergoing radiotherapy and/or hormone therapy Exclusion criteria: • regular physical activity higher than 4 h per week • any disease cardiac, respiratory, neurological or articular disease, which counteract the muscular training Country: • France
Interventions	(1) MBSR group (mindfulness-based-stress-reduction) (2) Control participants with no intervention (3) Endurance training programme (4) Endurance training programme combined with MBSR sessions
Outcomes	Endpoint relevant to this review:

NCT02900326 *(Continued)*

	• quality of life
Starting date	May 2015
Contact information	Principal Investigator: Lonsdorfer Evelyne, MD evelyne.lonsdorfer@chru-strasbourg.fr
Notes	According to the principal investigator, the trial was still ongoing in September 2017

NCT02931864

Trial name or title	Effects of an e-home based symptom management and mindfulness training programme on QoL in breast cancer survivors
Methods	RCT Follow-up: 24 weeks Sample size: 188 participants
Participants	Inclusion criteria: • women aged 21 or above • diagnosed with breast cancer stage 0 to 3 for the first time • have completed cancer treatment including breast surgery and/or adjuvant chemotherapy and/or radiotherapy between 6 months to 5 years previously • with and without ongoing HER2 target therapy (e.g. trastuzumab) and/or hormonal therapy • with ECOG performance status score of 0 to 1 • have access to the Internet through a handheld device Exclusion criteria: • have serious psychiatric disorders (e.g. schizophrenia, dementia, and intellectual disabilities) • with ECOG Performance Status score of 2 or above Country: • Singapore
Interventions	(1) Online mindfulness training programme • 5 weekly sessions of online self-administered mindfulness training programme (audio-recorded and video-recorded instructions, pictorial or text-based instructions for various mindfulness exercises such as body scan meditation, mindful breathing and walking meditation) (2) Usual care (3) Online symptom management + mindfulness training programme (4) Online symptom management programme
Outcomes	Outcomes relevant to this review: • quality of life • anxiety

NCT02931864 *(Continued)*

	• depression
Starting date	November 2016
Contact information	Principal Investigator: Karis Cheng National University, Singapore karis_cheng@nuhs.edu.sg
Notes	Estimated study completion date: September 2018

NCT03025139

Trial name or title	Mindfulness meditation or survivorship education in improving behavioral symptoms in younger stage 0-III breast cancer survivors (Pathways to Wellness) (PTW)
Methods	RCT Follow-up: 6 months Sample size: 360
Participants	Inclusion criteria: • women diagnosed with early stage, resectable breast cancer (Stage 0, I, II, or III) prior to age 45, and are within 5 years of diagnosis • have completed all surgery, radiation, and/or chemotherapy treatments at least 6 months previously; may still be receiving trastuzumab or endocrine adjuvant therapy • at least mild clinical depression on a standardised screening questionnaire Exclusion criteria: • breast cancer recurrence, metastasis, or another interval cancer diagnosis following the breast cancer (excluding non-melanoma skin cancer) • actively practicing mindfulness meditation • another serious or chronic medical or psychiatric condition that contributes to substantial physical or emotional disability that would detract from participating in either of the intervention programmes or from the measurement of intervention outcomes Country: • USA
Interventions	(1) Mindfulness awareness practices: • mindfulness meditation class over 2 h once weekly for 6 weeks • in person booster sessions that include guided meditation, questions, and discussion of how to maintain a mindfulness practice over 1 h once monthly for 3 months. (2) Usual care • usual care for 9 months. • participants are then offered a choice of participating in one of the treatment arms (3) Survivorship education intervention: • survivorship education class over 2 h once weekly for 6 weeks

NCT03025139 *(Continued)*	• monthly electronic newsletters with tailored information about topics of interest to younger survivors
Outcomes	Outcomes relevant to this review: • depressive symptoms • fatigue • sleep disturbance.
Starting date	February 2017
Contact information	Patricia Ganz (Principal Investigator) Jonsson Comprehensive Cancer Center University of California
Notes	Estimated study completion date: March 1, 2019

ECOG: Eastern Cooperative Oncology Group; **FACT-B**: Functional Assessment of Cancer Therapy, breast cancer version; **HER2**: trastuzumab (Herceptin); **MBSR**: mindfulness-based stress reduction; **RCT**: randomised controlled trial.

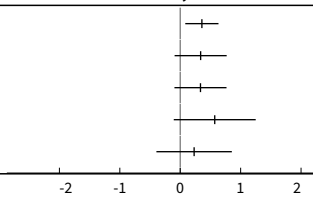
DATA AND ANALYSES

Comparison 1. MBSR vs usual care (short-term)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quality of life	3		Std. Mean Difference (IV, Random, 95% CI)	Totals not selected
2 Fatigue	5	693	Std. Mean Difference (IV, Random, 95% CI)	-0.50 [-0.86, -0.14]
3 Anxiety	6	749	Std. Mean Difference (IV, Random, 95% CI)	-0.29 [-0.50, -0.08]
4 Depression	6	745	Std. Mean Difference (IV, Random, 95% CI)	-0.54 [-0.86, -0.22]
5 Quality of sleep	4	475	Std. Mean Difference (IV, Random, 95% CI)	-0.38 [-0.79, 0.04]

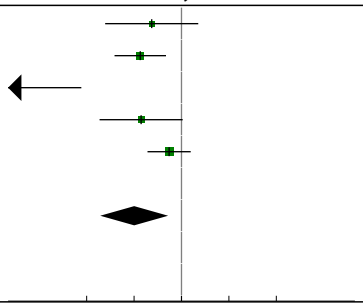
Analysis 1.1. Comparison 1 MBSR vs usual care (short-term), Outcome 1 Quality of life.

Study or subgroup	MBSR N	MBSR Mean(SD)	standard care N	standard care Mean(SD)	Std. Mean Difference Random, 95% CI	Std. Mean Difference Random, 95% CI
Hoffman 2012	101	103.6 (17.9)	106	96.8 (19.4)		0.36[0.08,0.63]
Lengacher 2009	41	50 (8.1)	43	46.7 (11.4)		0.34[-0.09,0.77]
Lengacher 2009	41	53.4 (10.9)	43	49.5 (12.2)		0.34[-0.1,0.77]
Lerman 2012	31	76.4 (8.3)	12	70.6 (13.8)		0.57[-0.11,1.25]
Lerman 2012	34	83.1 (12)	14	80.3 (12.6)		0.23[-0.39,0.85]



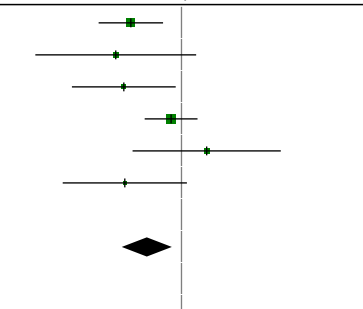
Analysis 1.2. Comparison 1 MBSR vs usual care (short-term), Outcome 2 Fatigue.

Study or subgroup	MBSR		standard care		Std. Mean Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI		Random, 95% CI
Bower 2015	35	3.6 (1.5)	30	4.1 (1.5)		18.53%	-0.31[-0.8,0.18]
Hoffman 2012	103	8.7 (6.1)	111	11.6 (7.2)		24.44%	-0.43[-0.71,-0.16]
Johns 2014	18	3 (1.3)	17	5.6 (1.3)		11.6%	-1.87[-2.67,-1.06]
Lengacher 2009	40	2 (2)	42	3 (2.6)		19.94%	-0.43[-0.86,0.01]
Lengacher 2014	152	12.3 (7.6)	145	13.4 (8.5)		25.49%	-0.13[-0.36,0.1]
Total ***	**348**		**345**			**100%**	**-0.5[-0.86,-0.14]**
Heterogeneity: Tau^2=0.12; Chi^2=17.53, df=4(P=0); I^2=77.18%							
Test for overall effect: Z=2.73(P=0.01)							



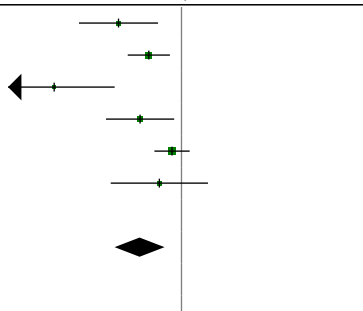
Analysis 1.3. Comparison 1 MBSR vs usual care (short-term), Outcome 3 Anxiety.

Study or subgroup	MBSR		standard care		Std. Mean Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI		Random, 95% CI
Hoffman 2012	103	10.3 (7)	111	13.4 (7.2)		25.74%	-0.43[-0.7,-0.16]
Johns 2014	18	3.9 (3.5)	17	5.9 (3.5)		7.98%	-0.55[-1.23,0.12]
Lengacher 2009	41	28.4 (11.8)	42	33.9 (10.9)		15.33%	-0.49[-0.92,-0.05]
Lengacher 2014	159	30.6 (12.8)	152	31.8 (13.2)		29.9%	-0.09[-0.31,0.13]
Lerman 2012	34	0.4 (0.6)	14	0.3 (0.3)		9.11%	0.21[-0.41,0.84]
Zhang 2017	28	41.7 (3.3)	30	43.5 (4.2)		11.94%	-0.48[-1,0.05]
Total ***	**383**		**366**			**100%**	**-0.29[-0.5,-0.08]**
Heterogeneity: Tau^2=0.03; Chi^2=8.36, df=5(P=0.14); I^2=40.2%							
Test for overall effect: Z=2.72(P=0.01)							



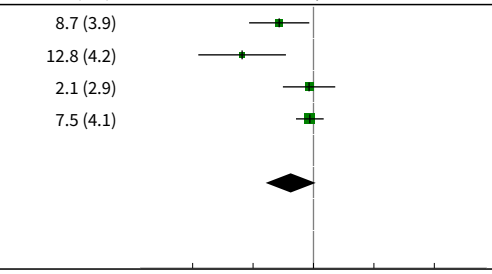
Analysis 1.4. Comparison 1 MBSR vs usual care (short-term), Outcome 4 Depression.

Study or subgroup	MBSR		standard care		Std. Mean Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI		Random, 95% CI
Bower 2015	35	10.1 (7.1)	30	17.7 (11.4)		15.53%	-0.81[-1.32,-0.3]
Hoffman 2012	103	10 (10)	111	15 (13.2)		21.52%	-0.42[-0.69,-0.15]
Johns 2014	18	4.6 (3.3)	17	10 (3.3)		10.2%	-1.64[-2.42,-0.86]
Lengacher 2009	40	5.6 (7.7)	43	10.2 (9.4)		17.25%	-0.53[-0.97,-0.09]
Lengacher 2014	154	8.1 (5.5)	146	8.8 (6.1)		22.56%	-0.12[-0.35,0.11]
Lerman 2012	34	0.6 (0.6)	14	0.8 (0.6)		12.94%	-0.28[-0.91,0.34]
Total ***	**384**		**361**			**100%**	**-0.54[-0.86,-0.22]**
Heterogeneity: Tau^2=0.11; Chi^2=18.42, df=5(P=0); I^2=72.85%							
Test for overall effect: Z=3.29(P=0)							



Analysis 1.5. Comparison 1 MBSR vs usual care (short-term), Outcome 5 Quality of sleep.

Study or subgroup	MBSR N	MBSR Mean(SD)	standard care N	standard care Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Bower 2015	35	6.5 (3.8)	30	8.7 (3.9)		23.89%	-0.57[-1.07,-0.07]
Johns 2014	18	7.7 (4.2)	17	12.8 (4.2)		17.23%	-1.18[-1.91,-0.46]
Lengacher 2009	40	1.9 (2.5)	42	2.1 (2.9)		26.07%	-0.07[-0.51,0.36]
Lengacher 2014	148	7.3 (4.5)	145	7.5 (4.1)		32.81%	-0.06[-0.29,0.17]
Total ***	**241**		**234**			**100%**	**-0.38[-0.79,0.04]**
Heterogeneity: Tau^2=0.12; Chi^2=10.89, df=3(P=0.01); I^2=72.44%							
Test for overall effect: Z=1.79(P=0.07)							

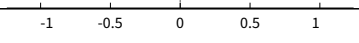


Comparison 2. MBSR vs usual care (medium-term)

Outcome or sub-group title	No. of studies	No. of partici-pants	Statistical method	Effect size
1 Quality of life	3		Std. Mean Difference (IV, Random, 95% CI)	Totals not selected
2 Fatigue	4	607	Std. Mean Difference (IV, Random, 95% CI)	-0.31 [-0.84, 0.23]
3 Anxiety	7	1094	Std. Mean Difference (IV, Random, 95% CI)	-0.28 [-0.49, -0.07]
4 Depression	7	1097	Std. Mean Difference (IV, Random, 95% CI)	-0.32 [-0.58, -0.06]
5 Quality of sleep	4	654	Std. Mean Difference (IV, Random, 95% CI)	-0.27 [-0.63, 0.08]

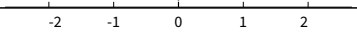
Analysis 2.1. Comparison 2 MBSR vs usual care (medium-term), Outcome 1 Quality of life.

