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Mindfulness-based stress reduction (MBSR) for improving health, quality of life and social functioning in adults: a systematic review and meta-analysis

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Title	Mindfulness-based stress reduction (MBSR) for improving health, quality of life and social functioning in adults: a systematic review and meta-analysis
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Declarations of interest

Michael de Vibe has carried out a research project on MBSR in Norwegian family practice that was published in the Norwegian Medical Journal in 2006 and is a MBSR instructor. He completed his doctorate based on a RCT trying out MBSR among students with Arild Bjørndal as his mentor. Michael de Vibe did not assess or extract data from his own studies, nor did Arild Bjørndal. Sabina Fattah, Gunvor M Dyrdal and Even Halland are MBSR instructors. None of the authors stand to gain financially from a positive or negative evaluation of MBSR.

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Plain language summary

Mindfulness training improves health and quality of life for adults

Mindfulness-based stress reduction (MBSR) is used to improve health, quality of life and social functioning. MBSR has a positive effect on mental health outcomes measured right after the intervention and at follow up. It also improves personal development, quality of life, and self-reported mindfulness.

What is this review about?

Stress and stress-related mental health problems are major causes of illness and disability. MBSR is a group-based health promotion intervention to improve health and the way people deal with stress and life's challenges. The core ingredient is mindfulness training through physical and mental exercises practiced daily for eight weeks. The mindful non-judgmental attitude of being present with what arises is practiced in the formal exercises and in everyday situations. This review assesses the effect of MBSR programs on outcome measures of mental and physical health, quality of life and social functioning in adults.

What is the aim of this review?

This review summarizes all studies that compare the effect of a MBSR program to a control group intervention, in which the participants had been randomly allocated to be in either the MBSR group or a control group. The review summarizes the results in two categories. First, where the effect of the MBSR program was compared to an inactive group (either a wait list group or one receiving ordinary care also received by the MBSR group). Second, where MBSR was compared with an alternative active group intervention.

What studies are included?

The review summarizes 101 randomized controlled trials with a total of 8,135 participants from USA, Europe, Asia and Australia. Twenty-two trials included persons with mild or moderate psychological problems, 47 targeted people with various somatic conditions and 32 of the studies recruited people from the general population. Seventy-two studies compared MBSR to an inactive control group, while 37 compared MBSR to an active control intervention. Seven studies compared MBSR to both. Ninety-six studies contributed data to the meta-analyses, with data from 7,647 participants.

Is mindfulness effective?

MBSR has a moderately large effect on outcome measures of mental health, somatic health, and quality of life including social function at post-intervention when compared to an inactive control. If 100 people go through the MBSR program, 21 more people will have a favourable mental health outcome compared to if they had been put on a wait-list or gotten only the usual treatment.

These results may be inflated by underreporting of negative trials and moderate heterogeneity (indicating differences between the trials).

MBSR has a small but significant effect on improving mental health at post-intervention compared to other active treatments. MBSR has the same effect as other active interventions on somatic health, and quality of life (including social function). There was no underreporting of negative trials, and heterogeneity (differences between trials) were small for mental health, moderate for quality of life and large for somatic health.

The effects were similar across all target groups and were generally maintained at follow-up (1–34 months). The effects were largely independent of gender and study sample. The effects seemed also largely independent of duration and compliance with the MBSR intervention. No studies report results regarding side-effects or costs.

Effects were strongly correlated to the effects on measures of mindfulness, indicating that the effects may be related to the increase in self-reported mindfulness.

Two thirds of the included studies showed a considerable risk of bias, which was higher among studies with inactive than active control groups. Studies of higher quality reported lower effects than studies with low quality. The overall quality of the evidence was moderate, indicating moderate confidence in the reported effect sizes. Further research may change the estimate of effect.

What do the findings of this review mean?

Based on this review it is reasonable to consider MBSR a moderately well-documented method for helping adults improve their health and cope better with the challenges and stress that life brings. New research should improve the way the trials are conducted addressing the pitfalls in research on mind-body interventions.

How up-to-date is this review?

The review authors searched for studies up to November 2015. This Campbell Systematic Review was published in October 2017.

Executive summary/Abstract

Background

There is an increasing focus on mind-body interventions for relieving stress, and improving health and quality of life, accompanied by a growing body of research trying to evaluate such interventions. One of the most well-known Programs is Mindfulness-Based Stress Reduction (MBSR), which was developed by Kabat-Zinn in 1979. Mindfulness is paying attention to the present moment in a non-judgmental way. The Program is based on old contemplative traditions and involves regular meditation practice. A number of reviews and meta-analyses have been carried out to evaluate the effects of meditation and mindfulness training, but few have adhered to the meta-analytic protocol set out by the Cochrane Collaboration and Campbell Collaboration, or focused on MBSR only. The first edition of this review was published in 2012 with a literature search done in 2010, comprising 31 studies. As the field is rapidly developing, an update is called for.

Objectives

To evaluate the effect of Mindfulness-Based Stress Reduction (MBSR) on health, quality of life and social functioning in adults.

Search methods

The following sources were searched, most recently in November 2015: PsycINFO (Ovid), MEDLINE (Ovid), EMBASE (Ovid), AMED (Allied and Complementary Medicine) (Ovid), CINAHL (Ebsco), Ovid Nursing Full Text Plus (Ovid), Cochrane Central Register of Controlled Trials (CENTRAL), British Nursing Index, (ProQuest), Eric (ProQuest), ProQuest Medical Library, ProQuest Nursing & Allied Health Source, ProQuest Psychology Journals, Web of Science, SveMed+, Social Services Abstracts, Sociological Abstracts and International Bibliography of Social Sciences.

Selection criteria

The review included randomised controlled trials (RCTs) where the intervention followed the MBSR protocol developed by Kabat-Zinn, allowing for variations in the length of the MBSR courses. All target groups were accepted, as were all types of control groups, and no language restrictions were imposed.

Data collection and analysis

Two reviewers read titles, retrieved studies, and extracted data from all included studies. Standardized mean differences (as Hedges' g) from all study outcomes were calculated using the software Comprehensive Meta Analysis. The meta-analyses were carried out using the Robumeta Package within the statistical program R, with a technique for handling clusters of internally correlated effect estimates. We performed separate meta-analyses for MBSR compared to either waitlists or treatment as usual (WL/TAU – named inactive), and for MBSR compared to control groups that were offered another active intervention.

Results

The review identified 101 RCTs including the 31 from the first review, with a total of 8,135 participants. Twenty-two trials included persons with mild or moderate psychological problems, 47 targeted people with various somatic conditions and 32 of the studies recruited people from the general population. Seventy-two studies compared MBSR to a WL/TAU control group, while 37 compared MBSR to an active control intervention. Seven studies compared MBSR to both a WL/TAU condition and to an active control group. Ninety-six studies contributed to the meta-analyses (based on information from 7,647 participants). Two thirds of the included studies showed a considerable risk of bias, and risk of bias was higher among studies with inactive than active control groups.

Post-intervention Hedges' g effect sizes for MBSR versus WL/TAU for the outcome measures of mental health, somatic health, and quality of life including social function were, respectively, 0.54 (95% CI 0.44, 0.63), 0.39 (95% CI 0.24, 0.54), and 0.44 (95% CI 0.31, 0.56). Some funnel-plot asymmetry points to a small degree of underreporting of negative trials. Heterogeneity was moderate for mental health and quality of life, and high for somatic health. Assuming a favourable outcome for 50% of the control group, the main finding of an effect size of 0.54 for improving mental health corresponds to a 65% chance that a random person from the treatment group will have a higher score than a person picked at random from the control group (probability of superiority). Another way of putting it, is that in order to have one more favourable mental health outcome in the treatment group compared to the control group at end of intervention, five people need to be treated (NNT=4.9, 95% CI 4.2, 5.9). Thus, if 100 people go through the treatment, 21 more people will have a favourable outcome compared to if they had been put on a wait-list or gotten the usual treatment. For 21 studies with follow-up data, the effect size was generally maintained at follow-up (1–32 months).

For the comparison of MBSR versus alternative psychosocial interventions at post-intervention there was a small, statistically significant difference in favour of MBSR improving mental health with a Hedges' g effect of 0.18 (95% CI 0.05, 0.30), and MBSR was not more effective than other active interventions on outcome measures of somatic health, 0.13 (95% CI -0.08, 0.34) and quality of life (including social function), 0.17 (95% CI -0.02, 0.35). Heterogeneity was low for mental health, moderate for quality of life and high for somatic health, and there was no funnel-plot asymmetry. Assuming a favourable outcome for

50% of the control group, the main finding of an effect size of 0.18 for improving mental health corresponds to a 57% chance that a random person from the treatment group will have a higher score than a person picked at random from the control group and the NNT=14, 95% CI 8, 50).

Since the measure of mental health includes outcomes from a larger proportion of the included studies compared to somatic health or quality of life, it is a more robust measure for the effect of the MBSR intervention. It is therefore treated as the main primary outcome for the meta-analyses. For all comparisons effect sizes were fairly similar across the range of target groups and the effects were generally maintained at follow-up (1–34 months). Effect sizes for measures of mental health were not particularly influenced by length of intervention, attendance or self-reported practice, but they were strongly correlated to the effects on measures of mindfulness, indicating that the effects of the MBSR intervention may be related to the increase in self-reported mindfulness. Sensitivity analyses with exclusion of studies with exceptional findings did not substantially change the results. A majority of studies suffered from risk of bias, and studies of higher quality reported lower effects than studies with low quality. We found no reports of side-effects or costs in any of the trials.

The overall quality of the evidence was moderate, indicating moderate confidence in the reported effect sizes. However, further research could impact on our confidence in the estimate of effect and may change the estimate.

Authors' conclusions

MBSR has moderate effect on mental health across a number of outcome measures, for a range of target groups and in a variety of settings, compared to a WL or TAU control group. NNT was 4.9 (95% CI 4.2, 5.9) post-intervention; on par with other well-established interventions in the health service. The effect on somatic health is smaller, but still statistically significant. MBSR also seems to improve measures of quality of life and social function when compared to inactive control groups. MBSR improved mental health compared to other active psychosocial interventions, with a NNT = 14 (95% CI 8, 50), and had a similar effect on improving somatic health, and quality of life and social function.

For all comparisons, the effects were maintained at follow-up and correlated to effects on mindfulness. The quality of the evidence was moderate and should be improved in future studies. There were many studies with considerable bias, and heterogeneity was mostly moderate. In addition, there is indication of underreporting of negative studies when MBSR was compared to inactive controls. These factors might have influenced the results found.

MBSR might be an attractive option to improve health, handle stress, and cope with the strains of life. Ways to further strengthen the effect should be sought. All new trials should include measures of mindfulness and explore moderators and mediators of effects. New studies should register study protocols and adhere to guidelines for reporting of randomized controlled trials.

1. Background

1.1 The problem, condition or issue

Stress is ubiquitous in modern life and can negatively influence mental health, health, wellbeing and quality of life. Prevalence rates for distress and mild to moderate psychological problems are high among children, adolescents and adults alike, and chronic musculoskeletal pain is widespread. While our understanding of these mass phenomena is limited, stress is probably both a cause and a consequence. Stress is also part of our working life. In surveys carried out every five years in the EU, the respondents name stress as the second most common threat posed by the working environment, affecting a fifth of the work-force at any time (European Risk Observatory 2009). It can lead to increased risk of diseases (Chandola et al., 2008; Cohen et al., 2012). Likewise, there is mounting evidence that stress caused by traumatic life events increases the risk for chronic somatic and psychological problems that affect health and quality of life (McEwen, 2008); adverse childhood experiences being especially harmful (Brown et al., 2009; Kelly-Irwing et al., 2013).

Demands may be external, but stress is also generated from within. The stressors can be actual or imagined. How we handle situations, persons and emotions - becoming stressed or keeping calm - is therefore central to staying healthy, dealing with illness and enjoying life. Coping with stress and life challenges is a skill that can be developed.

1.2 The intervention

1.2.1 Mindfulness-Based Stress Reduction (MBSR)

A well described group-based mind-body intervention Program that has received a lot of attention is Mindfulness-Based Stress Reduction or MBSR (Kabat-Zinn, 1990). Mindfulness may be defined as the skill to non-judgementally observe sensations, thoughts, emotions and the environment, while encouraging openness, curiosity and acceptance. A Program to strengthen this skill was developed at the University of Massachusetts Medical Center in 1979 as an intervention to relieve stress, cope with illness and promote health. It is now being offered at many health care facilities and in other settings around the world. Target groups are typically people with chronic somatic or mental illnesses, such as chronic pain, cancer, anxiety, depression, and burn-out. In addition, it is offered to various non-clinical groups such as students, health care workers, care-givers, teachers, and to the general population.

MBSR is an eight-week group Program in mindfulness training. The standard Program has weekly sessions of 2 to 2½ hours and one all-day session after six to seven weeks. Sometimes

shorter weekly sessions (30-90 minutes) or fewer sessions (4-7) are offered and others omit the all-day session. The weekly sessions have standardized core elements consisting of different mental and physical mindfulness exercises. In particular body scan exercises, mental exercises focusing one's attention on the breath, physical exercises with a focus on being aware of bodily sensations, and practicing being fully aware during everyday activities. Essential to all parts of the Program is developing an accepting and non-reactive attitude to what one experiences in each moment. The intervention derives its roots from ancient Buddhist practices of Samatha (concentration) and Vipassana (insight) meditation and yoga exercises, but has been adapted and is described in Western terminology free from religious affiliation.

In addition to the mindfulness practice, there are teachings (and reflections) on stress, stress management, and how to apply mindfulness to interpersonal communication and everyday situations. In each session group members reflect together on what they experience when they practice mindfulness. Between the sessions participants are encouraged to practice for 30-45 minutes daily listening to audiotapes with guided exercises in body-scan, and mindfulness practices focusing on the breath as well as yoga stretching. The groups usually have 10-30 members and are led by one or two instructors.

1.3 How the intervention might work

The MBSR Program provides systematic training in mindfulness as a self-regulation approach to stress reduction and emotion management. The intention is to foster increased awareness for what is happening in each moment, with an accepting attitude, without getting caught up in habitual thoughts, emotions and behavioural patterns. Increased awareness and acceptance allow for new ways to respond and cope in relation to oneself and the world around. Mindfulness training has been linked to changes in areas of the brain that are responsible for affect regulation and for how we react to stressful impulses, in turn influencing body functions such as breathing, heart rate, and immune function (Davidson et al., 2003; Hölzel et al., 2010; Lazar et al., 2005,). Brain studies of participants in a MBSR program showed changes in grey matter concentration in brain regions involved in learning and memory processes, emotion regulation, self-referential processing, and perspective taking (Hölzel et al., 2011).

Mediation analyses indicate that increases in self-compassion and mindfulness mediate MBSR's effects on worry and emotion regulation, highlighting their importance as key processes of change that underlie MBSR's outcomes (Keng, Smoski, Robins, Brantley, 2012). In addition to the reduction in worry and the resulting decrease in negative thoughts and emotions, there is also evidence indicating that mindfulness practice may cause an upward positive spiral of increased positive emotions and thoughts due to changes in the reappraisal of thoughts and emotions that arise during mindfulness practice (Garland 2015).

1.4 Why it is important to do the review

MBSR is becoming ever more widespread and it is important to find out if it works, for whom, and possibly under what circumstances. It is also of value to guide future research. This is an update of an earlier review published in 2012 (Vibe et al., 2012). It included 31 randomized controlled trials (RCTs), 26 of which could be used in the meta-analyses. Most studies used a wait-list control design; only three studies offered the control group an active intervention. Reviews published over the last few years generally suggest that MBSR is effective in reducing symptoms of anxiety, depression, and is helpful in stress-management, although a possible overreporting of positive effects in mindfulness studies has been described (Coronado-Montoya 2016). Most of the recent reviews have focused on particular target groups. Larger reviews have recently been performed, but they included both MBSR and other mindfulness based interventions such as mindfulness based cognitive therapy (Gotink 2016; Goyal , Singh, & Sibinga, 2014; Khoury et al., 2013). Although there is a clear overlap between various ways of integrating mindfulness into intervention programs, MBSR is of particular interest as it is the original and most widespread approach. The authors hoped to find more studies using an active treatment control group and more studies with longer follow-up.