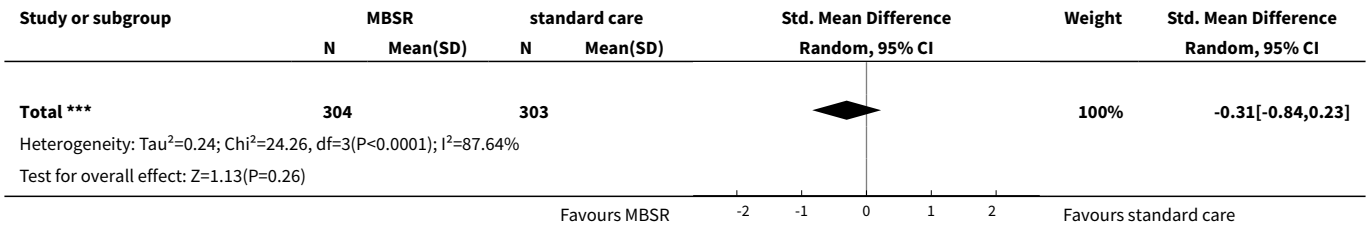
Study or subgroup	MBSR N	MBSR Mean(SD)	standard care N	standard care Mean(SD)	Std. Mean Difference Random, 95% CI	Std. Mean Difference Random, 95% CI
Henderson 2013	52	116.7 (15.1)	55	115.9 (14.8)		0.05[-0.33,0.43]
Hoffman 2012	101	103.8 (17.9)	106	96.2 (19.4)		0.4[0.13,0.68]
Kenne 2017	62	45.6 (11.6)	52	46.1 (13)		-0.05[-0.41,0.32]
Kenne 2017	62	46.7 (8.7)	52	46.4 (11.3)		0.03[-0.34,0.4]



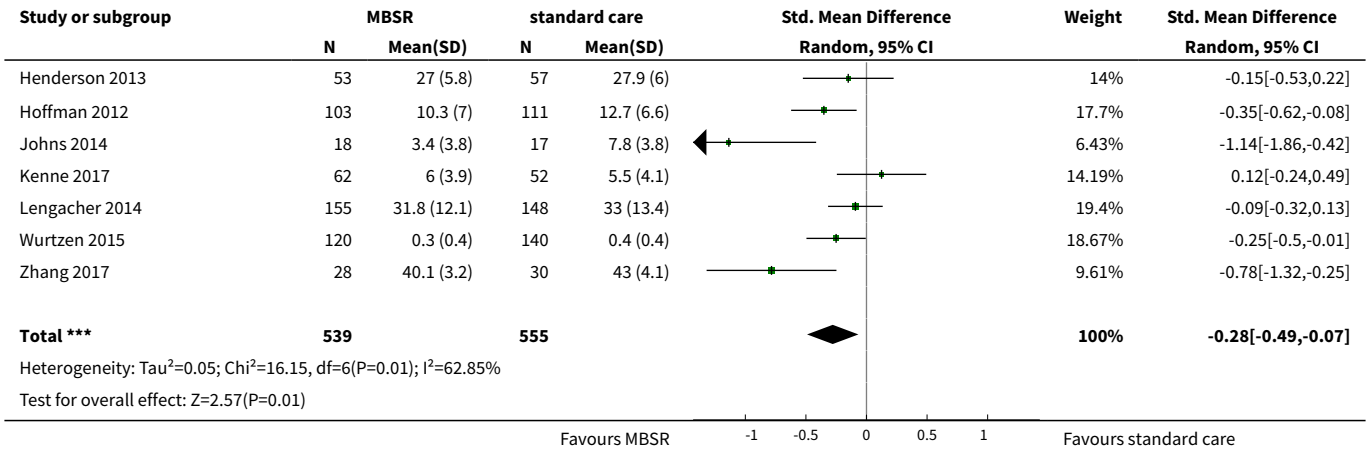
Analysis 2.2. Comparison 2 MBSR vs usual care (medium-term), Outcome 2 Fatigue.

Study or subgroup	MBSR N	MBSR Mean(SD)	standard care N	standard care Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Bower 2015	31	4.2 (1.5)	28	3.3 (1.4)		23.8%	0.58[0.06,1.1]
Hoffman 2012	103	9.3 (6.9)	111	11.4 (6.7)		28.62%	-0.31[-0.58,-0.04]
Johns 2014	18	3.2 (1.3)	17	5.5 (1.3)		18.32%	-1.74[-2.54,-0.95]
Lengacher 2014	152	12.2 (8.6)	147	13.3 (8.7)		29.26%	-0.12[-0.35,0.1]

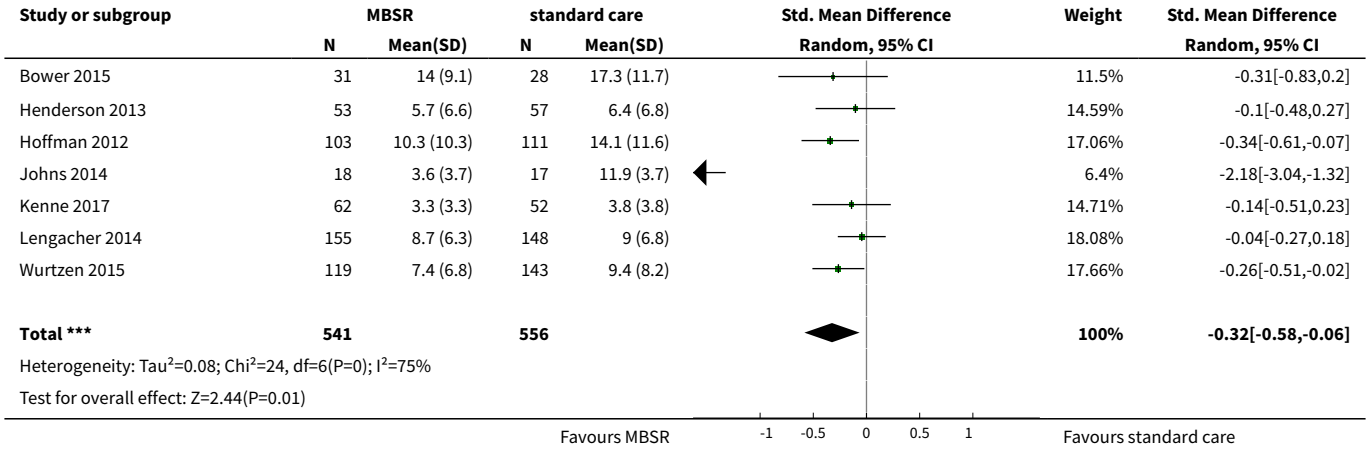




Analysis 2.3. Comparison 2 MBSR vs usual care (medium-term), Outcome 3 Anxiety.

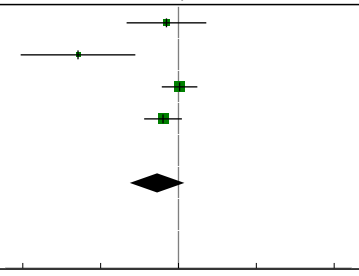


Analysis 2.4. Comparison 2 MBSR vs usual care (medium-term), Outcome 4 Depression.



Analysis 2.5. Comparison 2 MBSR vs usual care (medium-term), Outcome 5 Quality of sleep.

Study or subgroup	MBSR N	MBSR Mean(SD)	standard care N	standard care Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Bower 2015	31	7.3 (3.7)	28	7.9 (3.8)		20.99%	-0.15[-0.67,0.36]
Johns 2014	18	6.6 (5.1)	17	13.4 (5.1)		14.2%	-1.29[-2.03,-0.55]
Lengacher 2014	150	7.1 (4.4)	145	7 (4.1)		32.69%	0.01[-0.21,0.24]
Wurtzen 2015	122	26.5 (14.9)	143	29.6 (16)		32.13%	-0.2[-0.44,0.04]
Total ***	**321**		**333**			**100%**	**-0.27[-0.63,0.08]**
Heterogeneity: Tau²=0.08; Chi²=11.35, df=3(P=0.01); I²=73.57%							
Test for overall effect: Z=1.54(P=0.12)							



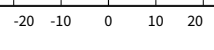
Favours MBSR — Favours standard care

Comparison 3. MBSR vs usual care (long-term)

Outcome or sub-group title	No. of studies	No. of partici-pants	Statistical method	Effect size
1 Quality of life	1	97	Mean Difference (IV, Random, 95% CI)	0.0 [-5.82, 5.82]
2 Anxiety	2	360	Std. Mean Difference (IV, Random, 95% CI)	-0.09 [-0.35, 0.16]
3 Depression	2	352	Std. Mean Difference (IV, Random, 95% CI)	-0.17 [-0.40, 0.05]

Analysis 3.1. Comparison 3 MBSR vs usual care (long-term), Outcome 1 Quality of life.

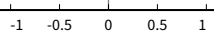
Study or subgroup	MBSR N	MBSR Mean(SD)	standard care N	standard care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Henderson 2013	48	119.3 (14.5)	49	119.3 (14.7)		100%	0[-5.82,5.82]
Total ***	**48**		**49**			**100%**	**0[-5.82,5.82]**
Heterogeneity: Not applicable							
Test for overall effect: Not applicable							



Favours standard care — Favours MBSR

Analysis 3.2. Comparison 3 MBSR vs usual care (long-term), Outcome 2 Anxiety.

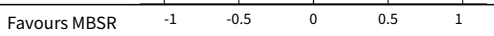
Study or subgroup	MBSR N	MBSR Mean(SD)	standard care N	standard care Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Henderson 2013	50	27.5 (5.7)	49	27 (5.6)		33.29%	0.09[-0.31,0.48]
Wurtzen 2015	120	0.4 (0.4)	141	0.5 (0.5)		66.71%	-0.19[-0.43,0.06]
Total ***	**170**		**190**			**100%**	**-0.09[-0.35,0.16]**
Heterogeneity: Tau²=0.01; Chi²=1.34, df=1(P=0.25); I²=25.1%							
Test for overall effect: Z=0.73(P=0.46)							



Favours MBSR — Favours standard care

Analysis 3.3. Comparison 3 MBSR vs usual care (long-term), Outcome 3 Depression.

Study or subgroup	MBSR N	MBSR Mean(SD)	standard care N	standard care Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Henderson 2013	50	6.5 (6.4)	49	6.5 (6.3)		30.46%	0[-0.39,0.39]
Wurtzen 2015	117	7.7 (7)	136	9.7 (8.8)		69.54%	-0.25[-0.5,-0]
Total ***	**167**		**185**			**100%**	**-0.17[-0.4,0.05]**
Heterogeneity: Tau^2=0; Chi^2=1.11, df=1(P=0.29); I^2=9.57%							
Test for overall effect: Z=1.51(P=0.13)							

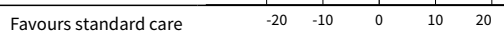


Comparison 4. Sensitivity analysis: low risk of bias for sequence generation (short-term)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quality of life	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
2 Fatigue	3	546	Std. Mean Difference (IV, Random, 95% CI)	-0.65 [-1.24, -0.06]
3 Anxiety	3	560	Std. Mean Difference (IV, Random, 95% CI)	-0.29 [-0.57, -0.00]
4 Depression	3	549	Std. Mean Difference (IV, Random, 95% CI)	-0.57 [-1.11, -0.04]
5 Quality of sleep	2	328	Std. Mean Difference (IV, Random, 95% CI)	-0.57 [-1.66, 0.53]

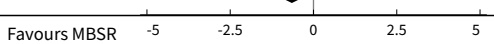
Analysis 4.1. Comparison 4 Sensitivity analysis: low risk of bias for sequence generation (short-term), Outcome 1 Quality of life.

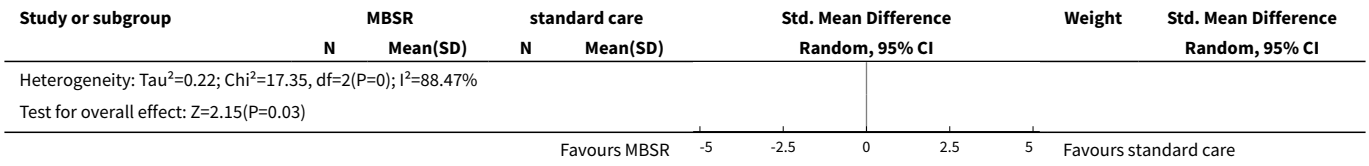
Study or subgroup	MBSR N	MBSR Mean(SD)	standard care N	standard care Mean(SD)	Mean Difference Random, 95% CI	Mean Difference Random, 95% CI
Hoffman 2012	101	103.6 (17.9)	106	96.8 (19.4)		6.72[1.64,11.8]



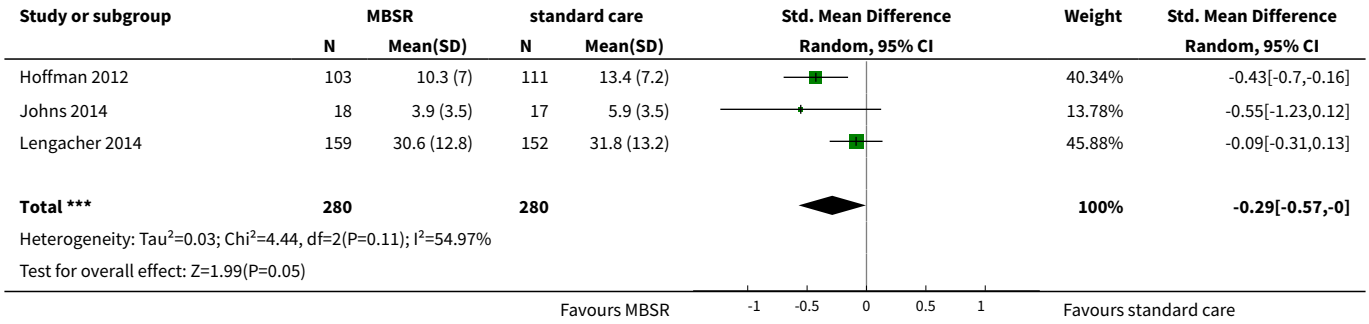
Analysis 4.2. Comparison 4 Sensitivity analysis: low risk of bias for sequence generation (short-term), Outcome 2 Fatigue.