2. Objectives

The objective of this review is to assess the effectiveness of MBSR in improving health, quality of life and social functioning in adults. Specifically, this review aims to answer the following research question: What are the effects of MSBR on physical health, mental health, quality of life and social functioning in adults who receive MBSR compared to adults in a waitlist, treatment as usual or other active comparison condition?

3. Methods

The protocol for the first edition of this review was approved in 2010 (Vibe 2010). We used the original protocol for this updated review.

3.1 Criteria for considering studies for this review

3.1.1 Types of studies

Studies of mind-body interventions like MBSR are especially prone to bias introduced by self-selection to intervention or control. Hence, only RCTs were included. Based on our prior review and knowledge of studies conducted since our original review, we expected to find a sufficient number of such RCT studies.

3.1.2 Types of participants

Since MBSR is a health promotion program that has been tried out on a variety of target groups, all types of participants were included. There were two exceptions; children and persons with severe cognitive impairment or severe mental illness. The effect of MBSR is thought to be dependent on the ability to pay attention and remember one moment to the next.

3.1.3 Types of interventions

Studies on MBSR training Programs that were based on the elements set out in the protocol by Jon Kabat-Zinn (1990) were included. The intervention had to contain all four core elements of MBSR: body-scan exercises, mental exercises focusing one's attention on the breath, physical exercises with focus on being aware of bodily sensations, and practicing being fully aware during everyday activities. Studies with varying duration and intensity of the MBSR course were included. Studies that combined MBSR with other therapeutic approaches, such as cognitive therapy or art therapy were excluded.

Acceptable control groups were either a wait-list or treatment-as-usual (labelled by us as inactive control groups) or various active control groups. Treatment as usual comparisons entailed that both the MBSR and the control group received ordinary care for the condition they had, but only the MBSR group received the mindfulness intervention. Studies that compared MBSR with inactive controls were analysed separately from those comparing MBSR with active controls.

3.1.4 Types of outcome measures

3.1.4.1 Primary outcomes

Primary outcomes were measures of mental health (anxiety, depression, stress/distress, and other measures of mental health), somatic health (self-reported physical health inventories and somatic measures such as antibodies, heart rate, respiratory and brain function), quality of life (only including measures designed specifically to measure quality of life, such as the WHO Quality Of Life Inventory, and health related quality of life measures like SF-36) and social functioning (such as the ability to work, sickness rates, and self-reported measures of social functioning such as The Social Functioning Questionnaire SFQ).

3.1.4.2 Secondary outcomes

Secondary outcomes were measures of personal development (e.g., self-acceptance, empathy, coping, and forgiveness), and measures of mindfulness. The different measurement scales are listed in Tables 1 and 2.

3.1.5 Duration of follow-up

The effect of the intervention was estimated from baseline to the end of the MBSR course, and from baseline to any follow-up measurement point after that.

3.1.6 Types of settings

The MBSR is a group Program, and all settings that used the MBSR in groups of participants were included.

3.2 Search methods for identification of studies

Appendix 3 contains full documentation of all the search terms used.

The Cochrane Collaboration search strategy includes a RCT search filter for identifying randomized trials in MEDLINE and this was used when searching this database. This filter was subsequently modified for other database searches. Since the search for the first edition of this review in 2012, the term mindfulness is now a subject heading in some of the databases and hence was applied in this update search which ended in November 2015. The review also included a search in the CINAHL database where without any time limit.

3.2.1 Electronic searches

The following sources were searched in October 2015.
PsycINFO (Ovid)
MEDLINE (Ovid)
EMBASE (Ovid)
AMED (Allied and Complementary Medicine) (Ovid)
CINAHL (Ebsco)
Ovid Nursing Full Text Plus (Ovid)
Cochrane Central Register of Controlled Trials (CENTRAL)

British Nursing Index (ProQuest)
Eric (ProQuest)
ProQuest Medical Library
ProQuest Nursing & Allied Health Source
ProQuest Psychology Journals
Web of Science
SveMed+
Social Services Abstracts
Sociological Abstracts
International Bibliography of Social Sciences

3.2.2 Searching other resources

Reference lists from the articles under consideration were examined. In addition, a search for 'grey literature' trials and for ongoing studies registered at www.clinicaltrials.gov and www.isrctn.com/ was carried out. No publication or geographic restrictions were applied.

3.3 Data collection and analysis

3.3.1 Selection of studies

Two reviewers independently started to read 100 abstracts to exclude obviously irrelevant reports. After checking the quality of this process (both excluded the same 85 abstracts), one reviewer continued to do the initial screening. Any citation deemed potentially relevant was reviewed by the other reviewer. When in doubt the article was retrieved in full text. Inclusion and exclusion of full-text studies was performed independently by two reviewers both with content and methodological competence. They read all retrieved studies to determine whether they met our selection criteria (Appendix 1). Readers were not blinded as to journal name, author names, author affiliation or results. Disagreements were resolved by discussing with a third author who also had methodological expertise. We corresponded with investigators, where necessary, to attempt clarification of study eligibility. Studies that met the screening criteria, but did not meet the full inclusion criteria when reviewed in full text are listed in the Characteristics of excluded studies table with reasons for exclusion. Multiple reports of the same study were linked together.

3.3.2 Data extraction and management

Information on study design and implementation, sample characteristics, intervention characteristics, outcomes and outcome data was extracted from the studies and entered into a paper form (Appendix 2). A coding list incorporated in the data extraction form was piloted on two papers at the outset of the data collection phase. Two reviewers independently extracted data from all studies. Disagreements were resolved by discussing with a third reviewer with methodological expertise.

3.3.3 Assessment of risk of bias in included studies

Risk of bias was evaluated according to criteria set out in the Cochrane Handbook (Higgins & Green, 2008). Hence, two independent reviewers judged sequence generation, allocation concealment, blinding of outcome by assessors, completeness of outcome data, outcome reporting and other sources of bias, resulting in a risk of bias score from 0-6, with higher numbers indicating a lower risk of bias. We performed further analysis of the quality of evidence related to each of the primary outcomes using the GRADE approach (Guyatt et al., 2008; Higgins & Green, 2008), rating the quality of the body of evidence as 'high', 'moderate', 'low', or 'very low'.

3.3.4 Measures of treatment effect

As expected, only outcome data from (a number of) ordinal scales were found; no binary data were identified. We therefore calculated standardised mean differences (as Hedges' g values) using the Comprehensive Meta-Analysis program, which is able to accept a variety of different data formats (Borenstein, Hedges, Higgins, & Rothstein, 2009). Effect sizes were calculated for gain scores (post-minus pre-measurements in the control group were subtracted from post-minus pre-measurements in the treatment group). These results were then standardised using the post-test pooled standard deviation. In twenty-one studies the effect sizes were calculated from other data: a) from the F values for the difference in change in the MBSR and control group (Astin, 1997; Arefnasab et al., 2013; Farb, Segal, & Anderson, 2013; Gaylord et al., 2011; Grossman et al., 2010; Hoge et al., 2013; Murphy, 1994; Nyklicek & Beugen, 2013), b) from the difference in mean change between the MBSR and control group and the corresponding p-values (Baker, Costa, Guarino, & Nygaard, 2014; Cohen-Katz, Wiley, Capuano, Baker, & Shapiro, 2005; Creswell, Myers, Cole, & Irwin, 2009; Hartmann et al., 2012; Johansson, Bjuhr, & Ronnback, 2012; Lengacher et al, 2014; MacCoon, MacLean, Davidson, Saron, & Lutz, 2012; Moynihan et al., 2013; Pipe et al., 2009; Polusny et al., 2015; Würtzen et al., 2013), and c) from the difference in mean change between the MBSR and control group and the corresponding p-values (Kilpatrick et al., 2011; Pickut et al., 2013).

In studies that reported related outcomes, for example for anxiety, we used all outcomes, as the robust standard error approach adjusts for this.

All effect sizes are expressed using Hedges' g values (Hedges & Olkin, 1985); positive values indicate beneficial effects of the MBSR intervention. In addition to describing conventional (and arbitrary) categories of low, moderate and large effects, we have explained effects in terms of probability of superiority (using Cohen's U3; see Lipsey & Wilson, 2001) and numbers needed to treat (Citrome, 2014). To calculate numbers needed to treat we used Kristoffer Magnusson's tool: http://rpsychologist.com/d3/cohend/. It should be noted that, for continuous outcomes, the "probability of superiority" and NNT include any improvement. These measures are most meaningful with dichotomous outcomes.

3.3.5 Unit of analysis issues

We assessed the unit of analysis of all the trials and found one study (Carson, Carson, Gil, & Baucom, 2004) that randomized couples (44 couples; 88 individuals) to conditions rather

than individuals. This study reported effect size estimates separately for women (44 individuals) and men (44 individuals); our synthesis only included those individual level, gender-specific effect sizes, and therefore the robust standard error approach (see Data synthesis) handled the dependencies arising from the multiple effect sizes available from the study. Because the effect sizes from this study did not suffer from unit of analysis errors (i.e., effect sizes were at the level of individuals and not couples), no cluster corrections were needed for the standard errors of the effect sizes from that study. In future updates to this review, , we will, if needed, correct for clustering using the corrections recommended in the Cochrane Handbook (Chapter 16).

3.3.6 Dealing with missing data

We contacted study authors to attempt to obtain missing information (e.g. information about standard deviations). Most authors did not respond or could not retrieve the data. Some studies presented data visually and this made it possible to read data from the graphs (Anderson, Lau, Segal, & Bishop, 2007; Cohen-Katz, Wiley, Capuano, Baker, & Shapiro 2005; Davidson et al., 2003; MacCoon et al., 2012; Malarkey, Jarjoura, & Klatt, 2013; Plews-Ogan, Owens, Goodman, Wolfe, & Schorling, 2005; Shapiro, Schwartz, & Bonner, 1998; Williams, Kolar, Reger, & Pearson, 2001). In other instances, we calculated standard deviations using standard errors, confidence intervals, t-values or p-values that related to the differences between the means in two groups (Anderson, Lau, Segal, & Bishop, 2007; Davidson et al., 2003; Lengacher et al., 2009; Moritz et al., 2006; Plews-Ogan, Owens, Goodman, Wolfe, & Schorling, 2005; Williams, 2001). We were left with five studies where lack of information prevented us from including them in the meta-analysis (Alterman, Koppenhaver, Mulholland, Ladden, & Baime 2004; Corsica, Hood, Katterman, Kleinman, & Ivan, 2014; Dykens et al., 2014; Lengacher et al., 2014; Wells et al., 2014). In addition, MacCoon (2014) gave some additional results to the primary study (MacCoon et al., 2012).

Means and standard deviations were included as provided by the study publications irrespective of the handling of missing data in the primary analysis. We chose unadjusted means where this was available and used the Intent-to-treat data when these were available.

3.3.7 Assessment of heterogeneity

The degree of heterogeneity was evaluated both informally (by checking the overlap of the confidence intervals) and statistically (by estimating the total heterogeneity using Tau^2 values (where <0.05 indicates low heterogeneity). The percentage of the total variability due to heterogeneity was estimated using I^2 values; 0% representing no heterogeneity, 50% indicating moderate heterogeneity and 75% indicating high heterogeneity (Higgins, 2003).

3.3.8 Assessment of reporting and publication biases

Possible reporting biases was examined reading the articles and checking whether all outcomes mentioned in the method sections were reported in the result sections. Publication bias was examined using funnel plots and tests for funnel plot asymmetry using Egger's regression test (Egger, Smith, Schneider, & Minder, 1997). Three trial registries were also searched to see how many of the studies had been registered before the start of the trials;

ClinicalTrials.gov, the Standard Randomized Controlled Trial Number Register, and the World Health Organization's International Clinical Trials Registry Platform.

3.3.9 Data synthesis

All analyses were conducted with random effects models. When evaluating the outcomes for mental health, the results were first grouped separately into four constructs, namely: anxiety, depression, stress/distress, and other measures of mental health. The majority of the studies included multiple measures of the same construct and multiple effects sizes were typically available for the same individuals. Since the covariance structure of these effect sizes was not reported in any of the studies we used a newly developed robust statistical technique for estimating standard errors under such circumstances (Hedges, Tipton, & Johnson, 2010).

This technique calculates standard errors using an empirical estimate of the variance; it does not require any assumptions regarding the distribution of the multiple dependent effect size estimates. Those assumptions that are required are minimal and generally met in practice. Simulation studies show that both confidence intervals and p-values generated this way typically reflect the correct size in samples, requiring as few as ten studies for the estimation of an average effect size, or between 20-40 studies for the estimation of a slope (Hedges, 2010). This more robust technique is therefore beneficial because it allows all of the effect size estimates to be included in meta-analyses.

An important feature of this more robust standard error analysis is that the results are valid regardless of the weights used. For efficiency purposes, we calculated the weights using a method proposed by Hedges and colleagues (2010). This method assumes a simple random-effects model in which study average effect sizes vary across studies (τ^2) and the effect sizes within each study are equicorrelated (ρ). The method is approximately efficient, since it uses approximate inverse-variance weights: they are approximate given that ρ is, in fact, unknown and the correlation structure may be more complex. For all analyses, weights were used based on estimates of τ^2 and I^2, assuming $\rho = 0.80$. Though not reported here, sensitivity tests were also conducted using a variety of ρ values; these indicated that the general results and estimates of the heterogeneity (τ^2 and I^2) were robust to the choice of ρ.

In addition to estimating an average effect for each of the four mental health constructs we also calculated an average effect for mental health across all the studies and measures. Clinicians commonly view anxiety, depression, and psychological stress/distress as different constructs. However, the actual questions used in the different inventories (many of which are fairly similar) and correlations between questions (which are often high) cast doubt over whether the standard methods of measuring anxiety and depression do in fact always tap into different constructs.

Social function was most often assessed as part of quality of life measures and only four studies reported effect on work ability (Barrett et al., 2012; de Vibe & Moum, 2006; Pbert et al., 2012 and Wong et al., 2011). Social function was therefore grouped together with quality of life outcomes.

There were a great variety of physical health measures, including measures of cognitive and brain function. These were analysed together as somatic health.

The robust standard error approach was also used to evaluate the outcomes of somatic health, quality-of-life measures, personal development and mindfulness, as well as for varying lengths of follow-up.

3.3.10 Subgroup analysis and investigation of heterogeneity

For theoretical and empirical reasons, we expected, by and large, similar effects across the various target groups, varieties of the intervention, and reported outcomes. Nevertheless, the following subgroup analysis was undertaken in order to explore potential differences in effects. This was done on any measures of mental health as the majority of studies contributed such outcome measures, making the subgroup analyses more robust. The a priori hypotheses tested in the first edition of the review were revised somewhat based on our findings in the first review (Vibe, 2012). The subgroup analyses were performed separately for studies comparing MBSR with inactive and active control groups.

- Clinical and non-clinical samples, expecting a similar effect in studies of patients with established health problems compared to studies where participants were recruited from the general population, based on findings in our first review.
- Psychological and somatic conditions, expecting a similar effect in studies of participants with psychological distress compared to studies of people with somatic problems, based on the findings in our first review.
- Effect of length of the MBSR intervention, expecting a similar effect in studies that used a shorter MBSR Program compared to a standard approach, based on the findings in our first review.
- Effect of compliance, expecting a somewhat larger effect in studies where participants generally attended most of the Program versus studies where attendance was lower, and where people spent more rather than less time practicing at home. Actual home practice is often not accurately reported, and we hoped we would find more studies where this was done.
- Effect of follow-up time for studies with follow-up data, expecting effect sizes to diminish over time in studies with a longer follow-up period.
- Risk of bias, expecting a somewhat larger effect in studies with higher risk of bias.
- Gender, expecting a similar effect in studies with different gender distribution.

Each of these questions was investigated using a separate bivariate meta-regression model. Each model was estimated using the robust standard error method outlined above (Hedges, 2010). Since this method uses degrees of freedom based on the number of studies (rather than the total number of effect sizes), first estimated individual bivariate meta-regression models was chosen to examine the effect of each characteristic (clinical vs non-clinical

samples, clinical somatic vs clinical psychological samples, length of MBSR invention, attendance, follow-up time, risk of bias, percent of female participants, and if the analysis was based on an intention-to-treat effect). Tables 7 and 14 provide a correlation matrix showing the bivariate associations between each of these variables for comparisons of MBSR vs inactive and active controls. To address potential confounding among these variables and in response to peer reviewer comments, Tables 8 and 15 also presents post-hoc analysis results from multivariable meta-regression models that simultaneously examined the variables available for the majority of included studies: clinical vs non-clinical samples, length of MBSR invention, risk of bias, percent of female participants, and if the analysis was based on an intention-to-treat effect.

Finally, we regressed the post-intervention effect size of mindfulness on the post-intervention mental health effect size for those studies reporting both outcomes in order to assess the strength of the relationship between self-reported mindfulness and mental health outcomes.

3.3.11 Sensitivity analysis

Sensitivity analyses for outliers were performed, excluding exceptional effect sizes that were three or more inter-quartile ranges above or below the upper or lower hinges of the effect size distribution, in order to assess the effect of outliers on the estimated effect sizes for mental health. This was done separately for comparisons using inactive and active control groups.

3.4 Differences between the protocol and the review

The use of the robust standard error approach in the analysis was not described in the protocol as the method was published after the protocol was accepted.

The suggested sensitivity analysis was handled by subgroup analysis, due to concerns about risk of bias and whether authors claimed to have done an ITT analysis. Further sensitivity analyses omitting outliers among the studies were performed.

Compliance was suggested both as a moderator and as part of the set of subgroup analyses. We chose the latter route.

In addition to bivariate meta-regression models in the subgroup analyses, this review presents post-hoc analysis results from multivariable meta-regression models that simultaneously examined the variables available for the majority of included studies: clinical (vs non-clinical) samples and length of the MBSR Program.

We looked at mindfulness as a mediator using regression of mindfulness on mental health effect at post-intervention.

4. Results

4.1 Description of studies

4.1.1 Results of the search

The first search for this review was undertaken in 2013 and we used the same search strategy as in 2008 and 2010. In addition, a more extensive search strategy was used in October 2015, as several of the databases now had mindfulness as a search term. Figure 1 describes the flow diagram for the search process.

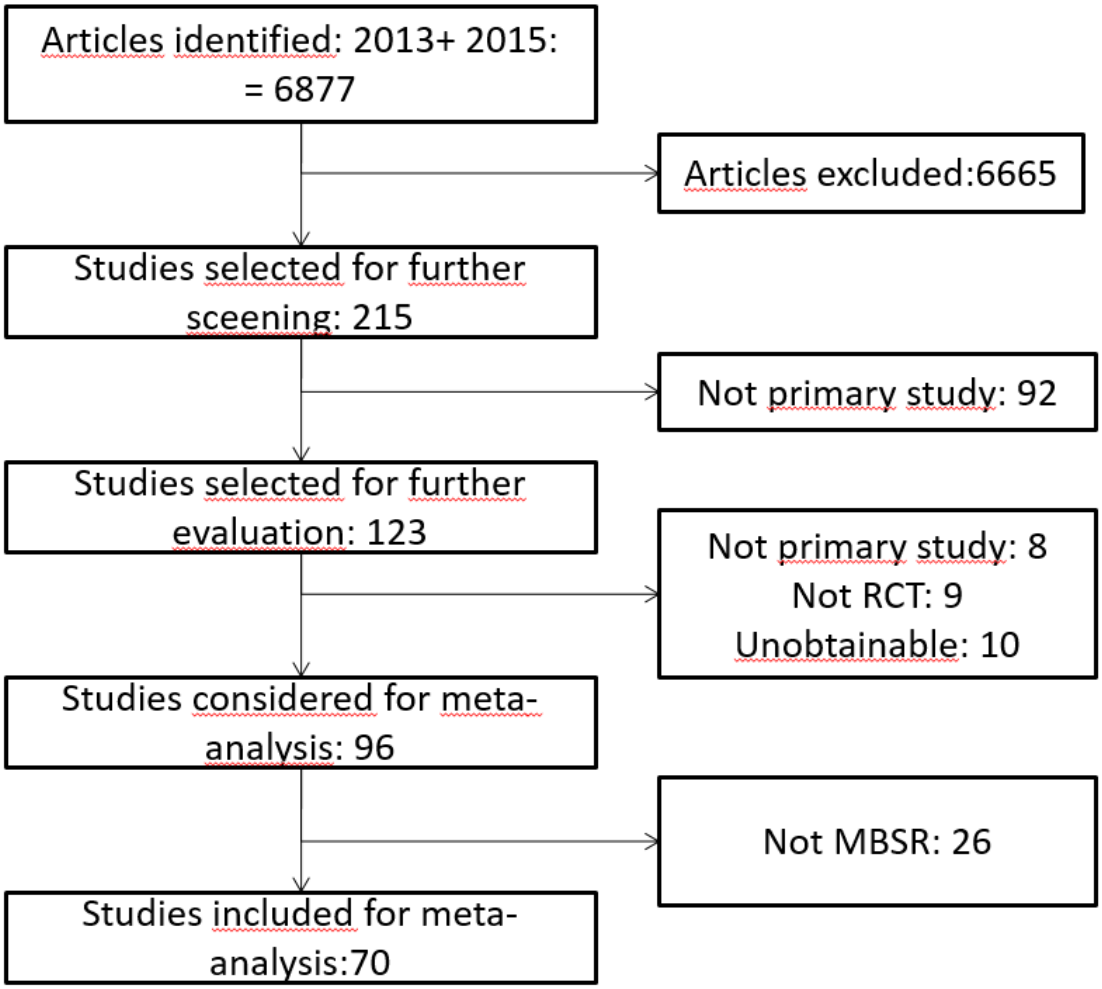

Figure 1: Flow diagram for inclusion of studies

The two most recent searches yielded a total of 6,877 potentially relevant articles. Based on our screening and inclusion criteria we identified 101 studies that met inclusion criteria, including the 31 from the first edition of this review, with a total of 8,135 participants who were randomized to MBSR or a control group (Table 1).

Table 1: Study characteristics

Study name	Target Group	Outcome Measures	F-up (ms)	N	MBSR hours	Practice Min/day	Atten-dance %	Women %	ITT / Non-ITT
Alterman 2004	Substance abusers	ASI, SF-36-Vit, SF-36 PH, SF-36 MH, SAS, LOT, LAP-R, PANAS-Pos	5	31	23			58	Non-ITT
Amutio 2015	Physicians	Basic relaxation, Positive energy, Transcendence, Core-mindfulness, FFMQ		72	28			57	ITT
Anderson 2007	Healthy adults	BAI, BDI, Anger Rum scale, Anx Sens Index, Novaco Anger Inv, PANAS neg, PANAS pos, PSWQ, Rumination scale, TMS		86	16	18	65		Non-ITT
Arch 2013	Anxiety disorders	CSR, MASQ-AAS, BDI, PSWQ	3	105	17		70	17	ITT
Arefnasab 2013	Pulm. injured veterans	SF36, FEV1, FEV1/FVC, FVC		40	16			0	Non-ITT
Astin 1997	Undergrad. students	GSI,, INSPIRIT, Shapiro control I		28	16	18		96	Non-ITT
Baker 2014	Urge incontinence	BladderQOL, HRQL, Total IE, UIE		30	16			100	ITT
Banth 2015	Chronic low back pain	SF-12 MH, SF-12 PH, McGill Pain	1	88	12			100	Non-ITT
Barrett 2012	Acute resp. infection	STAI, STAI Anx, PSS, PANAS neg, PANAS pos, LOT, Ryff-PR soc supp, SF-12 MH, SF-12 PH, A/Brisbane H1N1, A/Brisbane H3N2, B/Brisbane, PSQI, MAAS, Mean ARIdays, AreaUTCseverit	3	154	20			82	Non-ITT

Table 1: Study characteristics

Study name	Target Group	Outcome Measures	F-up (ms)	N	MBSR hours	Practice Min/day	Atten-dance %	Women %	ITT / Non-ITT
Blom 2014	Hypertension	24-h BP diast, 24-h BP syst, Awake BP diast, Awake BP syst, Night BP diast, Night BP syst		101	26			63	Non-ITT
Brown 2013	Chr musl.scel. pain	PSOCQ contemp, PSOCQ engagem, SF-36 MH, SF-36 PH, IPAQ, Laser pain, SF-McGill affective, SF-McGill sensory, MAAS		28	20			75	Non-ITT
Bränström 2010	Cancer patients	HADS Anx, HADS Depr, IES-aviodance, IES-hyperarousal, IES-intrusion, PSS, PSOM, FFMQ AA, FFMQ D, FFMQ NJ, FFMQ NR, FFMQ O, Coping self-efficacy	4	71	16		73	98,6	ITT
Carmody 2011	Hot flushes	HADS anx, PSS, Overall QOL, Sleep quality		110	27			100	Non-ITT
Carson 2004	Normal couples	BSI men, BSI women, Ind relax IRI men, Ind relax IRI wom, INSPIRIT men, INSPIRIT wom, LOT optimism men, LOT optimism wom	3	57	27	32	80	50	Non-ITT
Cohen-Katz 2005	Nurses	MBI depers, MBI emot exh, MBI pers acc, MAAS		27	26			100	Non-ITT
Corsica 2014	Stress related eating	PSS, EADES (Eating and Appraisal Due to Emotions ann Stress Q), Weight	1,5	53	6			98	ITT
Creswell 2009	HIV	CD4+Tlymf		40	22		57	7	Non-ITT
Creswell 2012	Healthy older adults	Log CRP, Log IL6, KIMS		48	23		90	80	ITT

Table 1: Study characteristics

Study name	Target Group	Outcome Measures	F-up (ms)	N	MBSR hours	Practice Min/day	Atten-dance %	Women %	ITT / Non-ITT
Davidson 2003	Healthy workers	STAI anx, ABtiter rise		41	26	7		43	Non-ITT
de Veer 2009	Stutters	Anx aboutspeech, PSS, Attitude, Coping, LCB, Self-efficacy fluency, Self-efficacy trust		37	20		80	22	Non-ITT
de Vibe 2006	Students	SCL-5, QOLWHO general, QOLWHO soc fun, Subj H Compl		144	26		81	12	Non-ITT
de Vibe 2013	Students	GHQ12, MBI-s, PMSS, SWB, FFMQ AA, FFMQ D, FFMQ NJ, FFMQ NR, FFMQ O		288	15	5	76	76	ITT
Duncan 2012	HIV	BDI, PSS, PANAS neg, PANAS pos, ART side eff.bother, ART side effects, Side effects, Side effects bother, FFMQ AA, FFMQ D, FFMQ NJ, FFMQ O	4	76	30	60		14	ITT
Dykens 2014	Mothers of autism ch.	BDI, BAI, PSI (Parent Distress Index), LSS (life satisfaction scale), PWB	2, 4, 6	243	9			100	ITT
Erogul 2014	Students	PSS, Resilience S, SCS	6	81	15	6	46		Non-ITT
Esmer 2010	Failed back surgery pas.	CPAQ, Analgesic medic, PSQI, RMDQ, VAS pain		40	22			44	Non-ITT
Farb 2013	Normal adults	IA recriutm ant gyr, IA recriutm insula, Resp Frequency, Resp Volume		36	26	31		75	Non-ITT
Flook 2013	Teachers	GSI, MBI Depression, MBI EmotExh, MBI PersAcc, CLASS ClsOrg, CLASS EmotSupp, CLASS InstrSupp, SCS Hum, AGN Tot Com, Cortisol, Sustained		18	26	22		89	Non-ITT

Table 1: Study characteristics

Study name	Target Group	Outcome Measures	F-up (ms)	N	MBSR hours	Practice Min/day	Atten-dance %	Women %	ITT / Non-ITT
		Attention, FFMQ AA, FFMQ D, FFMQ NJ, FFMQ NR, FFMQ O							
Fogarty 2015	Revmatoid Arthritis	DAS28-CRP, Early morning stiffness, Pain VAS, Patient global ass, Morning stiffness, Pain, DAS28-CR	2, 4	51	22			88	ITT
Friskvold 2009	Heart disease	CES-D, PSS, DASS, BMI, PSQI, WT/Ibs, CAM	2	40	26	29		100	Non-ITT
Garland 2014	Cancer and insomnia	C-SOSI, POMS, DBAS, ISI, PSQI, SE Actigraphy, SE Diary , SOL Actigraphy, SOL Diary, TST Actigraphy, TST Diary, WASO Actigraphy, WASO Diary	5	111	18			61	ITT
Gaylord 2011	Irritable Bowel Syndr.	BSI, Pain Catastroph, Reinterpreting pain, IBS-QOL, IBS severity, Visceral sensitivity, FFMQ AA, FFMQ D, FFMQ NJ, FFMQ NR, FFMQ O, BSI-18 anx, BSI-18 depr, BSI-18 general severity, IBS-QOL, BSI-18 somatization, IBS severity, VSI, FFMQ		75	20			100	Non-ITT
Gayner 2012	HIV	HADS anx, HADS depr, IES total, PANAS neg, PANAS pos	4	117	30	60		0	ITT
Goldin 2012	Sosal Anxiety Disorder	LSAS-SR, Neg Selfendors, Pos Selfendors, Sheehan Disablility Dcale, KIMS		56	26			55	ITT
Gross 2010	Solid organ transplant	STAI state, CES-D, QOL VAS, SF-12 MH, SF-12 PH, SF-36 Pain, SF-36 Vitality, Health VAS, PSQI	6, 12	30	26	29		45	Non-ITT

Table 1: Study characteristics

Study name	Target Group	Outcome Measures	F-up (ms)	N	MBSR hours	Practice Min/day	Atten-dance %	Women %	ITT / Non-ITT
Gross 2011	Chronic insomnia	STAI state, CES-D, DBAS, HRQOL, SF-12 MH, SF-12 PH, Diary SOL min, Diary TST, Diary WASO, Diary Sleep effic, ISI total score, PSQI, Sleep self-eff, Actigr Sleep effic, Actigr SOL, Actigr TST, Actigr WASO	5	138	26	23		73	Non-ITT
Grossman 2010	Mulitple Sclerosis	STAI, CES-D, MFIS, HAQUAMS, PQOLC	6	150	27	30	92	79	ITT
Hartmann 2012	Diabetes	PHQ-9 depression, PHQ-9 stress, SF-12 MH, SF-12 PH, 24h BP, ACTH, Albuminuria, BMI, Diast BT, fGlucose, GFR (ml/min*1,73m2), HbA1c, HDL-C, Hip-to-waist-ratio, LDL-C, max. syst BP (mmHg), max.dias.BP (mmHg), mean carotid IMT, metanephrine (pg/ml), normetanephrine (pg/ml), serum-Cholesterol, serum-cortisol (ug/dl), serum-creatinine (mg/dl), Syst BT, triglyceride, Urinary AlbCrR	10	110				22	ITT
Henderson 2012	Cancer (breast)	GSI, ActiveBehCoping, ActiveCogCoping, AvoidanceCoping, CECS, FACT Spirituality, MMAC Avoidance, MMAC Helpless, SOC Compr, SOC Meaning, FACT EmoWB, FACT SocFamilyWB	2, 10, 22	172	26			100	Non-ITT
Hoffman 2012	Cancer (breast)	POMS, FACT-B, FACT-ES, WHO-5	1	229	22			100	Non-ITT