Study or subgroup	MBSR N	MBSR Mean(SD)	standard care N	standard care Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Hoffman 2012	103	8.7 (6.1)	111	11.6 (7.2)		37.92%	-0.43[-0.71,-0.16]
Johns 2014	18	3 (1.3)	17	5.6 (1.3)		23.24%	-1.87[-2.67,-1.06]
Lengacher 2014	152	12.3 (7.6)	145	13.4 (8.5)		38.84%	-0.13[-0.36,0.1]
Total ***	**273**		**273**			**100%**	**-0.65[-1.24,-0.06]**

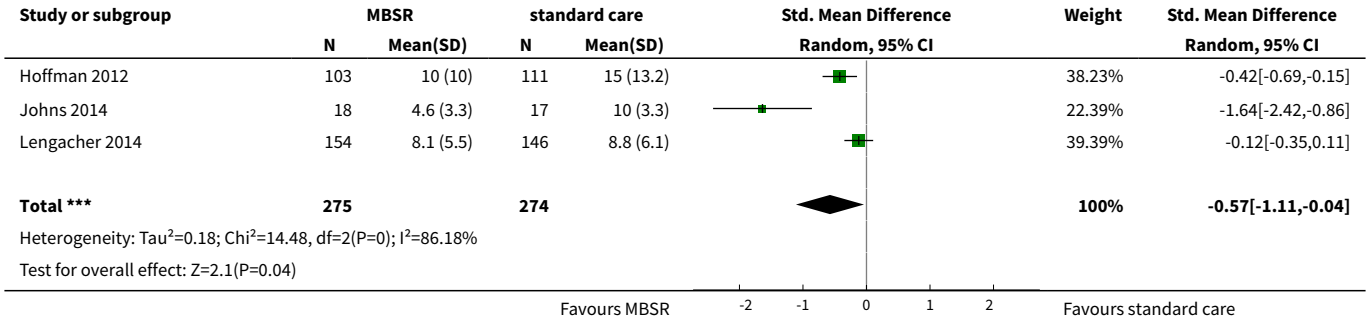




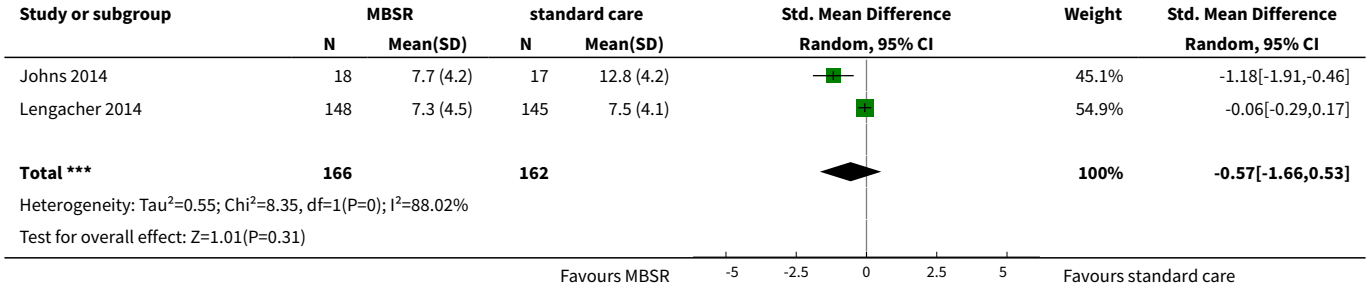
Analysis 4.3. Comparison 4 Sensitivity analysis: low risk of bias for sequence generation (short-term), Outcome 3 Anxiety.



Analysis 4.4. Comparison 4 Sensitivity analysis: low risk of bias for sequence generation (short-term), Outcome 4 Depression.



Analysis 4.5. Comparison 4 Sensitivity analysis: low risk of bias for sequence generation (short-term), Outcome 5 Quality of sleep.



Comparison 5. Sensitivity analysis: low risk of bias for sequence generation (medium-term)

Outcome or sub-group title	No. of studies	No. of partici-pants	Statistical method	Effect size
1 Quality of life	2		Std. Mean Difference (IV, Random, 95% CI)	Totals not selected
2 Fatigue	3	548	Std. Mean Difference (IV, Random, 95% CI)	-0.56 [-1.10, -0.01]
3 Anxiety	5	926	Std. Mean Difference (IV, Random, 95% CI)	-0.24 [-0.48, 0.00]
4 Depression	5	928	Std. Mean Difference (IV, Random, 95% CI)	-0.40 [-0.74, -0.05]
5 Quality of sleep	3	595	Std. Mean Difference (IV, Random, 95% CI)	-0.34 [-0.78, 0.11]

Analysis 5.1. Comparison 5 Sensitivity analysis: low risk of bias for sequence generation (medium-term), Outcome 1 Quality of life.

Study or subgroup	MBSR		standard care		Std. Mean Difference	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI	Random, 95% CI
Hoffman 2012	101	103.8 (17.9)	106	96.2 (19.4)		0.4[0.13,0.68]
Kenne 2017	62	46.7 (8.7)	52	46.4 (11.3)		0.03[-0.34,0.4]
Kenne 2017	62	45.6 (11.6)	52	46.1 (13)		-0.05[-0.41,0.32]

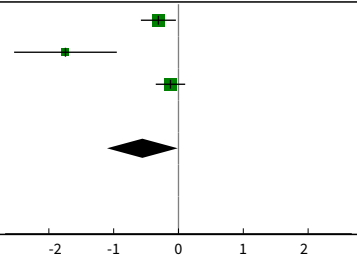
Favours standard care — Favours MBSR

Analysis 5.2. Comparison 5 Sensitivity analysis: low risk of bias for sequence generation (medium-term), Outcome 2 Fatigue.

Study or subgroup	MBSR		standard care		Std. Mean Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI		Random, 95% CI
Hoffman 2012	103	9.3 (6.9)	111	11.4 (6.7)		38.28%	-0.31[-0.58,-0.04]
Johns 2014	18	3.2 (1.3)	17	5.5 (1.3)		22.36%	-1.74[-2.54,-0.95]
Lengacher 2014	152	12.2 (8.6)	147	13.3 (8.7)		39.36%	-0.12[-0.35,0.1]
Total ***	**273**		**275**			**100%**	**-0.56[-1.1,-0.01]**

Heterogeneity: Tau^2=0.18; Chi^2=14.98, df=2(P=0); I^2=86.65%

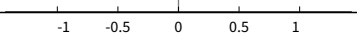
Test for overall effect: Z=2(P=0.05)



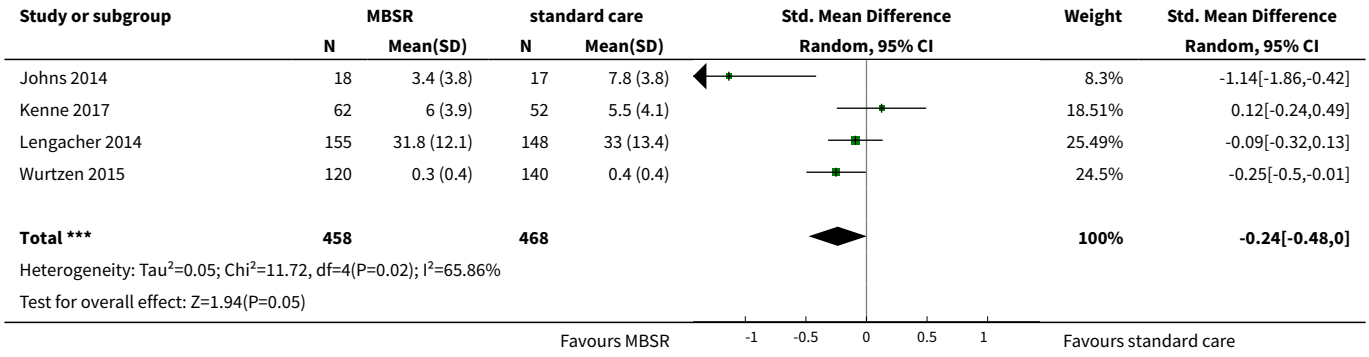
Favours MBSR — Favours standard care

Analysis 5.3. Comparison 5 Sensitivity analysis: low risk of bias for sequence generation (medium-term), Outcome 3 Anxiety.

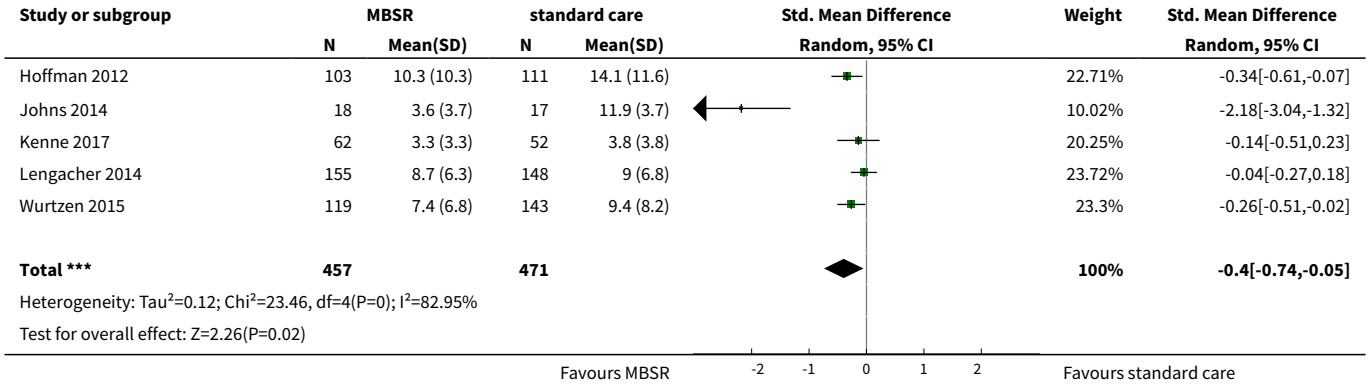
Study or subgroup	MBSR		standard care		Std. Mean Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI		Random, 95% CI
Hoffman 2012	103	10.3 (7)	111	12.7 (6.6)		23.21%	-0.35[-0.62,-0.08]



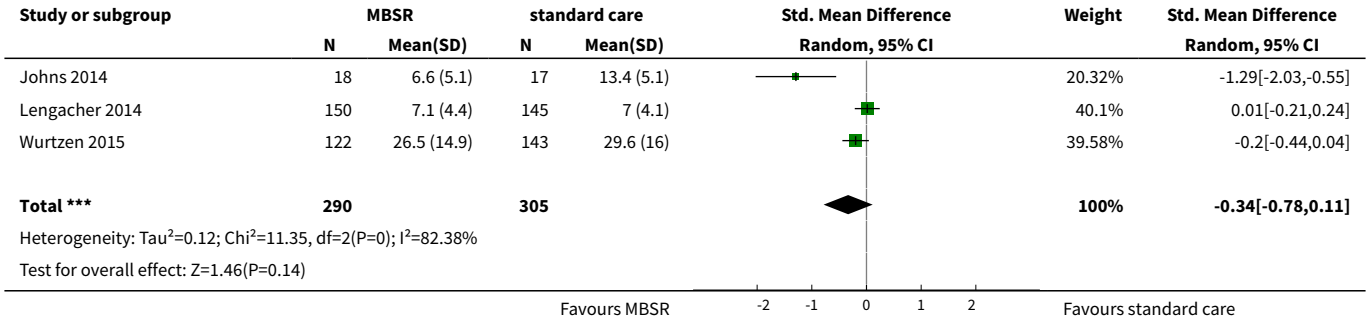
Favours MBSR — Favours standard care



Analysis 5.4. Comparison 5 Sensitivity analysis: low risk of bias for sequence generation (medium-term), Outcome 4 Depression.



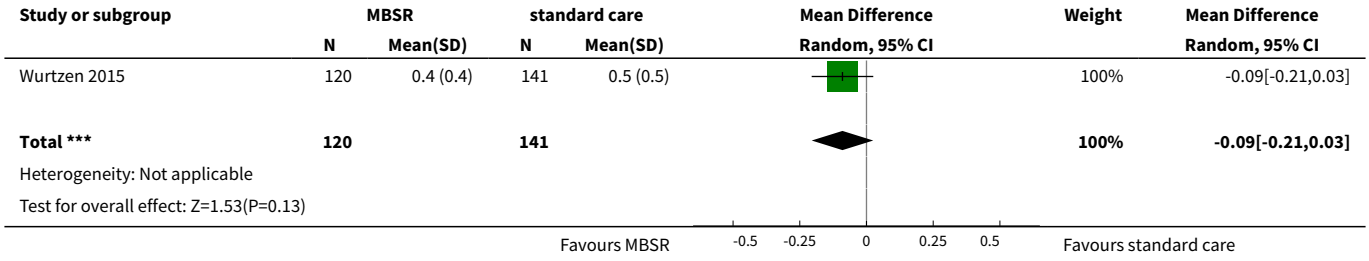
Analysis 5.5. Comparison 5 Sensitivity analysis: low risk of bias for sequence generation (medium-term), Outcome 5 Quality of sleep.



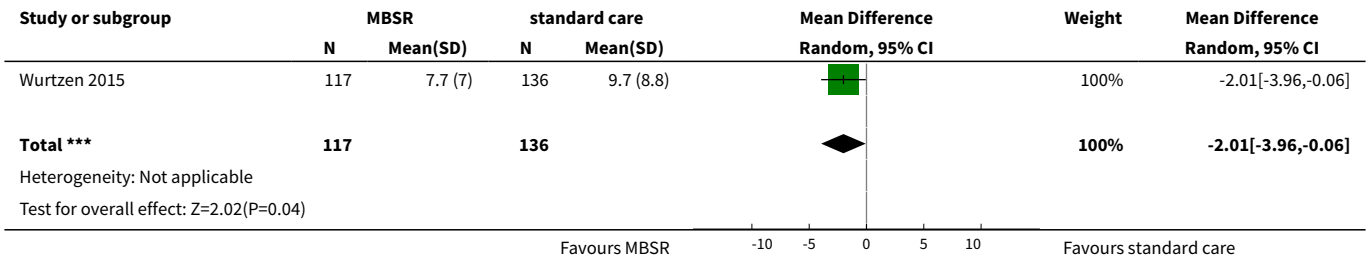
Comparison 6. Sensitivity analysis: low risk of bias for sequence generation (long-term)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Anxiety	1	261	Mean Difference (IV, Random, 95% CI)	-0.09 [-0.21, 0.03]
2 Depression	1	253	Mean Difference (IV, Random, 95% CI)	-2.01 [-3.96, -0.06]

Analysis 6.1. Comparison 6 Sensitivity analysis: low risk of bias for sequence generation (long-term), Outcome 1 Anxiety.



Analysis 6.2. Comparison 6 Sensitivity analysis: low risk of bias for sequence generation (long-term), Outcome 2 Depression.

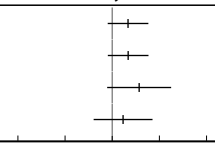


Comparison 7. Sensitivity analysis: unclear risk of bias for sequence generation (short-term)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quality of life	2		Std. Mean Difference (IV, Random, 95% CI)	Totals not selected
2 Fatigue	3	444	Std. Mean Difference (IV, Random, 95% CI)	-0.21 [-0.40, -0.02]
3 Anxiety	3	189	Std. Mean Difference (IV, Random, 95% CI)	-0.29 [-0.70, 0.12]
4 Depression	3	196	Std. Mean Difference (IV, Random, 95% CI)	-0.57 [-0.86, -0.28]
5 Quality of sleep	2	147	Std. Mean Difference (IV, Random, 95% CI)	-0.30 [-0.79, 0.18]

Analysis 7.1. Comparison 7 Sensitivity analysis: unclear risk of bias for sequence generation (short-term), Outcome 1 Quality of life.