Table 1: Study characteristics

Study name	Target Group	Outcome Measures	F-up (ms)	N	MBSR hours	Practice Min/day	Atten-dance %	Women %	ITT / Non-ITT
Hoge 2013	Sosal Anxiety Disorder	BAI, CGI-S, HAM-A, SSPS, PSQI		93	20			51	Non-ITT
Hou 2014	Family care givers	STAI state, STAI trait, CES-D, PSS, CRSE-OR, CRSE-UT, SCS, SF-12 MH, SF-12 PH, FFMQ		141	16			83	ITT
Huang 2015	Mental distress	GHQ12, PSS, Job control, Job demands, Fatigue	1, 2	144	16			44	ITT
Hughes 2013	Prehypertention	Diast BP, Syst BP		56	20		89	57	ITT
Jain 2007	Students	GSI, DER Distraction, DER Rumination, INSPIRIT		81	12	45		81	Non-ITT
Jazaieri 2012	Sosal Anxiety Disorder	LSAS-SR, SIAS-S, BDI, PSS, RSES, ULS-8, SCS, SWLS	3	56	27	30		52	ITT
Jedel 2015	Ulcerative colitis	BDI, PSQ, STAI, PHCS, IBDQ-Total, 24-hour Cortisol, ACTH, Calprotectin, CRP, IL-10, IL-6, IL-8, US-DAI, MAAS	12	55	20			56	ITT
Jensen 2012	Normal adults	PSS, AUC1, AUCg, MAAS		48	27		87	66	Non-ITT
Johansson 2012	Stroke or tr. brain dam.	MFS, TMT B, TMT C		29	26			57	NonITT
Johns 2015	Cancer fatigue	GAD7 Anx, PHQ-9 depression, FSI % of days, FSI fatigue days, FSI severity, FSI interference, SDS, SF-36 vitality, ISI Sleep dist	1	35	14	35	88	94	ITT
Kang 2009	Nursing students	STAI, BDI, PW1-SF		41	16			100	ITT

Table 1: Study characteristics

Study name	Target Group	Outcome Measures	F-up (ms)	N	MBSR hours	Practice Min/day	Atten-dance %	Women %	ITT / Non-ITT
Kearney 2013	PostTraumatic Stress D.	PHQ-9 depression, PCL-C, BADS, SF-8 MCS, SF-8 PCS, FFMQ	4	47	27			21	ITT
Kilpatrick 2011	Normal adults	Aud/SAl BA 19, Aud/SAl BA18, Aud/Sal BA9/32, Aud/Sal OP, Executive ctl BA40, Lat vis BA23, Lat vis BA4, Lat vis BA5, Med vis BA24/32, Med vis BA30, Med vis BA30/17, Sensimotor BA30, Sensimotor BA31, MAAS		31	27	48	90	100	Non-ITT
Klatt 2008	Normal adults	PSS, PSQI		45	6	17	80	75	Non-ITT
Koszycki 2007	Generalized Anx.D.	LSAS-SR Avoid, LSAS-SR Fear, SIAS-S, SPS, BDI, CGI-IllnessSeverity, InterperSensM, QOL		53	27,5		85	53	ITT
la Cour 2015	Chronic pain	HADS anx, HADS depr, Catastophic thinking, Control over pain, Minimizing pain, Pain acceptance, total score, Pain willingness, SF-36 PH, SF-36 MH, SF-36, vitality, BPI, average score		109	28		87	85	ITT
Lengacher 2009	Cancer (breast)	STAI state, STAI trait, CES-D, Distress, Fatigue, PSS, Sadness, LOT, Enjoyment of life, General activity, Housework, Mood, Relationship, Walking, % Activated T cells, %CCD3+IL-4,PHA, %CD3+IFNy,PHA, B lymphocytes, CD3+, CD4+, CD4+/CD8+, CD8+, Disturbed sleep, Drowsy, Dry mouth, Lack of appetite, Nausea, Nkcells, Numbness,		84	12	30	80	100	ITT

Table 1: Study characteristics

Study name	Target Group	Outcome Measures	F-up (ms)	N	MBSR hours	Practice Min/day	Atten-dance %	Women %	ITT / Non-ITT
		Pain, Shortness of breath, Th1/Th-2,PHA, Total lymphocytes, Trouble remembering, Vomiting							
Lengacher 2014	Cancer (breast)	ActigEfficiency, ActigLatencySleep, ActigMinSleep, ActigMinWakeup, ActigNoWakeup, PSQI, Sleep diary duration, Sleep diary latency	1,5	142	12			100	Non-ITT
Lengacher 2014a	Cancer (breast)	ActigEfficiency	1,5	79	12			100	ITT
MacCoon 2012	2 - normal adults	GSI, Thermal pain	4	63	28			82	Non-ITT
Majid 2012	1b - GAD	BAI, BDI, PSWQ		31	16			0	Non-ITT
Malarkey 2013	Normal adults	Cortisol mean, CRP, IL-6, TMS	6, 12	186	9	15		88	Non-ITT
Manotas 2012	Normal adults	BSI, PSS, AAQ-II flexibility, ESQ rumination, FFMQ		131	8			90	Non-ITT
Moritz 2006	Mood disturbance	POMS, SF-36 MH	1	165	12	18	65	82	ITT
Morone 2008	Chr. low back pain	CPAQ, SF-36 MH, SF-36 PH, MPQ-SF		37	12	32	84	57	Non-ITT
Moss 2015	Older adults	GSI, AAQ-II, SCS, SF36 MH, SF36 MH, SF36 PF, FFMQ AA, FFMQ D, FFMQ NJ, FFMQ NR, FFMQ O		39	16			82	ITT
Moynihan 2013	Older adults	PANAS pos, IgG, MAAS, Trials B/A	1, 6	201	27			62	Non-ITT

Table 1: Study characteristics

Study name	Target Group	Outcome Measures	F-up (ms)	N	MBSR hours	Practice Min/day	Atten-dance %	Women %	ITT / Non-ITT
Murphy 1995	2- prisoners	NegSelf-focusResp, Self-focus/negS-f, STAXI, STAXI Contol, STAXI In, STAXI Out, STAXI State, STAXI Trait, Cortisol20/40min, Cortisol20/60min		31	12			0	Non-ITT
Murrey 2004	Sex offenders	PANAS neg, PANAS pos, Coping Str I appr, Coping Str I avoid, Coping U Sex I, Neg Mood reg S,		27	12	35		82	Non-ITT
Neece 2014	Parents	CES-D, FIQ, PSI, SWLS		46	22			78	Non-ITT
Nyclicek 2008	Distress	MQ Vital exhaustion, PSS, PANAS neg, PANAS pos, WHOQOL, MAAS		60	26			67	ITT
Nyclicek 2013	Distress	PSS, PANAS neg, Diast BP, Syst BP, Trait NegAffect, Trait SocInhibition		146	26			71	Non-ITT
Oman 2008	Students	PSS, RRQ, ADHS hope, HFS forgiveness, IRI empathy, SCS self-compassion, SWB, MAAS	2, 12	30	12		83	87	Non-ITT
Ong 2014	Chronic insomnia	ISI, PSAS, SE Actigraphy, SE Diary, SE PSG, TST Actigraphy, TST Diary, TST PSG, TWT Actigraphy, TWT Diary, TWT PSG	3, 6	54	26			74	ITT
Pbert 2012	Chronic astma	PSS, AQOL, FEV1, PEF, PEF Var, Short term medic.	6, 12	83	26		62	67	ITT
Pickut 2013	Parkinson	GMD Amygdala, GMD Caudate, GMD Cerebellum , GMD Cerebellum ant, GMD Hippoc ParaHipp, GMD Hippocampus, GMD Occipital , GMD Occipital lobe lg, GMD Temporal lobe ig, GMD Temporal lobe mg, GMD Thalamus		30	20	55	97	48	Non-ITT

Table 1: Study characteristics

Study name	Target Group	Outcome Measures	F-up (ms)	N	MBSR hours	Practice Min/day	Atten-dance %	Women %	ITT / Non-ITT
Pipe 2009	Nurse leaders	GSI, Caring Efficacy Scale		33	10			98	Non-ITT
Plews-Ogan	Chronic Musc.Sc. pain	SF-12 MH, Pain unpleasa	1	30	20		79	77	Non-ITT
Polusny 2015	PostTraumatic Stress D.	PHQ9, PCL, WHOQOL-BREF, CAPS, FFMQ	2	116	22		77	16	ITT
Pradhan 2007	Revmatoid Arthritis	GSI, PWBScale, Dis activity, MAAS	4, 6	63	26	8	85	87	ITT
Reich 2014	Breast cancer	Cog/ps symptoms, Fatigue, GI symptoms		41	16			100	ITT
Robins 2012	Normal adults	ACS, CFQ, DERS, PSWO, RRS, SAES-Ex, SAES-In, SCS, FFMQ		56	27			84	Non-ITT
Rosenkranz 2013	Normal adults	GSI, Cortisol AUC, Flare size, MSC, TSST Cortisol	4	49	27	33		80	Non-ITT
Schmidt 2011	Fibromyalgia	STAI, CES-D, HRQOL, FIQ, GCQ, PPS affective, PPS sensory, PSQI, FMI	2	177	27			100	ITT
SeyedAlinaghi 2012	HIV	SCL-90, CD4, MSCL	3, 6, 9, 12	173	27			31	Non-ITT
Shapiro 1998	Health care prof.	STAI state, STAI trait, GSI, Empathy, INSPIRIT		18	18			56	Non-ITT
Shapiro 2005	Sudents	BSI, MBI, PSS, SCS, SWLS		38	16				Non-ITT
Song 2015	Sudents	DASS-A, DASS-D, DASS-S, MAAS		50	16			82	Non-ITT

Table 1: Study characteristics

Study name	Target Group	Outcome Measures	F-up (ms)	N	MBSR hours	Practice Min/day	Atten-dance %	Women %	ITT / Non-ITT
Speca 2000	Cancer outpatients	SOSI, POMS		109	11		85	71	ITT
Surawy 2005	Chronic fatigue	HADS Anx, HADS Depr, CFS, SF-36 PH		44	20		75	56	Non-ITT
Tacon 2003	CardioVascular D.	STAI state, CECS, PF-SOC Reactive, SF-36 PH, Catecholamin, Cortisol, Heart rate, Tidal volume, Ventilation		20	16			100	Non-ITT
Vieten 2008	Pregnant w/mood dist.	STAI state, CES-D, PSS, ARM, PANAS neg, PANAS pos, MAAS		31	16	11	90	100	Non-ITT
Vøllestad 2011	Anxiety disorders	BAI, STAI state, STAI trait, BDI, SCL-90, PSWQ, BIS, FFMQ	6	76	26	34	77	67	ITT
Weissbecker 2002	Fibromyalgia	PSS, BDI, SOC, CAR mean, Corisol mean, FIQ ph funct, FIQ sympt sev, FSI, SSQ, VASpain	2	91	26		69	100	ITT
Wells 2013	Mild cognitive impairm.	fMRILeftHippoc		14	22			57	Non-ITT
Wells 2014	Migraine	Migraine frequency and severity, HIT-6 (Headache Impact Test-6), MIDAS (Migraine Disability Assessment), MQOL (Migraine specific Quality of Life), PHQ-9, STAI, PSS, FFMQ, HMSES (Headache Management Self-Efficacy Scale)	1	19	22			90	ITT

Table 1: Study characteristics

Study name	Target Group	Outcome Measures	F-up (ms)	N	MBSR hours	Practice Min/day	Atten-dance %	Women %	ITT / Non-ITT
Whitebird 2013	Stress in caregivers	STAI, CED-S, PSS, Subjective stress burden, Caregiver burden, Social support total, Subjective demand burden, SF-12 MH, SF-12 PH	4	78	25	29	91	89	ITT
Williams 2001	Stress	DSI, GSI, MSCL	3	103	28		83	73	Non-ITT
Wong 2011	Chronic pain	STAI state, STAI trait, CES-D, POMS depression, Pain-related distress, POMS anger hostility, POMS confusion, POMS fatigue inertia, POMS tension anxiety, POMS vigor activity, SF-12 MH, SF-12 PH, Pain intensity, Sick leaves	3, 6	99	27			29	ITT
Würtzen 2013	Breast cancer	CES-D, SCL-90 anx, SCL-90 depr, FACIT-Sp, BCPT, optimal sleep 7-8, sleep probl index I, sleep probl.index II, sleep quantity/h, FFMQ	4, 10, 12	336	21			100	ITT
Zernicke 2013	Irritable Bowl Syndr.	C-SOSI, POMS, FACIT-sp, IBS-QOL, IBS-SSS	6	90	23	20	67	90	ITT

Notes:

AAQ-II= Acceptance and Action Questionnaire-II, A/Brisbane H1N1(and H3N2)= influenza virus antibody, AB titre=Influenza Antibody Titre, ACTH= Adrenocorticotrophic hormone, Actigr SE= Actigraphy sleep efficiency, Actigr SOL= Actigraphy sleep onset latency, Actigr MinSleep= Actigraphy minimum sleep at night, Actigr WASOMin= Actigraphy minutes of wake after sleep onset, Actigr WASONo= Number of wakeing bouts, Actigr TST= Actigraphy total sleep time, Actigr TWT= Actigraphy Total Wake Time, ActiveBehCoping= Active behavioural coping, ActiveCogCoping= Active cognitive coping, ACS= Affective control scale, % Activated T cells, ADHS= Adult dispositional hope scale, AGN Tot Com= Affective Go No Go

task total commissions, Albuminuria, Analgesic medic= Analgesic medication, Anger Rum S=Anger Rumination Scale, Anx Sens I=Anxiety Sensitivity Index, Anx aboutspeech= Anxiety about speech, AQOL= Asthma related quality of life, AreaUTCseverity= Area under the curve severity, ARM=Affect Regulation Measure, ART side effects= Anti-retroviral therapy side effects (bother and severity), ASI=Addiction Severity Index, AUC= Area under the curve, Aud/SAl (BA 9,18,19,32 andOD)= Auditory/Salience area, AvoidanceCoping, BAI=Beck Anxiety Index, Basic Relaxation, 24h BP= 24 hour Blood Pressure (systolic and diastolic), Awake BP= Awake blood pressure (systolic and diastolic), B lymphocytes, B/Brisbane= B Brisbane lymphocytes, BADS= Behavioural Activation for Depression Scale, BCPT= Breast Cancer Prevention Trial eight point checklist, BDI=Beck Depression Inventory, BIS= Bergen Insomnia Scale, BladderQOL= Bladder-related Quality of Life, BMI= Body Mass Index, BPI= Brief Pain Inventory, BSI= Basic Symptom Inventory (general, anxiety, depression, somatization), Calprotectin, CAM= Cognitive and Affective Mindfulness Scale, CAPS= Clinician Administered PTSD Scale, CAR Mean= Coritsol Awakening Response, Caregiver burden, Caring Efficacy Scale, Catastophic thinking, Catecholamin, CD(3,4,8)= lymphocytes, CECS=Courtauld Emotional Control Scale, CES-D=Centre for Epidemiologic Studies Depression Scale, CFS=Chalder Fatigue Scale, CFQ= Cognitive Failures Questionnaire, CGI=Clinical Global Impression, Cholesterol, 24-hour Cortisol, CLASS= Observer rated teacher classroom behavior (with subscales), Coping, Coping self-efficacy, Coping Str I= Coping Strategy Index (approach and avoidance), Coping U Sex I= Coping Using Sex Inventory, Core Mindfulness, CPAQ=Chronic Pain Acceptance Questionnaire, Cortisol (mean, morning, 20/40min, 20/60min), creatinine, CRP= C-reactiv protein, CRSE= Care-giver Self-efficacy Scale, CSI=Coping Strategy Index, CSR= Clinician Severity Rating, CUSI=Coping Using Sex Inventory, DAS28=Disease Activity Scale, DASS= Depression, Anxiety and Stress Scale, DER= Daily Emotion Report, DERS= Difficulties in Emotion Regulation Scale (distraction and rumination subscale), Diary SOL min= Diary sleep onset latency, Diary TST= Diary Total Sleep Time, Diary TWT= Diary Total Wake Time, Diary WASO= Diary Waking After Sleep Onset, Diary SE= Diary Sleep Efficiency, Dis activity= Disease Activity, Distress, Disturbed sleep, Drowsy, Dry mouth, DSI=Daily Stress Inventory, Early morning stiffness, ECRS=Empathy Construct Rating Scale, Empathy, Engagement activity, Enjoyment of life, ESQ rumination=Emotional Style Questionnaire, FACIT-Sp= Functional Assessment of Cancer-Spiritual wellbeing, FACT= Functional Assessment of Cancer Therapy (with subscales), Fatigue, FSI= Fatigue Symptom Inventory (with subscales), FEV1= Forced Expiratory Volume 1 second, FEV/FVC= Forced Expiratory Volume/Forced Vital Capasity, FFMQ= Five Facet Mindfulness Questionnaire (with subscales), fGlucose= fasting Glucose, FIQ= Fibromyalgia Impact Questionnaire (with subscales), Flare size, FMI= Friburgh Mindfulness Inventory, fMRILeftHippoc= functional MRI Left Hippocampus, GAD7 Anx= Patient Health Questionnaire Generalized Anxiety Disorder, GCQ= Giessen Complaint Questionnaire, General activity, GFR (ml/min*1,73m2)= Glomerular Filtration Rate, GHQ12= General Health Questionnaire, GI symptoms= Gastro-intestinal Symptoms, GMD= Grey Matter Density (different brain regions), GSI= General Severity Index from the Hopkins Symptom Checklist-90, HADS= Hospital Anxiety and Depression Scale, HAM-A= Hamilton Anxiety Scale, HAQUAMS=Hamburg Quality of Life Questionnaire in Multiple Sclerosis, HbA1c= Heamoglobin A1c, HDL-C= High Density Lipoprotein, Health VAS= Health Visual Analogue Scale, Heart rate, HFS= Heartland Forgiveness Scale, Hip-to-waist-ratio, Housework, HR=Heart Rate, HRQOL= Health-Related Quality of