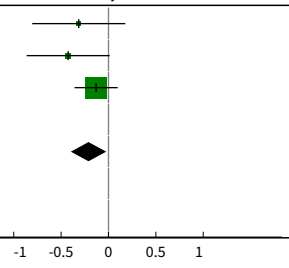
Study or subgroup	MBSR		standard care		Std. Mean Difference	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI	Random, 95% CI
Lengacher 2009	41	53.4 (10.9)	43	49.5 (12.2)		0.34[-0.1,0.77]
Lengacher 2009	41	50 (8.1)	43	46.7 (11.4)		0.34[-0.09,0.77]
Lerman 2012	31	76.4 (8.3)	12	70.6 (13.8)		0.57[-0.11,1.25]
Lerman 2012	34	83.1 (12)	14	80.3 (12.6)		0.23[-0.39,0.85]



Favours standard care | Favours MBSR

Analysis 7.2. Comparison 7 Sensitivity analysis: unclear risk of bias for sequence generation (short-term), Outcome 2 Fatigue.

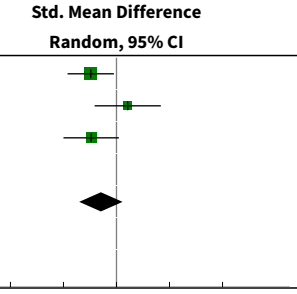
Study or subgroup	MBSR		standard care		Std. Mean Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI		Random, 95% CI
Bower 2015	35	3.6 (1.5)	30	4.1 (1.5)		14.5%	-0.31[-0.8,0.18]
Lengacher 2009	40	2 (2)	42	3 (2.6)		18.19%	-0.43[-0.86,0.01]
Lengacher 2014	152	12.3 (7.6)	145	13.4 (8.5)		67.31%	-0.13[-0.36,0.1]
Total ***	**227**		**217**			**100%**	**-0.21[-0.4,-0.02]**
Heterogeneity: Tau^2=0; Chi^2=1.57, df=2(P=0.46); I^2=0%							
Test for overall effect: Z=2.21(P=0.03)							



Favours MBSR | Favours standard care

Analysis 7.3. Comparison 7 Sensitivity analysis: unclear risk of bias for sequence generation (short-term), Outcome 3 Anxiety.

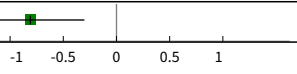
Study or subgroup	MBSR		standard care		Std. Mean Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI		Random, 95% CI
Lengacher 2009	41	28.4 (11.8)	42	33.9 (10.9)		39.74%	-0.49[-0.92,-0.05]
Lerman 2012	34	0.4 (0.6)	14	0.3 (0.3)		27.02%	0.21[-0.41,0.84]
Zhang 2017	28	41.7 (3.3)	30	43.5 (4.2)		33.24%	-0.48[-1,0.05]
Total ***	**103**		**86**			**100%**	**-0.29[-0.7,0.12]**
Heterogeneity: Tau^2=0.06; Chi^2=3.69, df=2(P=0.16); I^2=45.81%							
Test for overall effect: Z=1.41(P=0.16)							



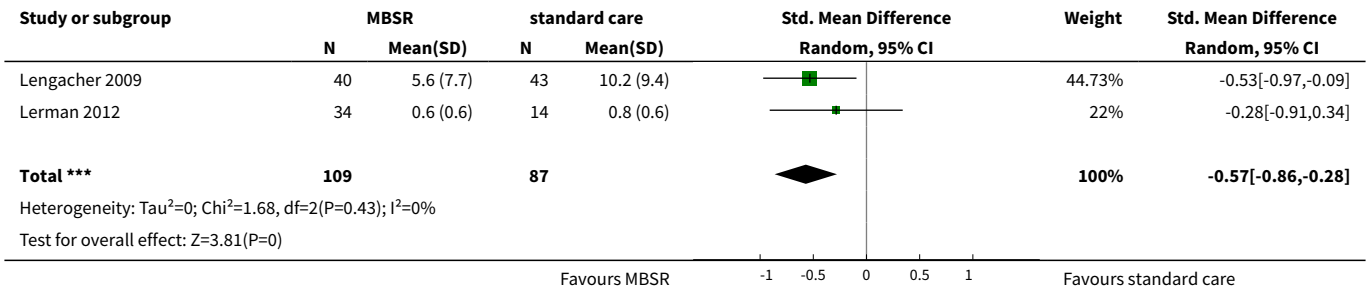
Favours MBSR | Favours standard care

Analysis 7.4. Comparison 7 Sensitivity analysis: unclear risk of bias for sequence generation (short-term), Outcome 4 Depression.

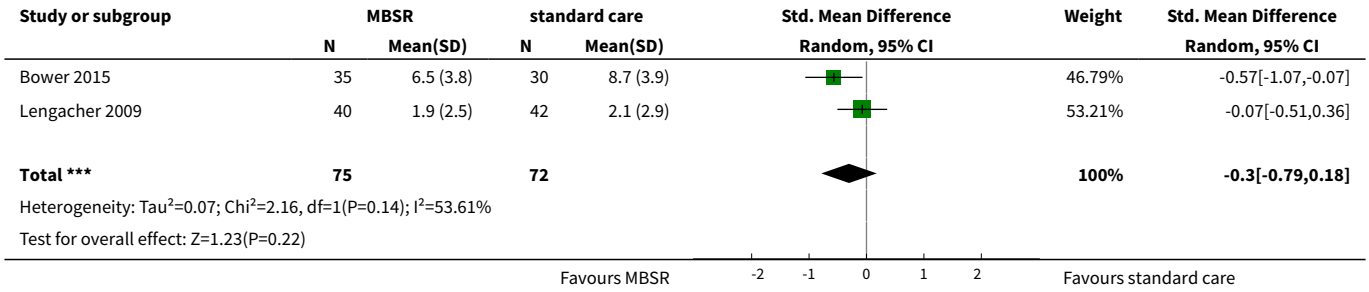
Study or subgroup	MBSR		standard care		Std. Mean Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI		Random, 95% CI
Bower 2015	35	10.1 (7.1)	30	17.7 (11.4)		33.27%	-0.81[-1.32,-0.3]



Favours MBSR | Favours standard care



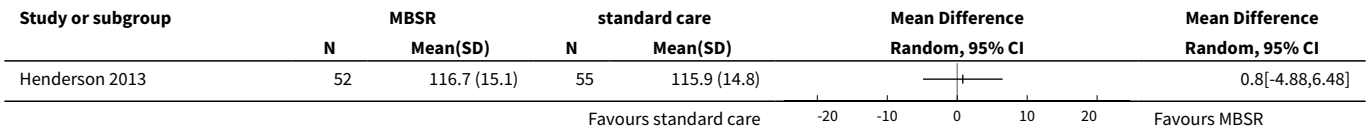
Analysis 7.5. Comparison 7 Sensitivity analysis: unclear risk of bias for sequence generation (short-term), Outcome 5 Quality of sleep.



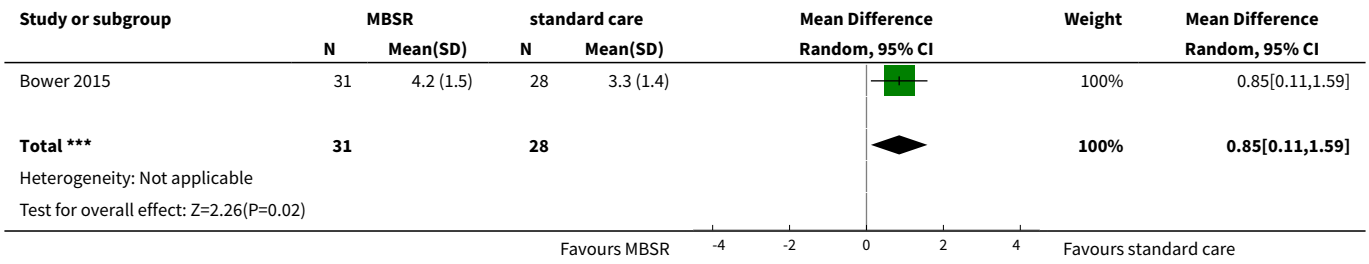
Comparison 8. Sensitivity analysis: unclear risk of bias for sequence generation (medium-term)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quality of life	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
2 Fatigue	1	59	Mean Difference (IV, Random, 95% CI)	0.85 [0.11, 1.59]
3 Anxiety	2	168	Std. Mean Difference (IV, Random, 95% CI)	-0.44 [-1.05, 0.18]
4 Depression	2	169	Std. Mean Difference (IV, Random, 95% CI)	-0.18 [-0.48, 0.13]
5 Quality of sleep	1	59	Mean Difference (IV, Random, 95% CI)	-0.59 [-2.52, 1.34]

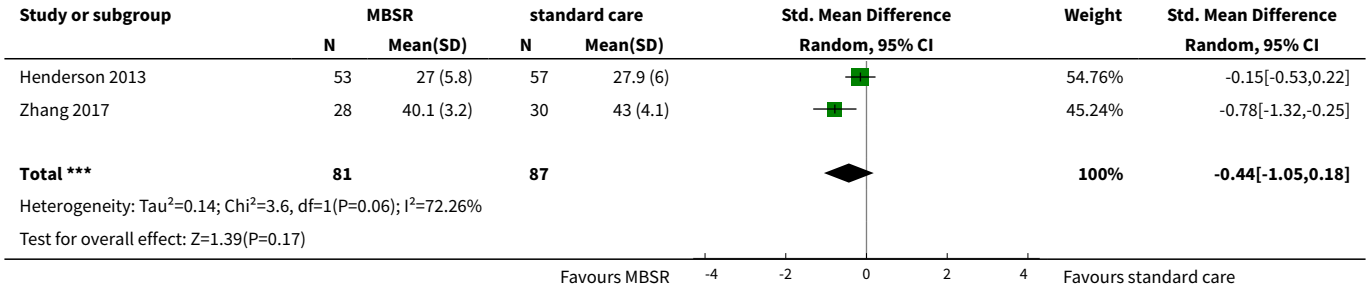
Analysis 8.1. Comparison 8 Sensitivity analysis: unclear risk of bias for sequence generation (medium-term), Outcome 1 Quality of life.



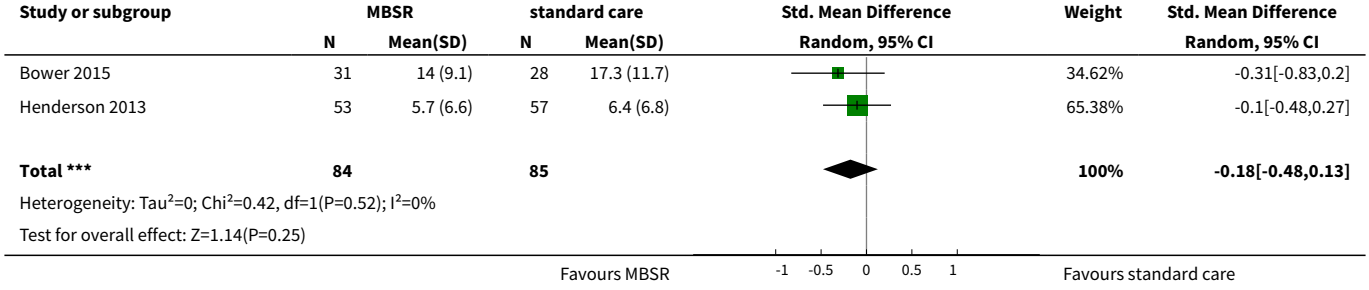
Analysis 8.2. Comparison 8 Sensitivity analysis: unclear risk of bias for sequence generation (medium-term), Outcome 2 Fatigue.



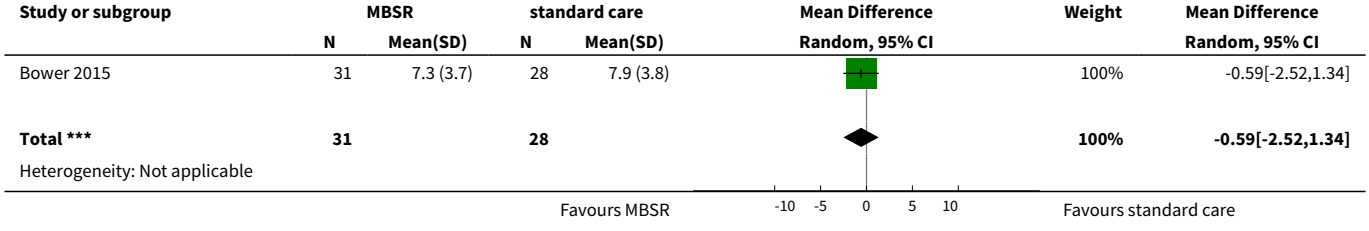
Analysis 8.3. Comparison 8 Sensitivity analysis: unclear risk of bias for sequence generation (medium-term), Outcome 3 Anxiety.

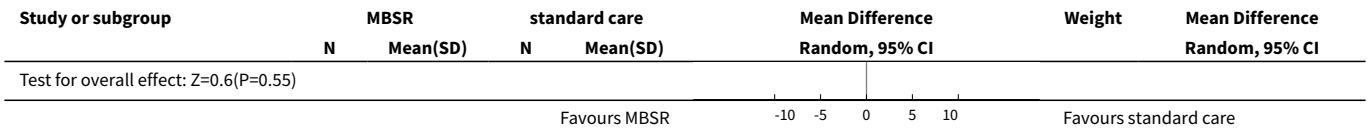


Analysis 8.4. Comparison 8 Sensitivity analysis: unclear risk of bias for sequence generation (medium-term), Outcome 4 Depression.



Analysis 8.5. Comparison 8 Sensitivity analysis: unclear risk of bias for sequence generation (medium-term), Outcome 5 Quality of sleep.