Life, IA recruit= Interoceptive Attention Recruitment (different brain areas), IBDQ= The Inflammatory Bowel Disease Quality of Life questionnaire, IBS severity= Inflammatory Bowel Syndrome Severity, IBS QOL= Inflammatory Bowel Syndrome Quality of Life, IES-R=Impact of Event Scale-Revised (subscales for intrusion, avoidance and hyperarousal, INSPIRIT= Index of Core Spiritual Experience, IgG= Immunoglobulin G, IL-6, 8 og 10= Interleukin, IPSM=Interpersonal Sensitivity measure, IRI=Individual Relaxation Index, IRI= Interpersonal Reactivity Index (with subscales), ISI= Insomnia Severity Index, ITT= Intention to treat analysis, Job control, Job demands, KIMS= Kentucky Inventory of Mindfulness Skills, Lack of appetite, LAP-R= Reker`s Life Attitude Profile-Revised, Laser pain, Lat vis BA4,5 and 23= Lateral visual cortex, LCB=Locus of Control of Behaviour Scale, LOT= Life Orientation Test, LSAS=Liebowitz Social Anxiety Scale (Fear and Avoidance subscales), LSRDS=Liebowitz Self-Rated Disability Scale, MAAS=Mindfulness Attention Awareness Scale, MASQ-AAS= Mini Mood and Anxiety Symptom Questionnaire-Anxious Arousal subscale, MBI= Maslach Burnout Inventory (subscales for Emotional Exhaustion, Depersonalization and Personal Accomplishment), MBI-s= Maslach Burnout Inventory – Student verison, MBSR= Mindfulness Based Stress Reduction, McGPQ=McGill Pain Questionnaire Short Form, Mean ARIdays= Mean Acute Respiratory Infection days, mean carotid IMT= mean Carotid Intima Media Thickness, Med vis BA24/32, 30 and 30/17= Medial visceral cortex, metanephrine (pg/ml), MFIS= Modified Fatigue Impact Scale, MFS= Mental Fatigue Scale, Minimizing pain, MMAC= Mental Adjustment to Cancer Scale (subscales), Mood, Morning stiffness, MPQ-SF= MQ=Maastrict Questionnaire, MSCL=Medical Symptom Checklist, N Anger I= Novaco Anger Inventory, Nausea, Neg Selfendors= Negative Self-endorsement, NegSelf-focusResp= Negative Self-focus on Respiration, Night BP= Night Blood Pressure (systolic and diastolic), NKcells= Normocytic Killer Cells, NMRS=Negative Mood Regulation Scale, normetanephrine (pg/ml), Novaco Anger Inv= Novaco Anger Inventory, Numbness, optimal sleep 7-8, Overall QOL= Overall Quality of Life, Pain (various aspects like acceptance, strength, willingness, catastrophizing, distress) PANAS= Positive and Negative Affect Scale, Patient global ass= Patient Global Assessment, PCL= PSTD Checklist, PEF= Peak Expiratory Flow (and variability), PF-SOC=Problem-Focused Styles of Coping, PHCS= Perceived Health Competence Scale, PHQ-9= Patient Health Questionnaire (with subscales), PMSS= Perceived Medical School Stress, POMS= Profile of Mood States (with subscales), Pos Selfendor= Positive Self-endorsement, positive energy, PPS (with subscales)= Pain Perception Scale (with subscales), PQOLC=Profile of Health-Related Quality of Life in Chronic Disorders, PSG SE= Polysomnography Sleep Efficiency, PSG TST= Polysomnography Total Sleep Time, PSG TWT= Polysomnography Total Wake Time, PSI= Perceptions of Stuttering Inventory, PSOCQ= Pain Stages Of Change Questionnaire (with subscales), PSOM= Positive States of Mind, PSQ= Perceived Stress Questionnaire, PSQl=Pittsburgh Sleep Quality Index, PSAS= Pre-Sleep Arousal Scale, PSS=Perceived Stress Scale, PW1-SF= Psychosocial Wellbeing short form, PWBScale= Psychological Wellbeing Scale, PSWQ=Penn State Worry Questionnaire, PUS=Pain Unpleasentness Scale, PWS=Positive Well-Being Scales, QoLI=Quality of Life Inventory, Vital Exhaustion, QOL VAS= Quality of Life Visual analogue scale, QOLWHO= Quality of Life World Health Organisation Brief inventory (with subscales), Reinterpreting pain, Relationship, Resilience S= Resilience Scale, Resp Frequency= Respiratory frequency, Resp Volume= Respiratory volume, RMDQ= Roland Morris Disability Questionnaire, RRQ= Rumination and Reflection Questionnaire, RRS= Ruminative Responses Scale, RSES= Rosenberg Self-Esteem Scale,

RSQ=Rumination Scale of the Response Styles Questionnaire, Rumination scale, Ryff-PR soc sup= Ryff's Positive Relationship to others social support scale, S-24= Attitude towards speech situations, Sadness, SAES= Spielberger Anger Expression Scale (with subscales), SAS=Hovden Spirituality Assesssment Scale, SCI=Shapiro Control Index, SCL-5= Hopkins Symptom Checklist-5, SCL-90 dep= Hopkins Symptom Checklist 90 (with subscales), SCS=Self-Compassion Scale (with subscales), Sensitivity Measure, SDS= Sheehan Disability Scale, Sensimotor BA30 and BA31= Sensimotor cortex, SESAS=Self-Efficacy Scale for Adults who Stutter, SF-8 MH= Health Survey Questionnaire-Mental summary score, SF-8 PH= Health Survey Questionnaire-Physical summary score SF-12 MH= Health Survey Questionnaire-Mental summary score, SF-12 PH= Health Survey Questionnaire-Physical summary score, SF36 PH= Health Survey Questionnaire - Physical Summary Score, SF36 MH= Health Survey Questionnaire - Mental Summary Score, SF-36-Vit= Health Survey Questionnaire-Vitality subscale, SF-McGill= Short Form McGill Pain Questionnaire (with subscales), Shapiro control I= Shapiro Control Inventory, SheehanDS= Sheehan Disability Index, SHC= Ursin Subjective Health Complaints, Short term medic.= Short term medication, Shortness of breath, SIAS=Social Interaction Anxiety Scale, Sick leaves, Side effects, Sleep diary duration, Sleep diary latency, sleep probl index (I and II), Sleep quality, sleep quantity/h, Sleep self-eff= Sleep self-efficacy, SOC=Sense of Coherence (with subscales), SOSI=Symptoms of Stress Inventory, Social support total, SPAQ= Surwey of Pain Attitude Questionnaire, SPS=Social Phobia Scale, SSC=Speech Situation Checklist, SSPS= Self Statements during Public Speaking scale, SSQ= Stanford Sleep Questionnaire, STAI Trait= Spielberger State-Trait Anxiety Inventory, STAXI= State-Trait Anger Expression Inventory, Subj H Compl= Subjective Health Complaint, Subjective demand burden, Subjective stress burden, Sustained Attention, SWB= Subjective Well-Being, SWLS=Satisfaction With Life Scale, Th1/Th2,PHA= T lymphocyte helper cells (1 and 2), Thermal pain, TMS= Toronto Mindfulness Scale, TMT (A,B and C)= Trial Making Test, Total IE= Total urge episodes, Total lymphocytes, Trait NegAffect= Trait Negative Affect, Trait SocInhibition= Trait Social Inhibition, transcendence, TSST Cortisol= Trier Social Stress Test, TV=Tidal Volume, Vent=Ventilation, VSI= Visceral Sensitivity Index, WHOQOL-BREF= World Health Organization Quality of Life Scale Brief version,

4.1.2 Included studies

Characteristics of the 101 included studies are listed in Table 1. Forty-seven studies recruited people with somatic health problems: 12 of these included patients with musculoskeletal pain or rheumatic disorders (Banth & Ardebil, 2015; Brown & Jones, 2013; Esmer, Blum, Rulf, & Pier, 2010; Fogarty, Booth, Gamble, Dalbeth, & Consedine, 2015; la Cour & Petersen, 2015; Morone, Greco, & Weiner, 2008; Plews-Ogan et al., 2005 ; Pradhan et al., 2007; Schmidt et al., 2011; Surawy, Roberts, & Silver, 2005; Weissbecker et al., 2002; Wong, 2011), 11 included cancer patients (Bränström, Kvillemo, Brandberg, & Moskowitz, 2010; Garland et al. 2014; Henderson et al., 2012; Hoffman et al., 2012; Johns et al. 2015; Lengacher et al., 2009; Lengacher et al., 2014; Lengacher et al., 2014a; Reich et al., 2014; Speca, Carlson, Goodey, & Angen, 2000; Würtzen, 2013), six included patients with neurological diseases (Gross et al., 2011; Grossman, 2010; Johansson, Bjuhr, & Ronnback, 2012; Ong et al., 2014; Pickut et al., 2013; Wells, 2014), six included patients with cardiovascular/lung diseases (Arefnasab, 2013; Blom et al.,2014; Frisvold, 2009; Hughes et al., 2013; Tacon, McComb, Caldera, & Randolph 2003; Pbert, 2012), five included patients with infectious diseases (Barrett, 2012; Creswell, Myers, Cole, & Irwin, 2009; Duncan et al., 2012; Gayner et al., 2012; SeyedAlinaghi et al., 2012), four included patients with gastrointestinal or urinary problems (Baker, Costa, Guarino, & Nygaard, 2014; Gaylord, 2011; Jedel et al., 2015; Zernicke et al., 2013), two included patients with endocrine disorders (Carmody et al., 2011; Hartmann et al., 2012), and one study included patients with solid organ transplants (Gross et al., 2010).

Twenty-two studies recruited people with mental health problems. Ten of these included participants with stress related problems (Kearney, McDermott, Malte, Martinez, & Simpson, 2013; Polusny et al., 2015; Dykens, 2014; Creswell et al., 2012; Huang, Li, Huang, & Tang, 2015; Nyclicek & Kuijpers, 2008; Nyclicek, 2013; Whitebird et al., 2013; Williams, 2001; Wells, 2013), seven included participants with anxiety disorders (Arch et al., 2013; Goldin, Ziv, Jazaieri, & Gross 2012; Hoge, 2013; Jazaieri, Goldin, Werner, Ziv, & Gross, 2012; Koszycki, Benger, Shlik, & Bradwejn, 2007; Majid, Seghatoleslam, Homan, Akhvast, & Habil, 2012; Vøllestad, Sivertsen, & Nielsen, 2011), two included participants with mood disorders (Moritz et al., 2006; Vieten & Astin, 2008), one included substance abusers (Alterman, 2004), one included sex-offenders (Murrey, 2004), and one included people who stutter (de Veer, Brouwers, Evers, & Tomic, 2009).

The remaining 32 studies included various groups without any particular clinical characteristics. Twelve studies included people from the general population (Anderson, Lau, Segal, & Bishop, 2007; Carson, 2004; de Veer, 2009; Farb, Segal, & Anderson, 2013; Jensen, Vangkilde, Frokjaer, & Hasselbalch, 2012; Kilpatrick et al., 2011; Klatt 2008; MacCoon, 2012; Malarkey, Jarjoura, & Klatt, 2013; Neece, 2014; Robins, Keng, Ekblad, & Brantley, 2012; Rosenkranz et al., 2013), eight included students (Astin, 1997; de Vibe et al., 2013; Erogul, Singer, McIntyre, & Stefanov, 2014; Jain et al., 2007; Kang, Choi, & Ryu, 2009; Oman, Shapiro, Thoresen, Plante, & Flinders, 2008; Shapiro, Astin, Bishop, & Cordova, 2005; Song & Lindquist, 2015), six included health care professionals (Amutio, Martinez-Taboada,

Hermosilla, & Delgado, 2015; Cohen-Katz, Wiley, Capuano, Baker, & Shapiro, 2005; Corsica Hood, Katterman, Kleinman, & Ivan, 2014; Manotas, Eraso, Segura, Oggins, & McGovern, 2012; Pipe et al., 2009; Shapiro, Schwartz, & Bonner, 1998), three included elderly people (Creswell, 2012; Moss et al., 2015; Moynihan, 2013), one study was carried out with family caregivers (Hou et al., 2014), one with teachers (Flook, Goldberg, Pinger, Bonus, & Davidson, 2013), and one with prisoners (Murphy, 1995).

Seventy-two studies compared MBSR with wait-list (WL) controls or treatment as usual (TAU). Thirty-seven studies compared MBSR with a different educational or treatment approach. Seven of the latter compared MBSR both with an active intervention, and a WL or TAU control group (Barrett, 2012; Henderson, 2012; Jain, 2007; Jensen, 2012; Moritz, 2006; Plews-Ogan, 2005; Schmidt, 2011), one of which compared MBSR with two other active interventions (Ong 2014). The active interventions were:

- Group health educational Programs in 15 studies (Frisvold, 2009; Garland, 2012; Gross, 2010; Henderson, 2012; Hou, 2014; Jedel, 2015; MacCoon, 2012; Malarkey, 2013; Pbert, 2012; Pipe, 2009; Rosenkranz, 2013; SeyedAlinaghi, 2012; Whitebird, 2013; Williams, 2001; Wong, 2011)
- Group therapy Programs in three studies (Arch, 2013 and Koszycki, 2007 with cognitive therapy, and Polusny, 2015 with patient centred therapy)
- Aerobic exercise Programs in three studies (Barrett, 2012; Goldin, 2012; Jazaieri, 2012)
- Progressive muscle relaxation in three studies (Hughes, 2013; Murphy, 1995; Schmidt 2011) and somatic relaxation in one study (Jain, 2007)
- Other mindfulness interventions in three studies (Creswell, 2009; Ong 2014; Oman, 2008)
- Stress management courses in two studies (Corsica, 2014; Hoge, 2013)
- Support group in one study (Gaylord, 2011)
- Pharmacotherapy in one study (Gross ,2011)
- Positive psychology course in one study (Dykens, 2014)
- Attentional control in one study (Jensen, 2012)
- Massage in one study (Plews-Ogan, 2005)
- A spirituality Program in one study (Moritz, 2006)
- A yoga Program in one study (Baker, 2014)
- Self-monitoring in one study (Ong, 2014)

Five of the included studies could not be used in the meta-analyses because of the way the data were presented (Alterman, 2004; Corsica, 2014; Dykens, 2014; Lengacher, 2014a; Wells, 2014). In addition, a second report from the MacCoon (2012) study, and findings from the Oman (2008) study, did not have results that could be used. The results from these studies are reported separately.

Fifteen included studies (Barrett, 2012; Bränström, 2010; Gaylord, 2011; Hartmann, 2012; Hoge, 2013; Lengacher, 2009; MacCoon, 2012; Manotas, 2012; Moynihan, 2013; Nyclicek,

2003; Oman, 2008; Robins, 2012; Tacon, 003; Weissbecker, 2002; Würtzen, 2013) were also reported on in one or more secondary publications (see References to included studies).

4.1.3 Excluded studies

In the current update, 145 studies were excluded because they were either not primary studies, not RCTs, the intervention did not conform to the MBSR protocol, or because they were not obtainable. Also, two articles were in Chinese. Reasons for exclusions are listed in the Characteristics of excluded studies section.

4.2 Risk of bias in included studies

Many of the studies presented insufficient information to enable us to decide whether the criteria for judging the risk of bias had been met or not. Two thirds of the studies carried a considerable risk of bias, scoring 0-4 (on a scale from 0 to 6, the latter value indicating no bias). Further risk of bias details are shown in Figures 1 and 2. The mean risk of bias score of the 70 new studies included in this update of the review was 4.0 compared to 3.3 for the 31 studies included in the first edition of this review, giving an overall risk of bias score of 3.7 for the 101 studies. The studies using active control groups had a mean risk of bias score of 4.3 while the score for studies with inactive control groups was 3.1. Table 2 shows the distribution across studies.

Table 2: Distribution of risk of bias in included studies (high score = low bias)

Risk of bias score	Number of studies
0	2
1	4
2	14
3	24
4	21
5	23
6	13

4.2.1 Allocation (selection bias)

32 studies failed to state clearly how randomisation was done, and it was therefore difficult to assess whether adequate concealment of allocation was obtained. Only 43 studies reported adequate concealment of allocation.

4.2.2 Blinding (performance bias and detection bias)

The quality item with lowest score was blinding. Blinding of participants and providers is impossible to achieve in studies where people receive stress reduction interventions. It is, however, possible to blind the assessors and this was done in 37 studies.

4.2.3 Incomplete outcome data (attrition bias)

Attrition was approximately 15%. Seven studies had definite incomplete reporting of all results (resulting in high risk of bias, see Figure 2-3). Forty-four studies reported intention to treat-analyses using different imputation methods for missing data.

4.2.4 Selective reporting (reporting bias)

Some studies reported negative findings for some outcomes, using terms like 'not significant' or p > .05, but without giving information that allowed us to include the outcomes in the meta-analyses. Since this was not done systematically, and because most studies did not publish protocols before the trials, the impact of this on the final results could not be assessed.

4.2.5 Publication bias

To assess potential publication bias, we used funnel plots and Egger's test for the post-intervention mental health effect sizes. The funnel plot was asymmetric for the MBSR versus inactive control (Figure 4), indicating a potential small study bias, i.e., some small studies that have not shown effect of MBSR vs inactive controls have not been published.

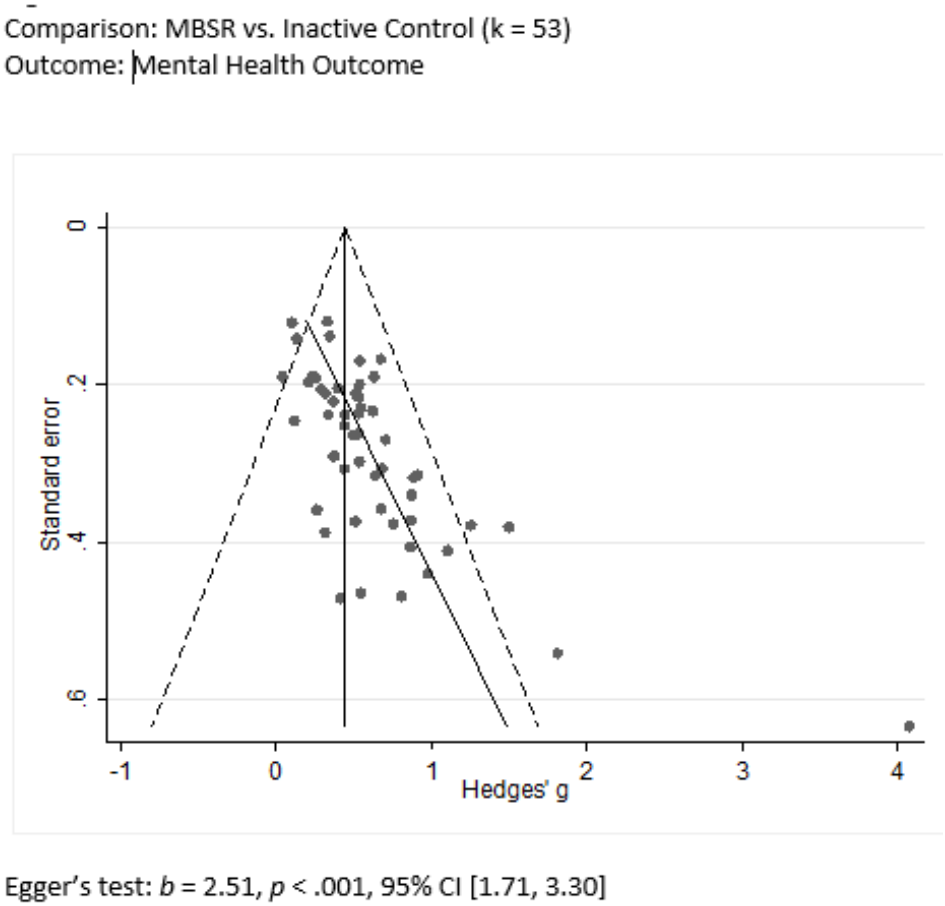

Figure 4: Funnel plot of MBSR studies using inactive controls

There was no evidence of asymmetry in the funnel plot for the MBSR versus active control conditions (Figure 5).

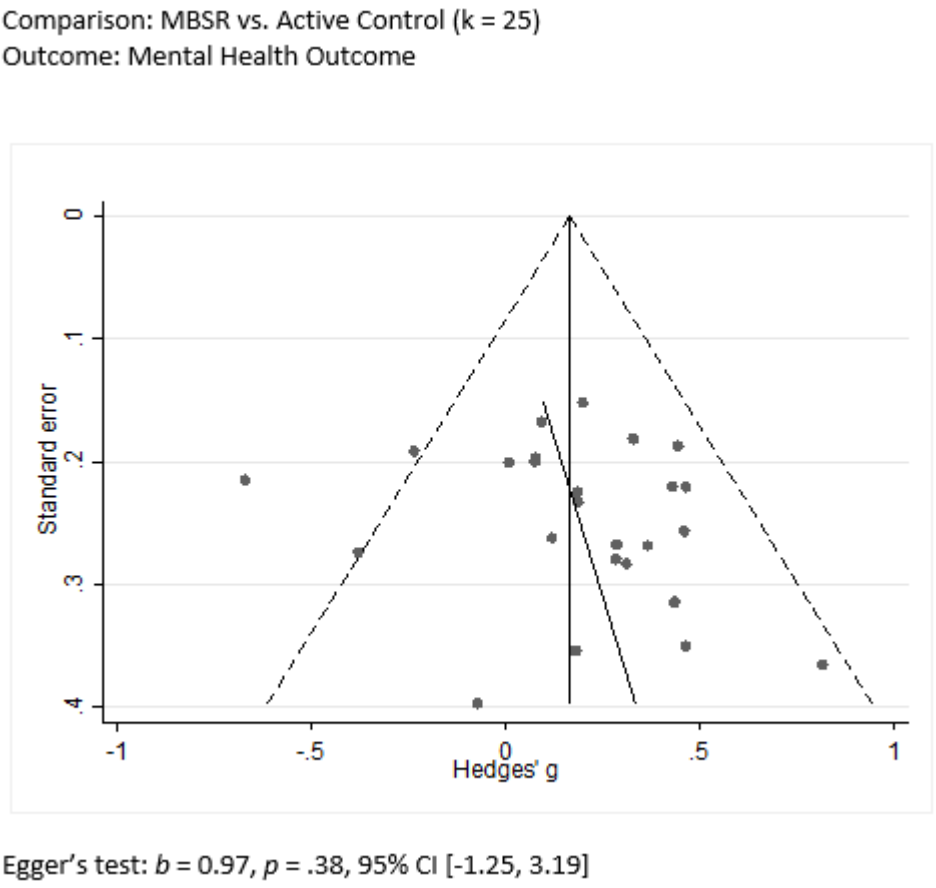

Figure 5. Funnel plot of MBSR studies using active controls

The search of the trial registers revealed that 28 (28%) of the 101 trials were registered. Seventeen (40%) of the 40 studies published from 2013-15 were registered. Fifteen of 37 (41%) trials using active control groups were registered before study start, compared to 13 of 72 (18%) with inactive control groups.

4.2.6 Other potential sources of bias

Other sources of bias were different assessors doing semi-structured interviews with the participants at baseline and after the intervention (Alterman, 2004), baseline differences between groups not accounted for (de Veer, 2009), some participants changing group after randomization (Oman, 2008), and some participants given additional sessions with a therapist (Surawy, 2005). Another bias arises from reporting different outcomes from the same study in several articles, but without sufficient correction of the significance level (Lengacher, 2009; Würtzen 2013). None of the first authors of the included studies have been involved in the development of the MBSR Program.

4.3 Synthesis of results

4.3.1 MBSR versus waitlist or treatment as usual (inactive control)

4.3.1.1 Primary outcomes

Effect sizes for the primary outcome groups are shown in Table 4 (showing which studies contributed to each outcome) and Figures 6-10 (showing the number of participants from each study that contributed to each outcome).

Table 4: Effect sizes of primary outcome groups, Anxiety, Depression, Stress, Other measures of mental health and composite Mental health, MBSR vs inactive controls

Outcomes	Studies	Measures	g	95% CI	Heterogeneity
Anxiety (20 studies, 24 outcomes)	Anderson, Barrett, Bränstöm, Carmody Davidson,de Veer, Gayner Grossman, Johns, Kang, la Cour, Lengacher 2009, Majid, Schmidt, Shapiro 1998, Song, Surawy, Tacon, Vieten, Vøllestad,	Anx about speech, BAI, DASS-A, GAD7 Anx, HADS Anx, STAI	0.56	0.41-0.71	Tau^2: 0.06 I^2: 47.74%
Depression (20 studies, 20 outcomes)	Anderson, Bränstöm, Duncan, Gayner, Grossman, Hartmann, Johns, Kang, Kearney, La Cour, Lengacher 2009, Majid, Neece, Schmidt, Song, Surawy, Vieten, Vøllestad, Weissbecker, Würtzen	BDI, CES-D, DASS-Depr, HADS-Depr, PHQ-9 depr	0.59	0.35-0.83	Tau^2: 0.15 I^2: 73.46%
Stress/distress (40 studies, 62 outcomes)	Astin, Barrett, Bränstöm, Carmody, Carson, Cohen-Katz,	BSI, CFS, C-SOSI, DASS-S, Distress	0.53	0.40-0.67	Tau^2: 0.11 I^2: 66.65%

	de Veer, de Vibe 2006, de Vibe 2013, Duncan, Erogul, Flook, Gayner, Grossman, Hartmann, Henderson, Huang, Jain, Jensen, Johansson, Johns, Kang, Klatt, Lengacher 2009, Manotas, Moss, Neece, Nyclicek, Oman, Pradhan, Shapiro 1998, Shapiro 2005, Song, Speca, Surawy, Vieten, Vøllestad, Weissbecker, Würtzen, Zernicke	Fatigue, FIQ, FSI, GHQ12, GSI, IES, MBI, MBI-s, MFIS, MFS MQ Vital exhaustion, PHQ-9 stress, PMSS, PSI, PSS, PW1-SF, SCL-5, SCL-90, SOSI			
Other measures of mental health (27 studies, 53 outcomes)	Amutio, Anderson, Barrett, Bränstöm, Carson, de Veer, Duncan, Gayner, Hoffman, Jain, Kearney, la Cour, Lengacher 2009, Majid 2012, Manotas, Moritz, Moss, Moynihan, Murrey, Nyclicek 2008, Nyclicek 2013, Oman, Robins, Speca, Vieten, Zernicke	AAQ-II, ACS, Anger Rum scale, Anx Sens Index, ARM, Attitude, Basic relaxation, Catastrophic thinking, CFQ, DER Rumination, DERS, ESQ rumination, IRI, Novaco Anger Inv, PANAS, PCL-C, POMS, Positive energy, PSOM, PSWQ, RRQ, RRS, Rumination scale, Sadness, SAES, Trait NegAffect, Trait SocInhibition	0.51	0.33-0.69	Tau^2: 0.14 I^2: 71.48%

Mental health (53 studies, 159 outcomes)	All studies in anxiety, depression, stress/distress and other measures of mental health	All outcomes in anxiety, depression, stress/distress and other measures of mental health	0.54	0.44-0.63	Tau²: 0.10 I²: 64.94%

Note: Some scales reported outcomes in many subscales

Average effects, all moderately large, were fairly similar for anxiety, depression, stress/distress, and other measures of mental health and heterogeneity was low to moderate (Figure 6-9).