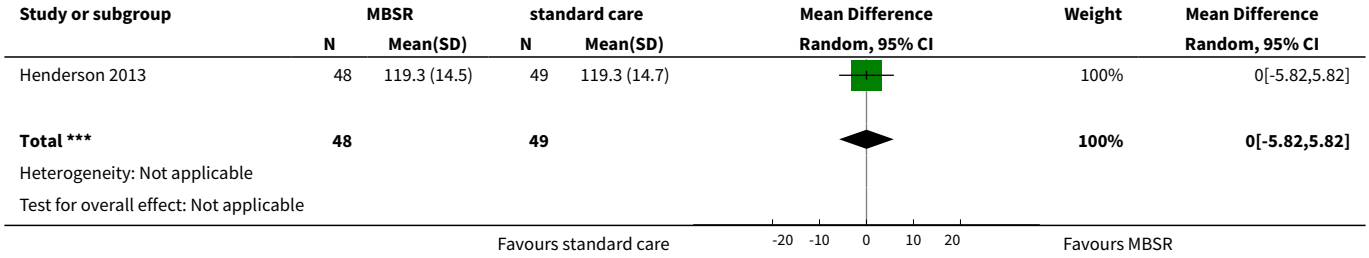




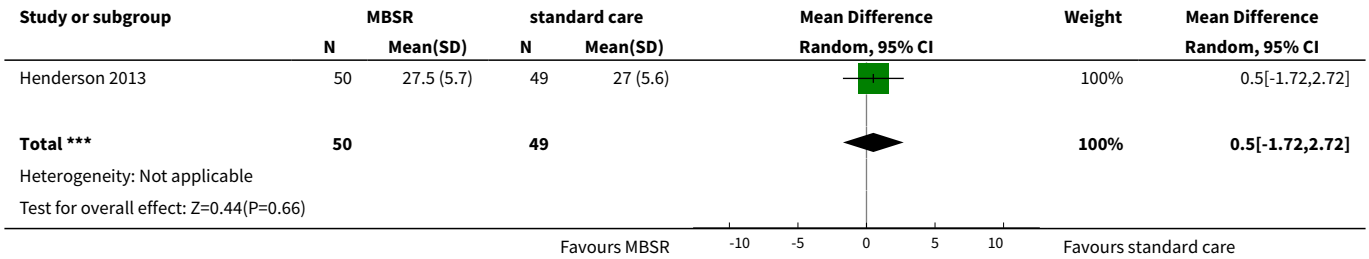
Comparison 9. Sensitivity analysis: unclear risk of bias for sequence generation (long-term)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quality of life	1	97	Mean Difference (IV, Random, 95% CI)	0.0 [-5.82, 5.82]
2 Anxiety	1	99	Mean Difference (IV, Random, 95% CI)	0.5 [-1.72, 2.72]
3 Depression	1	99	Mean Difference (IV, Random, 95% CI)	0.0 [-2.49, 2.49]

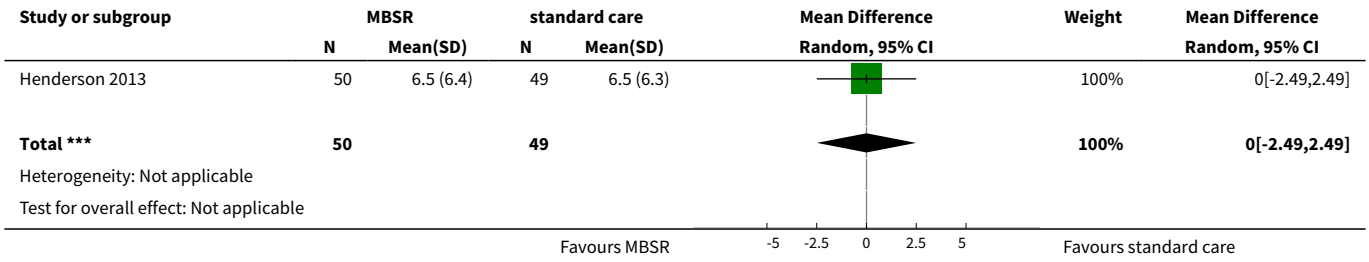
Analysis 9.1. Comparison 9 Sensitivity analysis: unclear risk of bias for sequence generation (long-term), Outcome 1 Quality of life.



Analysis 9.2. Comparison 9 Sensitivity analysis: unclear risk of bias for sequence generation (long-term), Outcome 2 Anxiety.



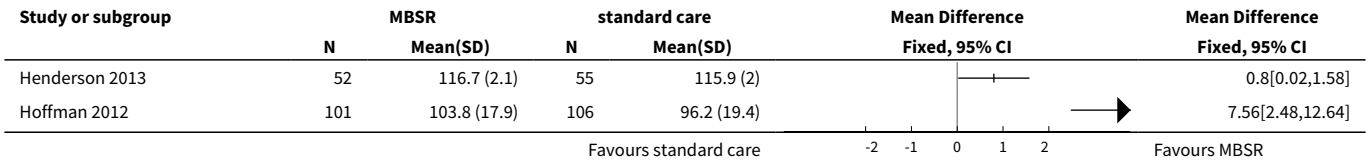
Analysis 9.3. Comparison 9 Sensitivity analysis: unclear risk of bias for sequence generation (long-term), Outcome 3 Depression.



Comparison 10. Sensitivity analysis: fixed effect model for QoL

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quality of life medium-term	2		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

Analysis 10.1. Comparison 10 Sensitivity analysis: fixed effect model for QoL, Outcome 1 Quality of life medium-term.

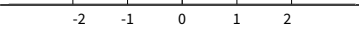


Comparison 11. Sensitivity analysis: no imputation of missing data (short-term)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quality of life	2		Std. Mean Difference (IV, Random, 95% CI)	Totals not selected
2 Fatigue	4	479	Std. Mean Difference (IV, Random, 95% CI)	-0.57 [-1.09, -0.05]
3 Anxiety	5	535	Std. Mean Difference (IV, Random, 95% CI)	-0.25 [-0.50, 0.01]
4 Depression	5	531	Std. Mean Difference (IV, Random, 95% CI)	-0.60 [-1.05, -0.16]

Analysis 11.1. Comparison 11 Sensitivity analysis: no imputation of missing data (short-term), Outcome 1 Quality of life.

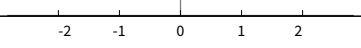
Study or subgroup	MBSR		standard care		Std. Mean Difference	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI	Random, 95% CI
Lengacher 2009	41	53.4 (10.9)	43	49.5 (12.2)		0.34[-0.1,0.77]
Lengacher 2009	41	50 (8.1)	43	46.7 (11.4)		0.34[-0.09,0.77]
Lerman 2012	31	76.4 (8.3)	12	70.6 (13.8)		0.57[-0.11,1.25]
Lerman 2012	34	83.1 (12)	14	80.3 (12.6)		0.23[-0.39,0.85]



Favours standard care | Favours MBSR

Analysis 11.2. Comparison 11 Sensitivity analysis: no imputation of missing data (short-term), Outcome 2 Fatigue.

Study or subgroup	MBSR		standard care		Std. Mean Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI		Random, 95% CI
Bower 2015	35	3.6 (1.5)	30	4.1 (1.5)		25.11%	-0.31[-0.8,0.18]
Johns 2014	18	3 (1.3)	17	5.6 (1.3)		18.2%	-1.87[-2.67,-1.06]
Lengacher 2009	40	2 (2)	42	3 (2.6)		26.3%	-0.43[-0.86,0.01]
Lengacher 2014	152	12.3 (7.6)	145	13.4 (8.5)		30.39%	-0.13[-0.36,0.1]
Total ***	**245**		**234**			**100%**	**-0.57[-1.09,-0.05]**
Heterogeneity: Tau^2=0.22; Chi^2=16.82, df=3(P=0); I^2=82.16%							
Test for overall effect: Z=2.14(P=0.03)							



Favours MBSR | Favours standard care

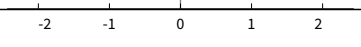
Analysis 11.3. Comparison 11 Sensitivity analysis: no imputation of missing data (short-term), Outcome 3 Anxiety.

Study or subgroup	MBSR		standard care		Std. Mean Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI		Random, 95% CI
Johns 2014	18	3.9 (3.5)	17	5.9 (3.5)		11.26%	-0.55[-1.23,0.12]
Lengacher 2009	41	28.4 (11.8)	42	33.9 (10.9)		20.95%	-0.49[-0.92,-0.05]
Lengacher 2014	159	30.6 (12.8)	152	31.8 (13.2)		38.45%	-0.09[-0.31,0.13]
Lerman 2012	34	0.4 (0.6)	14	0.3 (0.3)		12.78%	0.21[-0.41,0.84]
Zhang 2017	28	41.7 (3.3)	30	43.5 (4.2)		16.56%	-0.48[-1,0.05]
Total ***	**280**		**255**			**100%**	**-0.25[-0.5,0.01]**
Heterogeneity: Tau^2=0.03; Chi^2=6.43, df=4(P=0.17); I^2=37.76%							
Test for overall effect: Z=1.92(P=0.06)							

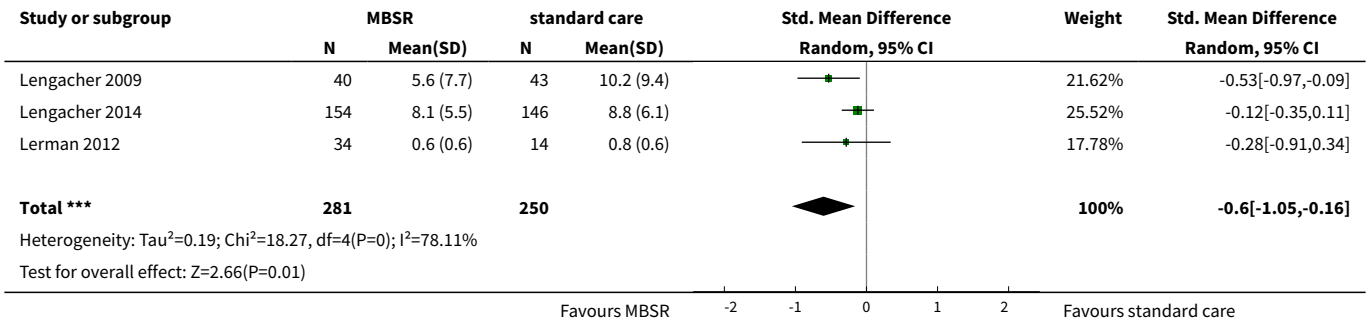
Favours MBSR | Favours standard care

Analysis 11.4. Comparison 11 Sensitivity analysis: no imputation of missing data (short-term), Outcome 4 Depression.

Study or subgroup	MBSR		standard care		Std. Mean Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI		Random, 95% CI
Bower 2015	35	10.1 (7.1)	30	17.7 (11.4)		20.16%	-0.81[-1.32,-0.3]
Johns 2014	18	4.6 (3.3)	17	10 (3.3)		14.92%	-1.64[-2.42,-0.86]



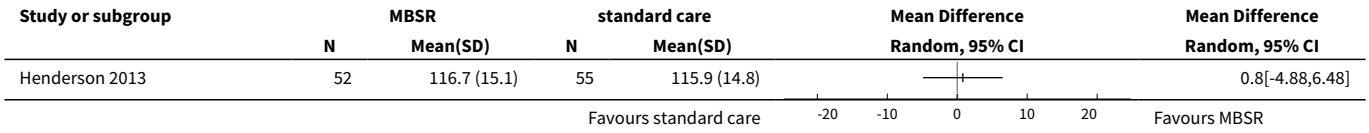
Favours MBSR | Favours standard care



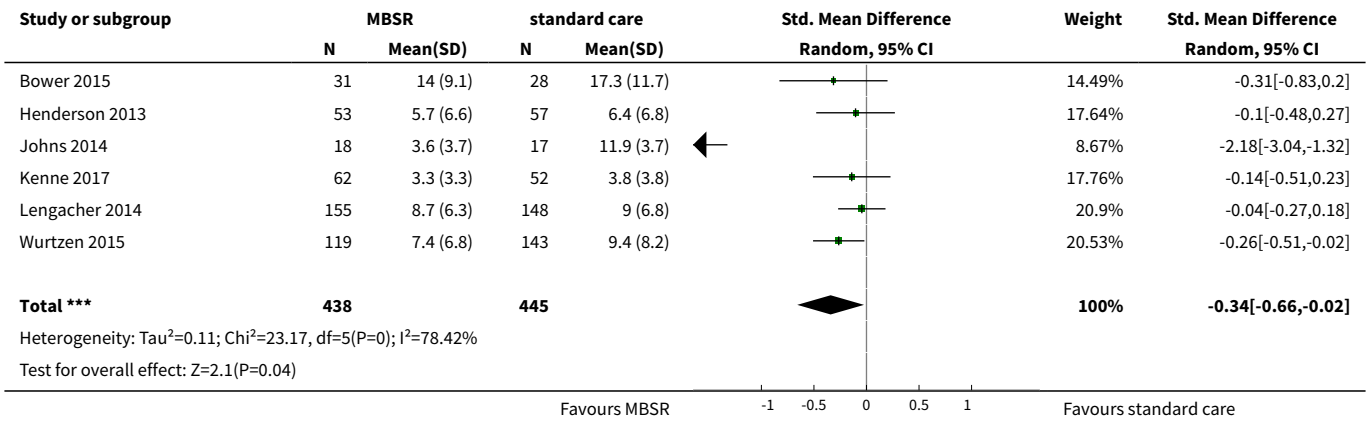
Comparison 12. Sensitivity analysis: no imputation of missing data (medium-term)

Outcome or sub-group title	No. of studies	No. of partici-pants	Statistical method	Effect size
1 Quality of life	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
2 Depression	6	883	Std. Mean Difference (IV, Random, 95% CI)	-0.34 [-0.66, -0.02]
3 Fatigue	3	393	Std. Mean Difference (IV, Random, 95% CI)	-0.37 [-1.32, 0.58]
4 Anxiety	6	880	Std. Mean Difference (IV, Random, 95% CI)	-0.27 [-0.53, -0.02]

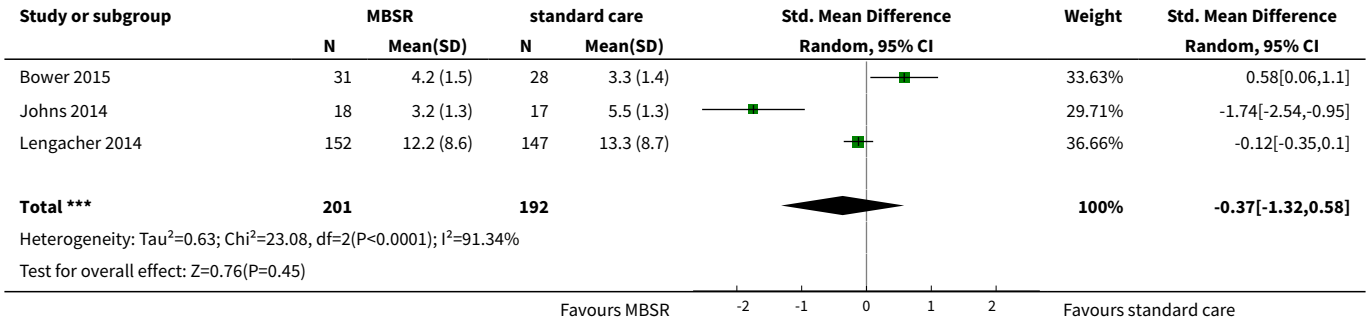
Analysis 12.1. Comparison 12 Sensitivity analysis: no imputation of missing data (medium-term), Outcome 1 Quality of life.