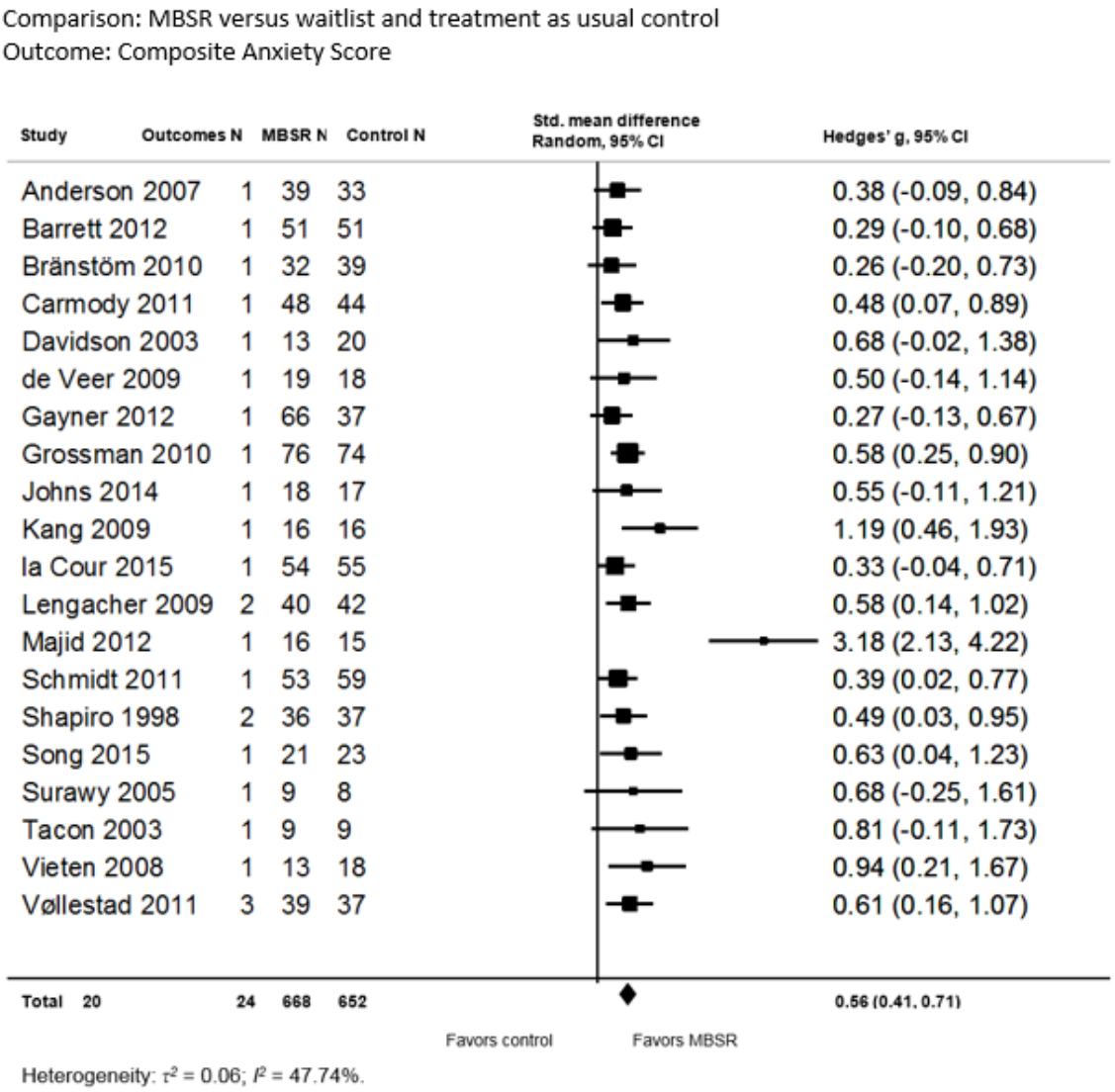

Figure 6: MBSR vs. inactive control. Composite anxiety outcome

Comparison: MBSR versus waitlist and treatment as usual control
Outcome: Composite Depression Score

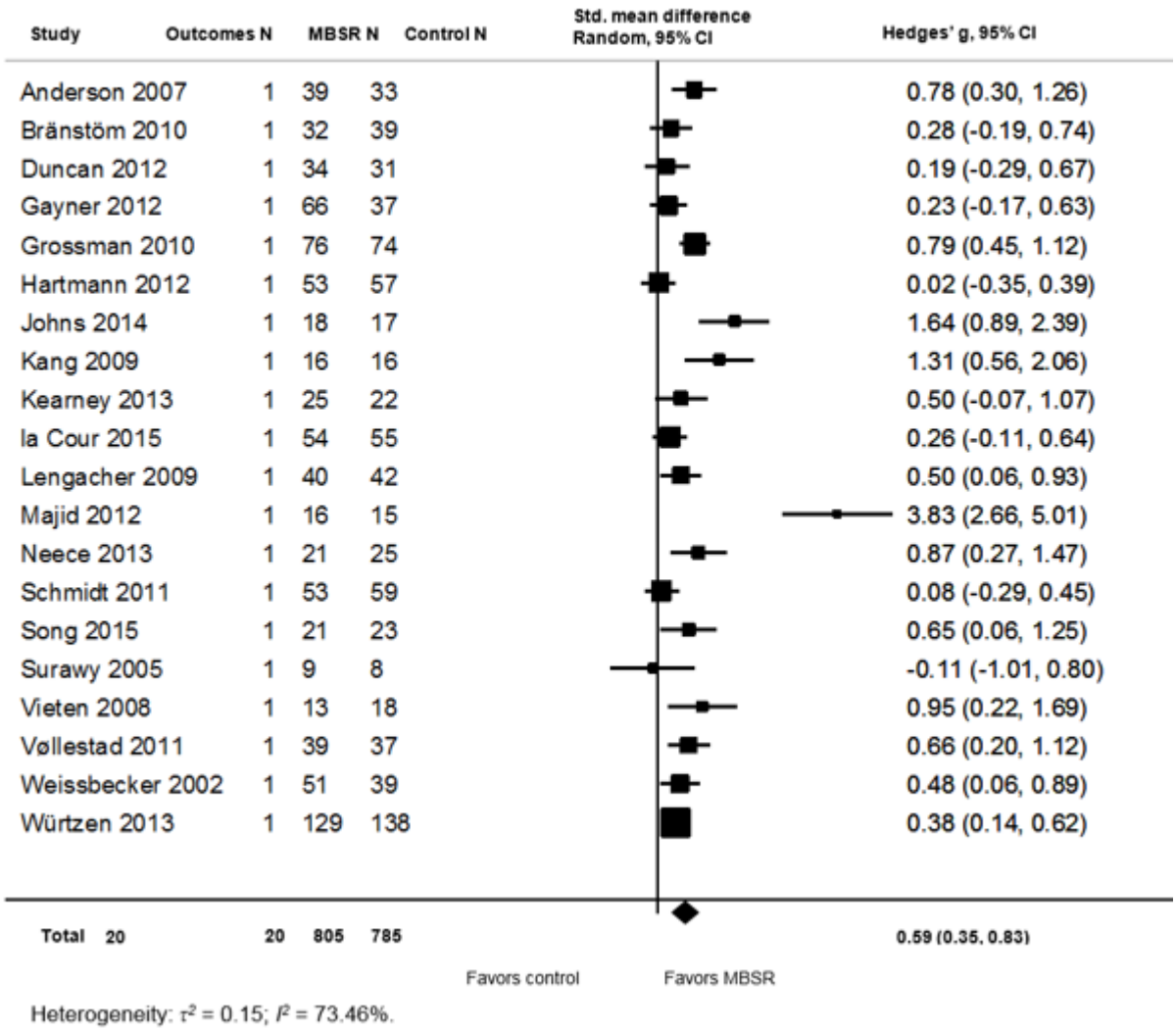

Figure 7: MBSR vs. inactive control. Composite depression outcome

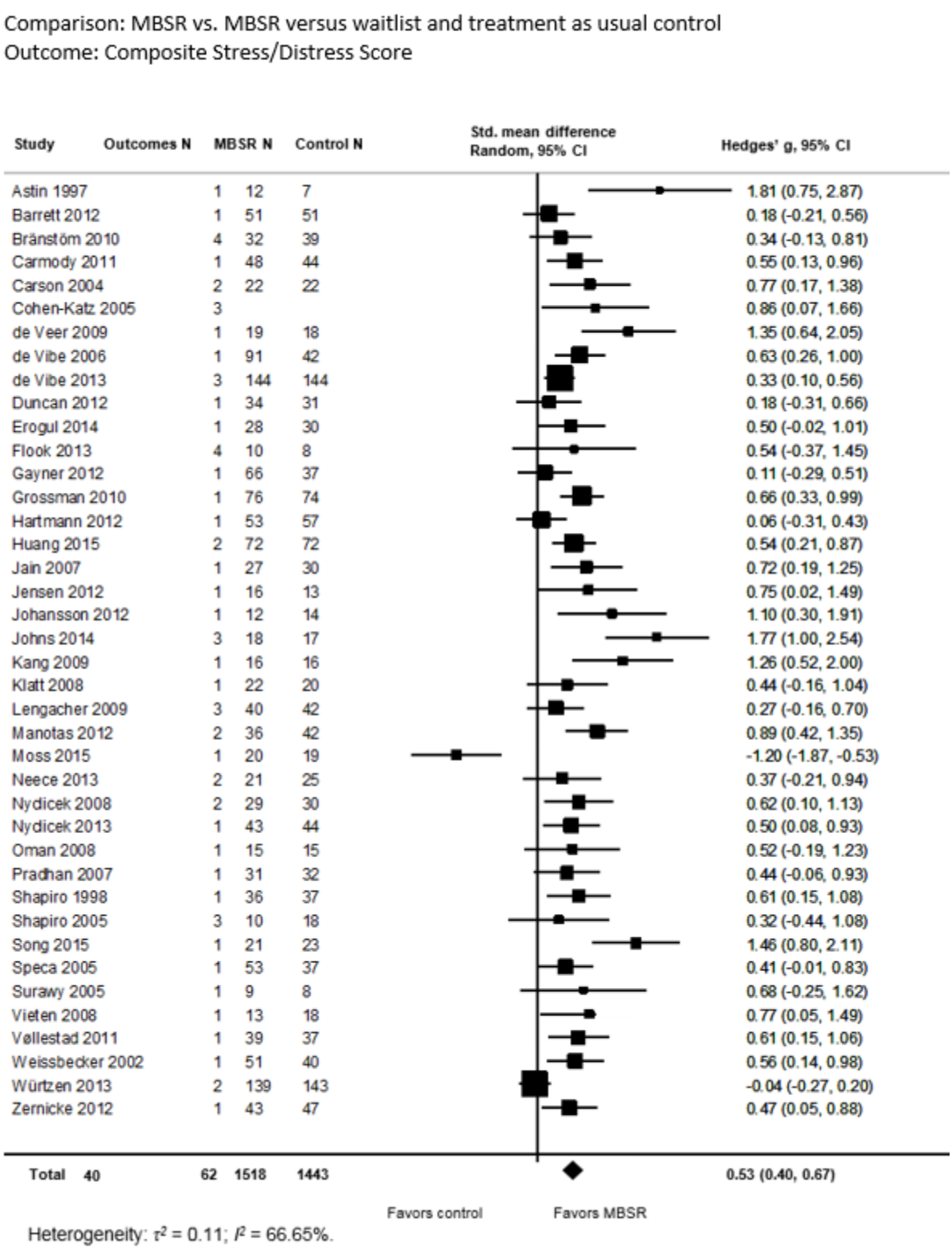

Figure 8: MBSR vs. inactive control. Composite stress/distress outcome

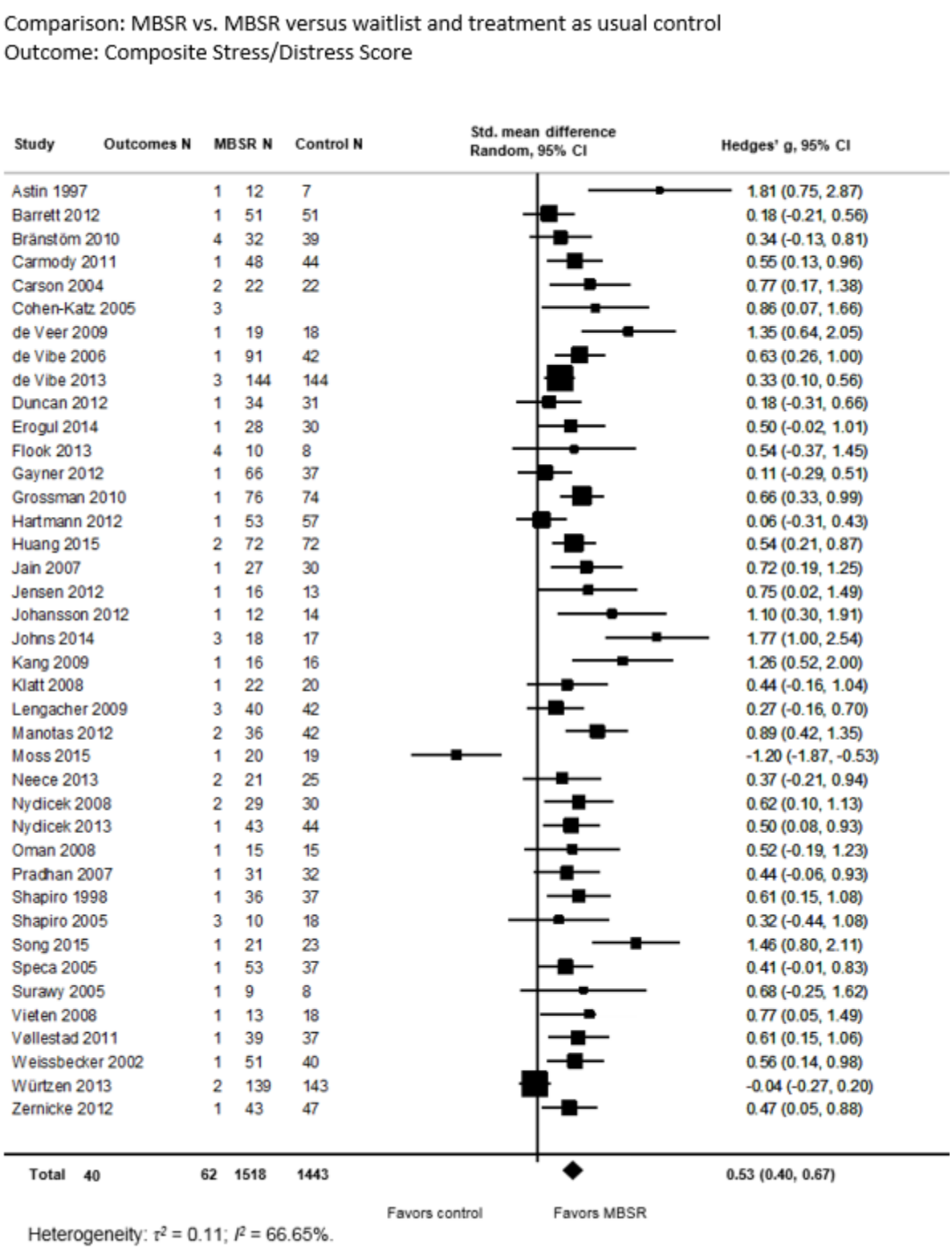

Figure 9: MBSR vs. inactive control. Composite other measures of mental health outcome

Fifty-three studies with 159 post-intervention measurements (of anxiety, depression, stress/distress, and various other measurements of psychological functions) contributed to the meta-analysis of composite mental health using the robust standard error approach (Table 4 and Figure 10).

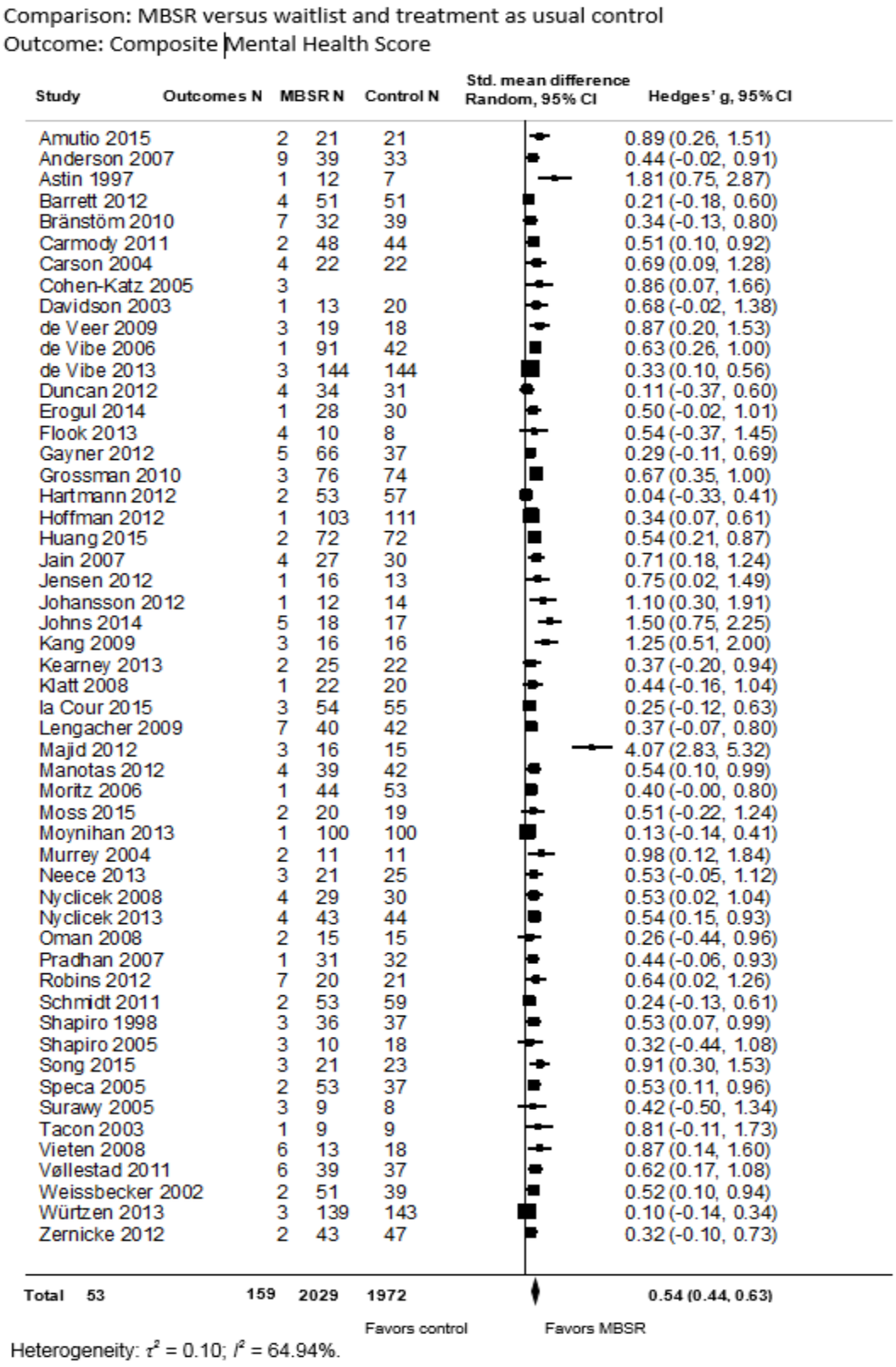

Figure 10: MBSR vs inactive controls, Composite mental health outcome

The overall effect size for mental health outcome was 0.54 (95% CI 0.44, 0.63). Heterogeneity across studies was moderate (Tau²: 0.10, I²: 64.94%). Assuming that 50% of participants in the control group have a favourable outcome, an effect size of 0.54 means that

71% of the treatment group will score above the mean of the control group, and there is a 65% chance that a random person from the treatment group will have a higher score than a person picked up at random from the control group (probability of superiority). In order to have one more favourable outcome in the treatment group compared to the control group post-intervention we need to treat 4.9 people (95% CI 4.2, 5.9). Thus, if 100 people go through the treatment, 20.5 more people will have a favourable outcome compared to if they had received the control treatment.