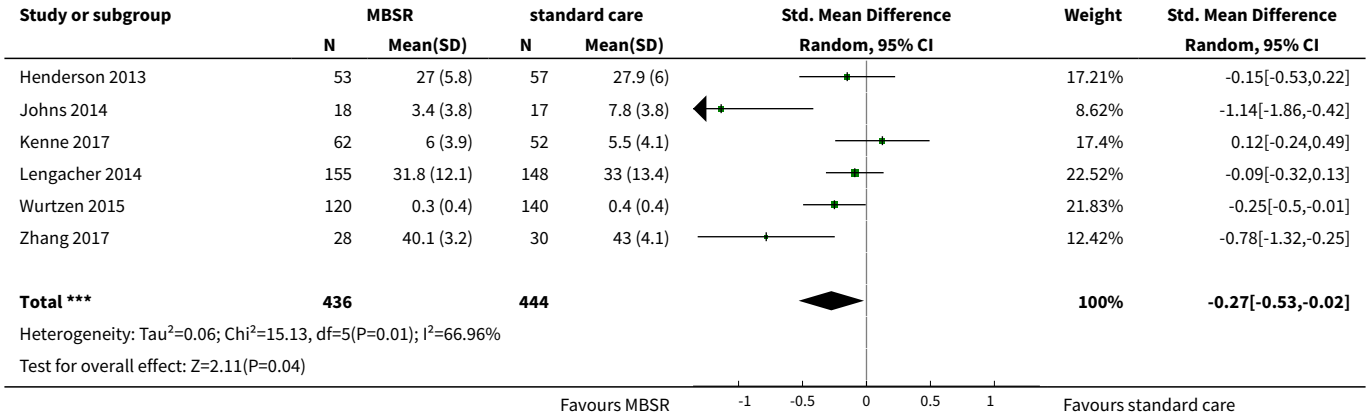
Analysis 12.2. Comparison 12 Sensitivity analysis: no imputation of missing data (medium-term), Outcome 2 Depression.



Analysis 12.3. Comparison 12 Sensitivity analysis: no imputation of missing data (medium-term), Outcome 3 Fatigue.



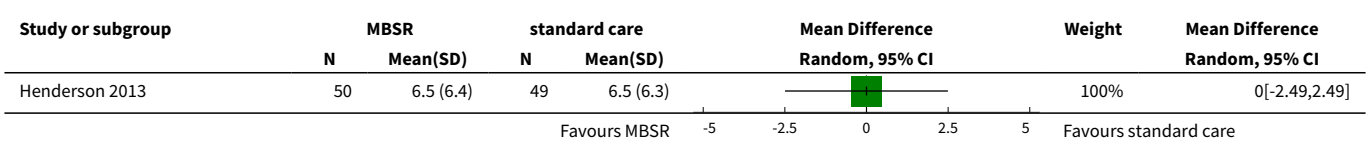
Analysis 12.4. Comparison 12 Sensitivity analysis: no imputation of missing data (medium-term), Outcome 4 Anxiety.

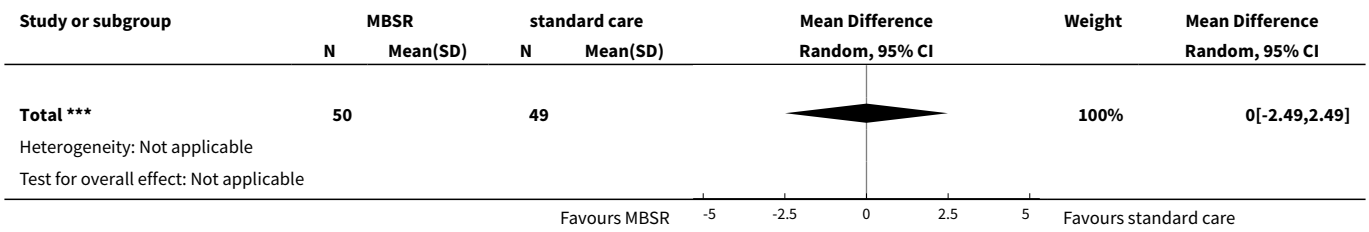


Comparison 13. Sensitivity analysis: < 30% missing data from participants

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Depression long-term	1	99	Mean Difference (IV, Random, 95% CI)	0.0 [-2.49, 2.49]

Analysis 13.1. Comparison 13 Sensitivity analysis: < 30% missing data from participants, Outcome 1 Depression long-term.

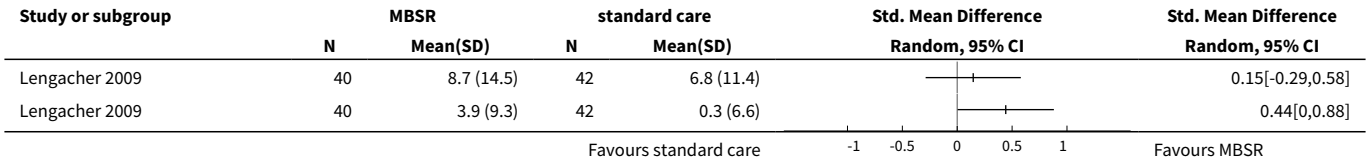




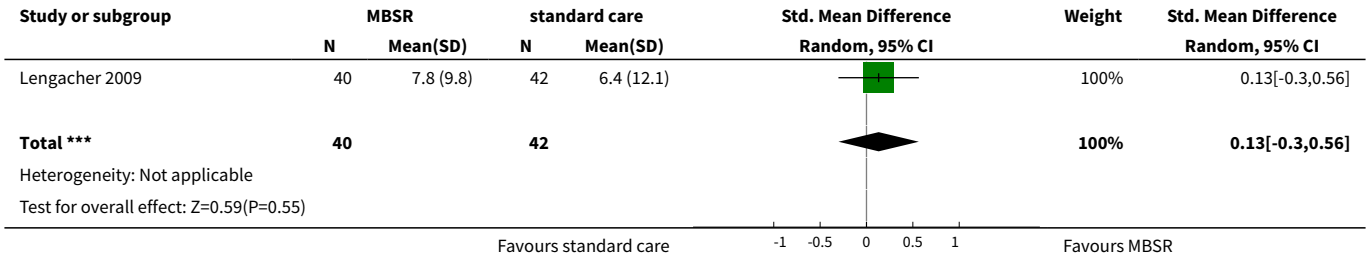
Comparison 14. Sensitivity analysis: change data (short-term)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quality of life	1		Std. Mean Difference (IV, Random, 95% CI)	Totals not selected
2 Anxiety	1	82	Std. Mean Difference (IV, Random, 95% CI)	0.13 [-0.30, 0.56]
3 Depression	1	82	Std. Mean Difference (IV, Random, 95% CI)	0.41 [-0.03, 0.85]
4 Quality of sleep	1	276	Std. Mean Difference (IV, Random, 95% CI)	-0.41 [-0.65, -0.18]

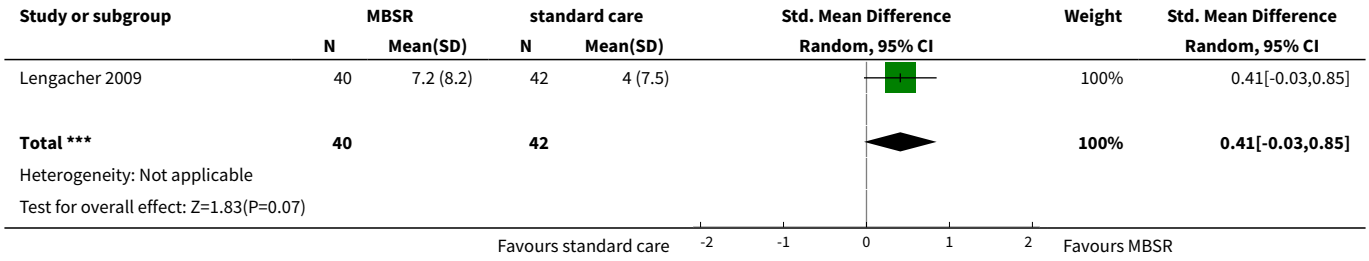
Analysis 14.1. Comparison 14 Sensitivity analysis: change data (short-term), Outcome 1 Quality of life.



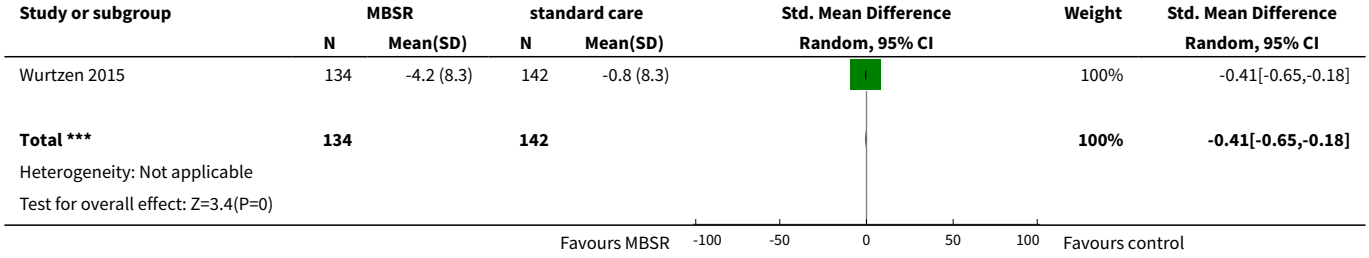
Analysis 14.2. Comparison 14 Sensitivity analysis: change data (short-term), Outcome 2 Anxiety.



Analysis 14.3. Comparison 14 Sensitivity analysis: change data (short-term), Outcome 3 Depression.



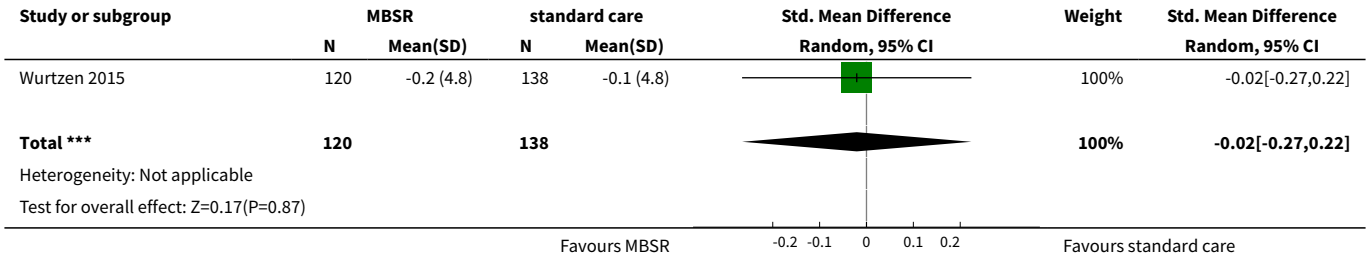
Analysis 14.4. Comparison 14 Sensitivity analysis: change data (short-term), Outcome 4 Quality of sleep.



Comparison 15. Sensitivity analysis: change data (long-term)

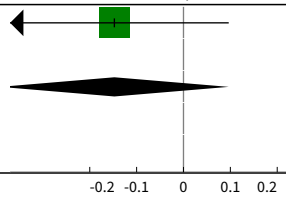
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Anxiety	1	258	Std. Mean Difference (IV, Random, 95% CI)	-0.02 [-0.27, 0.22]
2 Depression	1	259	Std. Mean Difference (IV, Random, 95% CI)	-0.15 [-0.39, 0.10]

Analysis 15.1. Comparison 15 Sensitivity analysis: change data (long-term), Outcome 1 Anxiety.



Analysis 15.2. Comparison 15 Sensitivity analysis: change data (long-term), Outcome 2 Depression.

Study or subgroup	MBSR		standard care		Std. Mean Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI		Random, 95% CI
Wurtzen 2015	126	-3.3 (9.6)	133	-1.8 (9.6)		100%	-0.15[-0.39,0.1]
Total ***	**126**		**133**			**100%**	**-0.15[-0.39,0.1]**
Heterogeneity: Not applicable							
Test for overall effect: Z=1.18(P=0.24)							



ADDITIONAL TABLES

Table 1. Subgroup allocation of studies

Subgroup	Bower 2015	Henderson 2013	Hoffman 2012	Johns 2014	Kenne 2017	Lengacher 2009	Lengacher 2014	Lerman 2012	Wurtzen 2015	Zhang 2017
Mean age										
< 40 years										
> 40 years	x	x	x	x	x	x[a]	x	x	x	x
< 60 years	x	x	x	x	x		x	x	x	x
> 60 years										
Stage										
Early BC	x	x	x	x[b]	x	x	x		x	x
Metastatic BC										
Unclear								x		
Type of BC										
ER-positive					x					
ER-negative										
Unclear/less than 80% in either category	x	x	x	x		x	x	x	x	x
MBSR during or after active[c] therapy										
During active therapy										
After active therapy	x		x	x	x	x	x			
Unclear/less than 80% in either category		x						x[d]	x	x
Concomitant therapies										

Table 1. Subgroup allocation of studies *(Continued)*

Chemotherapy										
Radiotherapy										
Neither	x		x	x	x	x	x			
Less than 80% in each category		x						x[d]	x	x

BC: breast cancer; **ER**: oestrogen receptor;**MBSR**: mindfulness-based stress reduction; **UC**: usual care.

[a]No data on mean age; allocation to subgroup derived from percentages for age categories.
[b]The stages for breast cancer only are not reported; however, even the maximum participants (n = 2) with stage IV still results in less than 20%.
[c]Active therapy was defined as active anticancer therapy like radiotherapy and chemotherapy (not endocrine therapy).
[d]"Potential participants were excluded if they had not completed their cancer treatments ... Those who were on maintenance chemotherapy, were accepted if their treatment or disease was not expected to limit participation."

Table 2. Characteristics of included participants

Study		N randomised	Stage	Age in years (mean ± SD)	Time since diagnosis (mean ± SD)	% receiving concomitant therapy	% with at least some college education	Other information
Bower 2015	MBSR	39	Stage I to III	46 (28 to 60)[a]	4.0 ± 2.4 years	No[b]	87%[c]	Currently on ET (% of pts): MBSR: 62% UC: 66%
	UC	32		48 (31 to 60)[a]	4.1 ± 2.3 years		78%[c]	
Henderson 2013	MBSR	53[d]	I (55%[c]) II (45%[c])	49.8 ± 8.4[e]	0-6 months: 14 pts 7-12 months: 16 pts > 12 months: 21 pts	CT (% of pts[c]) before study: 34% during study: 13%	83%[c]	—
	UC	58[d]	I (52%[c]) II (48%[c])		0-6 months: 20 pts	CT (% of pts[c]) Before study: 36% During study: 12%	74%[c]	

Table 2. Characteristics of included participants *(Continued)*

					7-12 months: 13 pts > 12 months: 24 pts			
Hoffman 2012	MBSR	114	0 (10%[c]) I (30%[c]) II (41%[c]) III (19%[c])	49.0[f]	17.44 ± 13 months	No[b]	74%[g]	—
	UC	115	0 (5%[c]) I (39%[c]) II (41%[c]) III (15%[c])	50.1[f]	18.98 ± 15 months		78%[g]	
Johns 2014	MBSR	18	Cancer (83% BC) I (28%[c]) II (28%[c]) III (22%[c]) IV (11%[c])	59 ± 9	—	No[b]	67%	Recent mental health treatment: 5%
	UC	17	Cancer (83% BC) I (41%[c]) II (41%[c]) III (12%[c]) IV (6%[c])	56 ± 9			77%	Recent mental health treatment: 41%
Johnson 2015	*No information available*							
Kenne 2017	MBSR	66	Early stage BC	57.2[f]	—	No[b]	69%[c,h]	—
	UC	51					77%[c,h]	
Koumarianou 2014	No information available							
Lengacher 2009	MBSR	41	0 (12%) I (63%) II (17%) III (7%)	< 55: 44% 55-64: 22% > 65: 34%	—	No[b]	88%[c]	Antidepressants: 22% Anxiolytics: 17%

Table 2. Characteristics of included participants *(Continued)*

	UC	34	0 (21%) I (44%) II (28%) III (7%)	< 55: 35% 55-64: 44% > 65: 21%			79%[c]	Antidepressants: 28% Anxiolytics: 12%
Lengacher 2014	MBSR	167	0 (13%) I (32%) II (37%) III (19%)	56.6[c]	—	No[b]	82%[c]	Antidepressants: 14% Anxiolytics: 18%
	UC	155	0 (12%) I (36%) II (35%) III (17%)				83%[c]	antidepressants: 9% anxiolytics: 10%
Lerman 2012	MBSR	53	Cancer[i]	58 ± 11	3.9 ± 5.1 years	Unclear	83%[c]	—
	UC	24		57 ± 10	3.7 ± 3.5 years		75%[c]	
Shapiro 2003	MBSR	31	No information available					
	UC	32						
Wurtzen 2015	MBSR	168	I (30%) II (65%) III (5%)	54 ± 10	7.5 ± 5.0 months	RT (74%) CT (46%)	77%[e]	ET: 54% of pts Use of subsidised psychologist sessions: 18%
	UC	168	I (38%) II (60%) III (2%)	54 ± 11	7.9 ± 5.1 months	RT (86%) CT (49%)		ET: 52% of pts Use of subsidised psychologist sessions: 24%
Zaidi 2015	No information available							
Zhang 2017	MBSR	30	I (10%[c]) II (91%[c]) III (17%[c])	48.7 ± 8.5	—	RT or CT (60%[c]) RT and CT (40%[c])	30%[c]	—
	UC	30	I (17%[c]) II (70%[c]) III (13%[c])	46 ± 5.1		RT or CT (73%[c])	20%[c]	

Table 2. Characteristics of included participants *(Continued)*

						RT and CT (27%[c])				

BC: breast cancer; **CT**: chemotherapy; **ET**: endocrine therapy; **MBSR**: mindfulness-based stress reduction; **pts**: participants; **RT**: radiation; **SD**: standard deviation; **UC**: usual care.

[a]Mean, range.
[b]See Characteristics of included studies for exclusion criteria.
[c]Calculated by review author (LS).
[d]Patients analysed.
[e]Not reported per arm respectively.
[f]SD not reported.
[g]Social grade: AB ("higher and intermediate managerial/ administrative/professional"), ranging from AB to E (no data on college attendance).
[h]At least some additional education after secondary school.
[i]Data available for breast cancer patients only (34/48 of analysed patients in MBSR group, 14/20 of analysed participants in control group)
.

Table 3. Selected time points for outcomes

Assessment time points[a]	Bower 2015	Hender-son 2013	Hoffman 2012	Johns 2014	Kenne 2017	Lengach-er 2009	Lengach-er 2014	Lerman 2012	Wurtzen 2015	Zhang 2017
Short-term analysis										
End of intervention	**FT**, **DE**, **SL**	—	—	**FT**, **AX**, **DE**, **SL**	—	**QoL**, **FT**, **AX**, **DE**, **SL**	**FT**, **AX**, **DE**, **SL**	**QoL**, **AX**, **DE**	—	**AX**
8 to 12 weeks from baseline	—	—	**QoL**, **FT**, **AX**, **DE**	—	—	—	—	—	—	—
Medium-term analysis										
12 to 14 weeks from baseline	—	—	**QoL**, **FT**, **AX**, **DE**	—	—	—	—	—	—	—
12 weeks from baseline	—	—	—	—	—	—	**FT**, **AX**, **DE**, **SL**	—	—	—
1 month after intervention	—	—	—	**FT**, **AX**, **DE**, **SL**	**QoL**,**AX**, **DE**	—	—	—	—	—

Table 3. Selected time points for outcomes *(Continued)*

2 months from baseline	—	—	—	—	—	—	—	—	AX, DE, SL	—
3 months after intervention	**FT**, **DE**, **SL**	—	—	—	—	—	—	—	—	**AX**
4 months from baseline[b]	—	**QoL**, **AX**, **DE**	—	—	—	—	—	—	—	—
6 months from baseline	—	—	—	—	—	—	—	—	**AX**, **DE**, **SL**	—
Long-term analysis										
12 months from baseline	—	QoL, AX, DE	—	—	—	—	—	—	**AX**, **DE**[c], —[d]	—
24 months from baseline	—	**QoL**, **AX**, **DE**	—	—	—	—	—	—	—	—

AX: anxiety; **DE**: depression; **FT**: fatigue; **QoL**: quality of life; **SL**: quality of sleep

[a]Selected time points for an outcome are marked in **bold.**
[b]End of intervention for Henderson 2013.
[c]At 12 months, fewer than 70% of randomised participants were evaluated for depression in the study Wurtzen 2015.
[d]No SD for quality of sleep reported (neither obtainable from Haller 2017)

Table 4. Questionnaires used

Questionnaire	Score reported	Higher scores #	Maximum score	MID	Comment
Beck Anxiety Inventory (BAI)	Global score	Anxiety ↑	63 (Mapi Research Trust)	—	—
Beck Depression Inventory (BDI)	Global score	Depression ↑	63 (Mapi Research Trust)	—	—
Center for Epidemiological Studies Depression Scale (CES-D)	Global score	Depression ↑	60 (Vilagut 2016)	—	Depending on the test objectives, a cut-off of 16 or 20 for depression may be adequate (Vilagut 2016)
EORTC Quality of Life Questionnaire - Core Questionnaire (EORTC QLQ-30)	Overall combined score	QoL ↑	100 (Cortes 2015)	—	—
EORTC Quality of Life Questionnaire - Breast Cancer Module (EORTC QLQ-30 BR23)	Overall combined score	QoL ↑	100 (Cortes 2015)	10[a] (Cortes 2015)	—
Functional Assessment of Cancer Therapy - Breast Cancer (FACT-B)	Global score	QoL ↑	148 (FACT-B Scoring Guidelines)	7-8 points (Eton 2004)	—
Fatigue Symptom Inventory (FSI)	Subscale severity	Fatigue ↑	Unclear	—	
Generalized Anxiety Disorder - 7 (GAD-7)	Global score	Anxiety ↑	21 (Spitzer 2006)	—	
Hospital Anxiety and Depression Scale (HADS)	Domain anxiety	Anxiety ↑	21 (Stern 2014)	—	a cutoff of 5 is recommended for early breast cancer (Love 2002)
	Domain depression	Depression ↑	21 (Stern 2014)	—	
Insomnia Severity Index (ISI)	Global score	Insomnia ↑	28 (Morin 2011)	—	—
MD Anderson Symptom Inventory (MDASI)	Item fatigue	Fatigue ↑	10 (Mapi Research Trust)	—	—
	Item disturbed sleep	Disturbed sleep ↑	10 (Mapi Research Trust)	—	—
Medical Outcome Study Sleep Scale (MOSS)	Sleep problem index II	Disturbed sleep ↑	unclear	—	—
Patient Health Questionnaire-8 (PHQ-8)	Global score	Depression ↑	27 (Kroenke 2001)	—	—
Profile of Mood States (POMS)	Subscale fatigue/inertia	Fatigue ↑	28 (Mapi Research Trust)	—	—

Table 4. Questionnaires used *(Continued)*

	Subscale tension/anxiety	Anxiety ↑	36 (Mapi Research Trust)	—	—
	Subscale tension/depression	Depression ↑	60 (Mapi Research Trust)	—	—
Pittburgh Sleep Quality Index (PSQI)	Global score	Disturbed sleep ↑	21 (Buysse 1989)	—	—
Symptom Checklist-90-Revised (SLC-90-R)	Subscale anxiety	Anxiety ↑	Unclear	—	—
	Subscale depression	Depression ↑	Unclear	—	—
SF-36	Mental Composite Score (MCS)	QoL ↑	100 (Lemieux 2018)	5 (Grunfeld 2006)	—
	Physical Component Score (PCS)	QoL ↑	100 (Lemieux 2018)	5 (Grunfeld 2006)	—
State-Trait Anxiety Inventory (STAI)	Subscale state	Anxiety ↑	60 (Tuncer 2014)	—	—

MID: minimally important difference; **QoL**: quality of life.

[a]"Because there are not any published MIDs on the QLQ-BR23, a 10-point change was considered consistent with previous estimates."

APPENDICES

Appendix 1. CENTRAL search strategy

ID	Search
#1	MeSH descriptor: [Breast Neoplasms] explode all trees
#2	breast near cancer*
#3	breast near neoplasm*
#4	breast near carcinom*
#5	breast near tumour*
#6	breast near tumor*
#7	breast near malignan*
#8	#1 or #2 or #3 or #4 or #5 or #6 or #7
#9	MeSH descriptor: [Mind-Body Therapies] explode all trees
#10	body-mind*

(Continued)

#11	mind-body*
#12	(mind-body near/3 (program* or therap* or medicin*))
#13	#9 or #10 or #11 or #12
#14	mindfulness based stress reduction*
#15	mindfulness based*
#16	mbsr* or mbct*
#17	MeSH descriptor: [Meditation] explode all trees
#18	meditation*
#19	MeSH descriptor: [Relaxation Therapy] explode all trees
#20	(relaxation* near/2 (technique* or therap*))
#21	#13 or #14 or #15 or #16 or #17 or #18 or #19 or #20
#22	#8 and #21 in Trials

Appendix 2. CENTRAL search strategy 04/2018

#1	MeSH descriptor: [Breast Neoplasms] explode all trees
#2	MeSH descriptor: [Neoplasms, Ductal, Lobular, and Medullary] explode all trees
#3	MeSH descriptor: [Fibrocystic Breast Disease] explode all trees
#4	#1 or #2 or #3
#5	MeSH descriptor: [Breast] explode all trees
#6	breast
#7	#5 or #6
#8	breast near milk
#9	breast near tender*
#10	#8 or #9
#11	#7 not #10
#12	MeSH descriptor: [Neoplasms] explode all trees
#13	#11 and #12

(Continued)

#14	MeSH descriptor: [Lymphedema] explode all trees
#15	#14 and #11
#16	breast near/25 neoplasm*
#17	breast near/25 cancer*
#18	breast near/25 tumour
#19	breast near/25 tumor*
#20	breast near/25 carcinoma*
#21	breast near/25 adenocarcinoma*
#22	breast near/25 sarcoma*
#23	breast near/50 dcis
#24	breast near/25 ductal
#25	breast near/25 infiltrating
#26	breast near/25 intraductal
#27	breast near/25 lobular
#28	breast near/25 medullary
#29	#16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28
#30	#4 or #13 or #15 or #29
#31	MeSH descriptor: [Mastectomy] explode all trees
#32	#30 or #31
#33	MeSH descriptor: [Diagnostic Techniques, Obstetrical and Gynecological] explode all trees
#34	#33 and #11
#35	#34 or #32
#36	MeSH descriptor: [Mammary Neoplasms, Animal] explode all trees
#37	mammary near/25 neoplasm*
#38	mammary near/25 cancer*
#39	mammary near/25 tumour*
#40	mammary near/25 tumor*
#41	mammary near/25 carcinoma*

(Continued)

#42	mammary near/25 adenocarcinoma*
#43	mammary near/25 sarcoma*
#44	mammary near/50 dcis
#45	mammary near/25 ductal
#46	mammary near/25 infiltrating
#47	mammary near/25 intraductal
#48	mammary near/25 lobular
#49	mammary near/25 medullary
#50	#36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49
#51	#35 or #50
#52	MeSH descriptor: [Breast Self-Examination] explode all trees
#53	breast near/25 self*
#54	breast near/25 screen*
#55	MeSH descriptor: [Mammography] explode all trees
#56	#51 or #52 or #53 or #54 or #55
#57	mammograph*
#58	#57 and #11
#59	#56 or #58
#60	MeSH descriptor: [Mind-Body Therapies] explode all trees
#61	body-mind*
#62	mind-body*
#63	(mind-body near/3 (program* or therap* or medicin*))
#64	#60 or #61 or #62 or #63
#65	mindfulness based stress reduction*
#66	mindfulness based*
#67	mbsr* or mbct*
#68	MeSH descriptor: [Meditation] explode all trees
#69	meditation*

(Continued)

#70	MeSH descriptor: [Relaxation Therapy] explode all trees
#71	(relaxation* near/2 (technique* or therap*))
#72	#65 or #66 or #67 or #68 or #69 or #70 or #71
#73	#64 or #72
#74	#59 and #73 Publication Year from 2017 to 2018

Appendix 3. MEDLINE search strategy

1	randomized controlled trial.pt.
2	controlled clinical trial.pt.
3	randomized.ab.
4	placebo.ab.
5	Clinical Trials as Topic/
6	randomly.ab.
7	trial.ti.
8	(crossover or cross-over).tw.
9	Pragmatic Clinical Trials as Topic/
10	pragmatic clinical trial.pt.
11	or/1-10
12	exp Breast Neoplasms/
13	(breast adj6 cancer$).tw.
14	(breast adj6 neoplasm$).tw.
15	(breast adj6 carcinoma$).tw.
16	(breast adj6 tumo?r$).tw.
17	or/12-16
18	exp Mind-Body Therapies/
19	body-mind$.tw,kf,ot.
20	mind-body$.tw,kf,ot.

(Continued)

21	(mind-body adj3 (program$ or therap$ or medicin$)).tw,kf,ot.
22	or/18-21
23	mindfulness based stress reduction$.tw,kf,ot.
24	mindfulness based$.tw,kf,ot.
25	(mbsr$ or mbct$).tw,kf,ot.
26	Meditation/
27	meditation$.tw,kf,ot.
28	Relaxation Therapy/
29	(relaxation$ adj2 (technique$ or therap$)).tw,kf,ot.
30	or/23-29
31	or/22,30
32	and/11,17,31
33	exp animals/ not humans/
34	32 not 33

Appendix 4. MEDLINE search strategy 04/2018

1	exp breast neoplasms/
2	exp "neoplasms, ductal, lobular, and medullary"/
3	exp fibrocystic disease of breast/
4	or/1-3
5	exp breast/
6	breast.tw.
7	5 or 6
8	(breast adj milk).ti,ab,sh.
9	(breast adj tender$).ti,ab,sh.
10	8 or 9
11	7 not 10

(Continued)

12	exp neoplasms/
13	11 and 12
14	exp lymphedema/
15	14 and 11
16	(breast adj25 neoplasm$).ti,ab,sh.
17	(breast adj25 cancer$).ti,ab,sh.
18	(breast adj25 tumour$).ti,ab,sh.
19	(breast adj25 tumor$).ti,ab,sh.
20	(breast adj25 carcinoma$).ti,ab,sh.
21	(breast adj25 adenocarcinoma$).ti,ab,sh.
22	(breast adj25 sarcoma$).ti,ab,sh.
23	(breast adj50 dcis).ti,ab,sh.
24	(breast adj25 ductal).ti,ab,sh.
25	(breast adj25 infiltrating).ti,ab,sh.
26	(breast adj25 intraductal).ti,ab,sh.
27	(breast adj25 lobular).ti,ab,sh.
28	(breast adj25 medullary).ti,ab,sh.
29	or/16-28
30	4 or 13 or 15 or 29
31	exp mastectomy/
32	30 or 31
33	exp "Analytical, Diagnostic and Therapeutic Techniques and Equipment"/
34	33 and 11
35	34 or 32
36	exp mammary neoplasms/
37	(mammary adj25 neoplasm$).ti,ab,sh.
38	(mammary adj25 cancer$).ti,ab,sh.
39	(mammary adj25 tumour$).ti,ab,sh.

(Continued)

40	(mammary adj25 tumor$).ti,ab,sh.
41	(mammary adj25 carcinoma$).ti,ab,sh.
42	(mammary adj25 adenocarcinoma$).ti,ab,sh.
43	(mammary adj25 sarcoma$).ti,ab,sh.
44	(mammary adj50 dcis).ti,ab,sh.
45	(mammary adj25 ductal).ti,ab,sh.
46	(mammary adj25 infiltrating).ti,ab,sh.
47	(mammary adj25 intraductal).ti,ab,sh.
48	(mammary adj25 lobular).ti,ab,sh.
49	(mammary adj25 medullary).ti,ab,sh.
50	or/36-49
51	35 or 50
52	exp Breast Self-Examination/
53	(breast adj25 self$).ti,ab,sh.
54	(breast adj25 screen$).ti,ab,sh.
55	exp mammography/
56	or/51-55
57	mammograph$.tw.
58	57 and 11
59	56 or 58
60	Mind-Body Therapies/
61	body-mind$.tw,kf,ot.
62	mind-body$.tw,kf,ot.
63	(mind-body adj3 (program$ or therap$ or medicin$)).tw,kf,ot.
64	or/60-63
65	mindfulness based stress reduction$.tw,kf,ot.
66	mindfulness based$.tw,kf,ot.
67	(mbsr$ or mbct$).tw,kf,ot.

(Continued)

68	Meditation/
69	meditation$.tw,kf,ot.
70	Relaxation Therapy/
71	(relaxation$ adj2 (technique$ or therap$)).tw,kf,ot.
72	or/65-71
73	64 or 72
74	randomized controlled trial.pt.
75	controlled clinical trial.pt.
76	randomi?ed.ab.
77	placebo.ab.
78	drug therapy.fs.
79	randomly.ab.
80	trial.ab.
81	groups.ab.
82	or/74-81
83	exp animals/ not humans/
84	82 not 83
85	59 and 73
86	59 and 73 and 84
87	limit 85 to ed=20160927-20170714
88	limit 85 to ed=20170714-20180329
89	from 88 keep 1-34

Appendix 5. Embase search strategy

1. **random*** OR **factorial*** OR **crossover*** OR **cross** NEXT/1 **over*** OR **placebo*** OR (**doubl*** AND **blind***) OR (**singl*** AND **blind***) OR **assign*** OR **allocat*** OR **volunteer*** OR **'crossover procedure'**/exp OR **'double blind procedure'**/exp OR **'randomized controlled trial'**/exp OR **'single blind procedure'**/exp
2. **'breast'**/exp OR **'breast disease'**/exp AND **'neoplasm'**/exp OR **'breast tumor'**/exp OR (**breast*** NEAR/5 **neoplas***):ab,ti OR (**breast*** NEAR/5 **cancer***):ab,ti OR (**breast*** NEAR/5 **carcin***):ab,ti OR (**breast*** NEAR/5 **tumo***):ab,ti OR (**breast*** NEAR/5 **metasta***):ab,ti OR (**breast*** NEAR/5 **malig***):ab,ti
3. **'breast cancer'**/exp OR **'breast cancer'** OR **'breast neoplasm'** OR **'breast carcinoma'**/exp OR **'breast carcinoma'** OR **'breast tumour'** OR **'breast tumor'**/exp OR **'breast tumor'**
4. **#2** OR **#3**

5. **'mindfulness'**/exp OR **mindfulness***
6. **'mindfulness based'** AND **stress** AND **reduction** OR (**mindfulness** AND **based** AND **stress** AND **reduction**)
7. **'stress reduction'**
8. **'mindfulness based therapy'**
9. **'mindfulness based'** AND (**therap*** OR **interven*** OR **stress***)
10. **'mindfulness based'** NEAR/6 (**therap*** OR **interven*** OR **stress***)
11. **'mbsr'**
12. **'meditation'**/exp OR **meditation***
13. **'mind-body'**
14. **'body-mind'**
15. **'body-mind'** NEAR/5 (**program*** OR **therap*** OR **medicin***)
16. **'relaxation therapy'**
17. **'relaxation training'**/exp
18. **relaxation$** NEAR/5 (**technique*** OR **therap***)
19. **#5** OR **#6** OR **#7** OR **#8** OR **#9** OR **#10** OR **#11** OR **#12** OR **#13** OR **#14** OR **#15** OR **#16** OR **#17** OR **#18**
20. **#1** AND **#4** AND **#19**
21. **#20** AND [humans]/lim AND [embase]/lim

Appendix 6. WHO ICTRP search strategy

Basic search
1. breast cancer AND mindfulness based
2. breast cancer AND mbsr
3. breast cancer AND meditation
4. breast cancer AND mind-body
5. breast cancer AND relaxation

Advanced search
Condition: Breast cancer* OR breast neoplasm* OR breast carcinoma*
Intervention: mindfulness based OR mindfulness-based OR mbsr OR meditation OR mind-body OR relaxation OR stress reduction
Recruitment status: ALL

Appendix 7. ClinicalTrials.gov search strategy

Basic search
breast cancer AND (mindfulness OR mindfulness based OR mindfulness-based OR mbsr OR meditation OR mind-body OR relaxation OR stress reduction)

Advanced search
Conditions: Breast cancer* OR breast neoplasm* OR breast carcinoma*
Interventions: mindfulness based OR mindfulness-based OR mbsr OR meditation OR mind-body OR relaxation OR stress reduction
Recruitment: All studies
Study type: Interventional studies
Gender: Studies with Female Participants

CONTRIBUTIONS OF AUTHORS

Lisa Katharina Schell: drafted the review, extracted data from studies, entered data into RevMan 5 (RevMan 2014), carried out the analysis, interpreted the analysis, drafted the final review and updated the review.

Ina Monsef: development of the search strategies.

Achim Wöckel: clinical expertise and advice.

Nicole Skoetz: extracted data from studies, interpreted the analysis, methodological advice.

DECLARATIONS OF INTEREST

Lisa Katharina Schell: since July 2014, I have been working at the Institute for Quality and Efficiency in Healthcare (IQWiG). This Cochrane Review was prepared in my free time and has not been influenced by my employment.

Ina Monsef: none known.

Achim Wöckel: none known.

Nicole Skoetz: none known.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Types of intervention

We considered studies applying MBSR both during or after active therapy.

Some deviations to the Kabat-Zinn MBSR programme were allowed: not all components described in the Background section needed to be implemented. Studies were eligible when: their intervention did not include a one-day retreat, the participants were offered at least six of the eight foreseen weekly group sessions, and there were fewer requirements for home assignment than in the original programme designed by Kabat-Zinn. Thus, the studies differ with regard to dose and intensity of the MBSR programme.

Types of participants

Studies were eligible for inclusion in this review if more than 80% of included participants had breast cancer.

Measures of treatment effect

Post hoc, an we defined an SMD of 0.2 as a small effect, 0.5 a moderate effect, and 0.8 a large effect.

Post hoc, we decided to pool data in three separate analyses.

- Short-term analysis (end of intervention)
- Medium-term analysis (up to 6 months after baseline)
- Long-term analysis (more than 12 months after baseline)

Studies were eligible for pooling in each separate analysis, so we considered up to three time points per study. For each study, we chose the latest time point available for the respective analysis.

We did not prespecify whether we preferred to use adjusted or unadjusted outcome data in our data extraction and analyses. If both unadjusted and adjusted data were available, we considered the unadjusted data.

Data synthesis

Since the studies included were clinically heterogeneous and the intervention was implemented differently in each, we used the random-effects model for meta-analysis. We used the fixed-effect model specified in the protocol in a sensitivity analysis for the primary outcome (quality of life) only.

Post hoc, we decided to present the medium-term data in the 'Summary of findings' table.

In case we were unable to undertake a meta-analysis due to concerns about missing data, we decided post hoc to apply vote counting to describe the available results (see McKenzie 2018). For vote counting, we judged an effect as showing benefit if the standardised effect size suggested a beneficial effect and the confidence interval was not compatible with a harmful effect. We judged an effect as showing harm if the standardised effect size suggested a harmful effect and the confidence interval was not compatible with a beneficial effect.

Subgroup analysis

For the subgroup analysis 'MBSR during or after active therapy', we defined active therapy as active anticancer therapy like radiotherapy and chemotherapy (not endocrine therapy).

Due to the paucity of available data and an unclear subgroup allocation (see Table 1), we were unable to conduct any of the subgroup analyses planned.

Sensitivity analysis

We could not conduct all prespecified sensitivity analyses as planned. We rated no studies as having a high risk of bias with regards to sequence generation and therefore compared studies at low risk with those at unclear risk. We conducted the sensitivity analysis for fixed-effect modelling for the primary outcome (quality of life) only, since we decided post hoc to use the random-effects model for meta-analysis.

In an additional post hoc sensitivity analysis, we checked whether the trials included only data with less than 30% attrition and less than 15 percentage points' difference in missing participants between groups. This was the case only for the long-term depression data from Wurtzen 2015 (more than 30% of long-term data were missing for included participants).

If studies presented change data (MD and SD) in addition to or instead of end-of-treatment data, we presented the change values in a further post hoc sensitivity analysis. As suggested in Higgins 2018, change SDs were calculated from P values but not imputed, since imputation techniques involve making assumptions about unknown statistics.

NOTES

Parts of the Methods section of the protocol are based on a standard template established by the Cochrane Haematological Malignancies Group.

INDEX TERMS

Medical Subject Headings (MeSH)

*Mindfulness; Anxiety [psychology]; Breast Neoplasms [*psychology]; Depression [psychology]; Fatigue [psychology]; Quality of Life; Randomized Controlled Trials as Topic; Sleep Wake Disorders [psychology]; Stress, Psychological [*therapy]; Time Factors

MeSH check words

Female; Humans