The effect size of measures for quality of life (including social functioning) and somatic health were somewhat lower and heterogeneity was moderate (Table 5 and Figures 11-12).

Table 5: Effect sizes of primary outcome groups, Quality of life and Physical health, MBSR vs inactive controls

Outcomes	Studies	Measures	g	95% CI	Heterogeneity
Quality of life + social function (25 studies, 44 outcomes)	Arefnasab, Banth, Barrett, Brown, Carmody, de Vibe 2006, Esmer, Grossman, Hartmann, Hoffman, Johns, Kearney, la Cour, Lengacher 2009, Moritz, Morone, Moss, Neece, Nyclicek 2008, Plews-Ogan, Schmidt, Shapiro, Surawy, Tacon, Zernicke	CPAQ, Enjoyment of life, FACT-B, FACT-ES, FSI interference, General activity, HAQUAMS, Housework, HRQOL, IBS-QOL, Mood, Overall QOL, PQOLC, QOLWHO, Relationship, SDS, SF-12, SF-36, SF-8, SWLS, Walking, WHO-5, WHOQOL	0.44	0.31-0.56	Tau^2: 0.06 I^2: 51.65%
Physical health + cognitive and brain function (38 studies, 142 outcomes)	Arefnasab, Banth, Barrett, Blom, Brown, Carmody, Creswell 2012, Davidson, de Vibe 2006,	% Activated T cells, %CCD3+IL-4,PHA, %CD3+IFNy,PHA, 24h BP, A/Brisbane (H1N1, H3N2), ABtiter rise, ACTH, Actigr (MinSleep, SE, SO, WASOMin, WASONo), AGN Tot Com, Albuminuria, Analgesic medic, ART side effects, AUC(1, g), Aud/SAl (BA 9, 18, 19, 32),	0.39	0.24-0.54	Tau^2: 0.19 I^2: 75.80%

Duncan, Esmer, Farb, Flook, Fogarty, Hartmann, Huang, Jensen, Johansson, Johns, Kilpatrick, Klatt, la Cour, Lengacher 2009, Lengacher 2014, Morone, Moynihan, Nyclicek 2013, Pickut, Plews-Ogan, Pradhan, Reich, Schmidt, Tacon, Vøllestad, Weissbecker, Wells, Würtzen, Zernicke 2013	Aud/Sal OP, Awake BP, B lymphocytes, B/Brisbane, BCPT, BIS, BMI, BPI, CAR mean, Catecholamin, CD(3+, 4+, 8, 4+/8+), Cog/ps symptoms, Cortisol, DAS28-CRP, Dis activity Disturbed sleep, Drowsiness, Dry mouth, Early morning stiffness, Executive ctl BA40, Fatigue, FEV1, FEV1/FVC, fGlucose, FIQ, fMRILeftHippoc, FSI, FVC, GCQ, GFR, GI symptoms, GMD, HbA1c, HDL-C, Heart rate, Hip-to-waist-ratio, IA recruitm ant gyr, IBS severity, IgG, ISI Sleep dist, Lack of appetite, Laser pain, Lat vis (BA4, 5, 23), LDL-C, Log CRP, Log IL6, max. (syst BP, dias.BP), McGPQ, carotid IMT, Med vis (BA24/32, 30, 30/17), metanephrine, Morning stiffness, Nausea, Night BP, NKcells, normetanephrine, Numbness, optimal sleep 7-8, Pain, Pain unpleasantness, Pain VAS, Patient global ass, PPS , PSQI, Resp Frequency, Resp Volume RMDQ, Sensimotor BA30, BA 31, serum-Cholesterol, serum-creatinine (mg/dl), SF-McGill, Shortness of breath, Side effects, Diary (Sleep duration, latency, sleep probl index (I+II), Sleep (quality, quantity/h), SPAQ, SSQ, Subj H Compl, Sustained Attention, Th1/Th2,PHA, TMT (B +C), Total lymphocytes, triglyceride, Trouble remembering, TV, Urinary AlbCrR, VAS pain, Ventilation, Vomiting

Note: Some scales reported outcomes in many subscales

Comparison: MBSR versus waitlist and treatment as usual control
Outcome: Composite Somatic Health Score

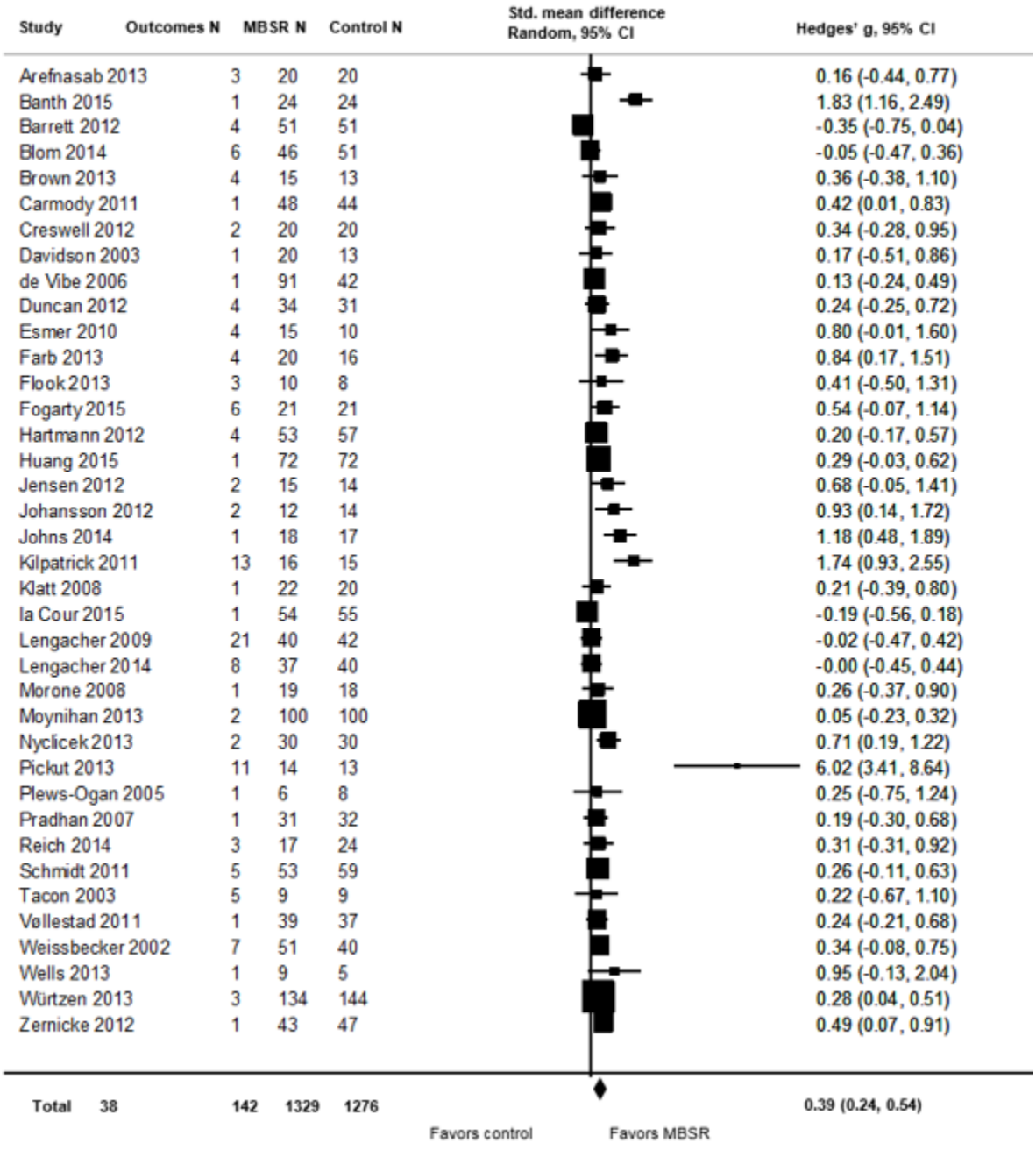

Figure 11: MBSR vs inactive controls, Composite Somatic Health outcome

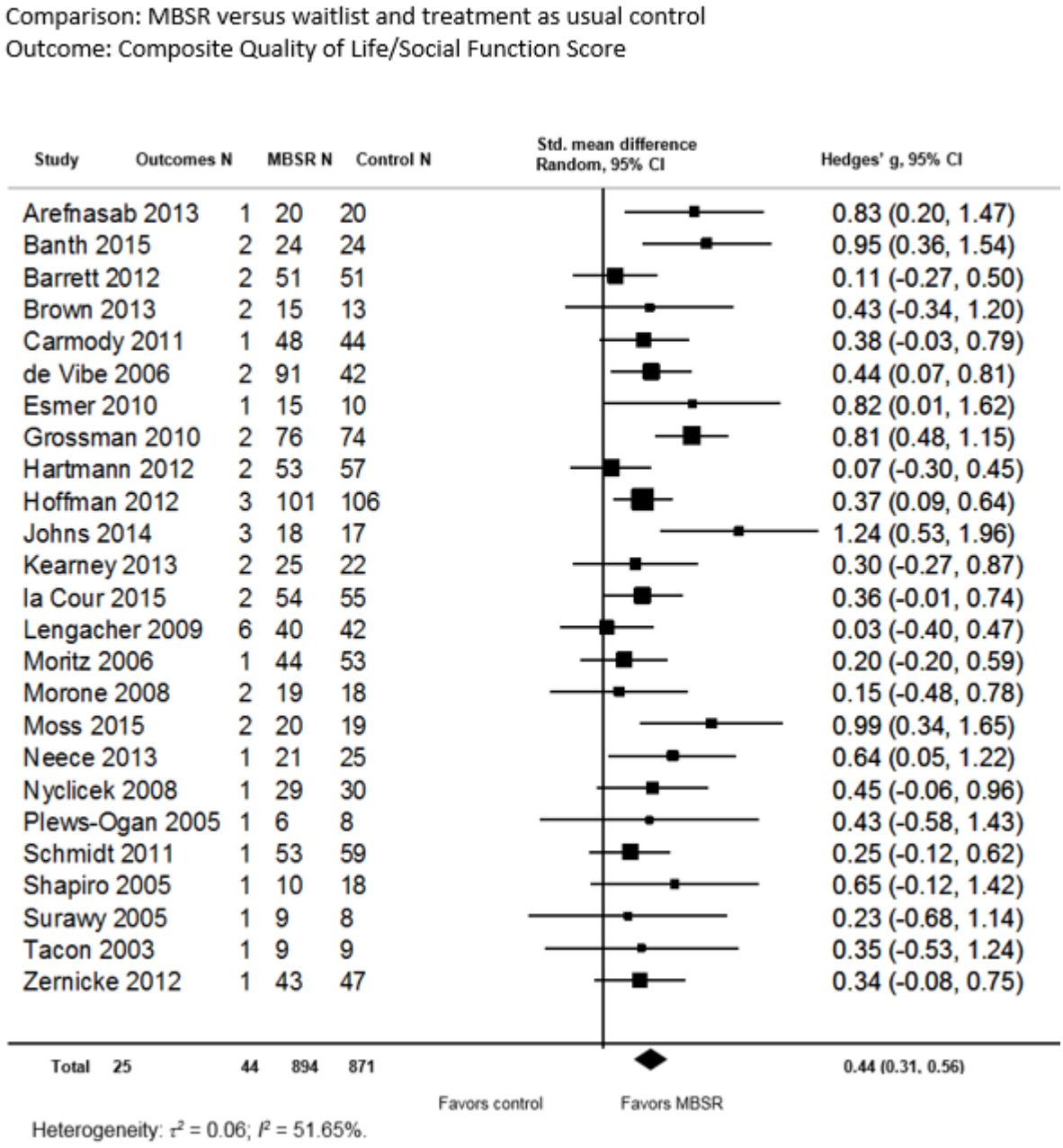

Figure 12: MBSR vs inactive controls. Composite Quality of life and social function outcome

4.3.1.2 Secondary outcomes

The effect sizes for measures of personal development and for mindfulness are shown in table 5 and figures 13-14. Heterogeneity was moderate across studies for personal development, and large for mindfulness.

Table 5: Effect sizes of secondary outcome groups, Personal development and Mindfulness, MBSR vs Inactive controls

Outcomes	Studies	Measures	g	95% CI	Heterogeneity
Personal development (25 studies, 53 outcomes)	Amutio, Astin, Barrett, Brown, Carson, de Veer, de Vibe, Erogul, Flook, Huang, Jain, Kearney, la Cour, Lengacher 2009, Morone, Moss, Murrey, Oman, Robins, Shapiro 1998, Shapiro 2005, Tacon, Weissbecker, Würtzen, Zernicke	ADHS hope, BADS, CECS, CLASS, Control over pain, Coping, Coping Str I, Coping U Sex I, CPAQ, Empathy, Engagement activity, FACIT-Sp, HFS forgiveness, INSPIRIT, IRI empathy, Job control, Job demands, LCB, LOT, Minimizing pain, NMRS, Pain acceptance, Pain willingness, PF-SOC, Reactive, PSOCQ, Resilience S, Ryff-PR SCS, Self-efficacy, SF-36 PH, Shapiro control I, SOC, SWB, Transcendence	0.41	0.31-0.51	Tau^2: 0.02 I^2: 20.12%
Mindfulness (24 studies, 44 outcomes)	Amutio, Anderson, Barrett, Brown, Bränström 2010, Cohen-Katz, Creswell 2012, de Vibe 2013, Duncan, Flook, Jensen, Kearney, Kilpatrick, Manotas, Moss, Moynihan, Nyclicek 2008, Oman, Pradhan, Robins, Song, Vieten, Vøllestad, Würtzen	FFMQ, KIMS, MAAS	0.53	0.31-0.74	Tau2: 0.19 I2: 76.37%

Note: Some scales reported outcomes in many subscales

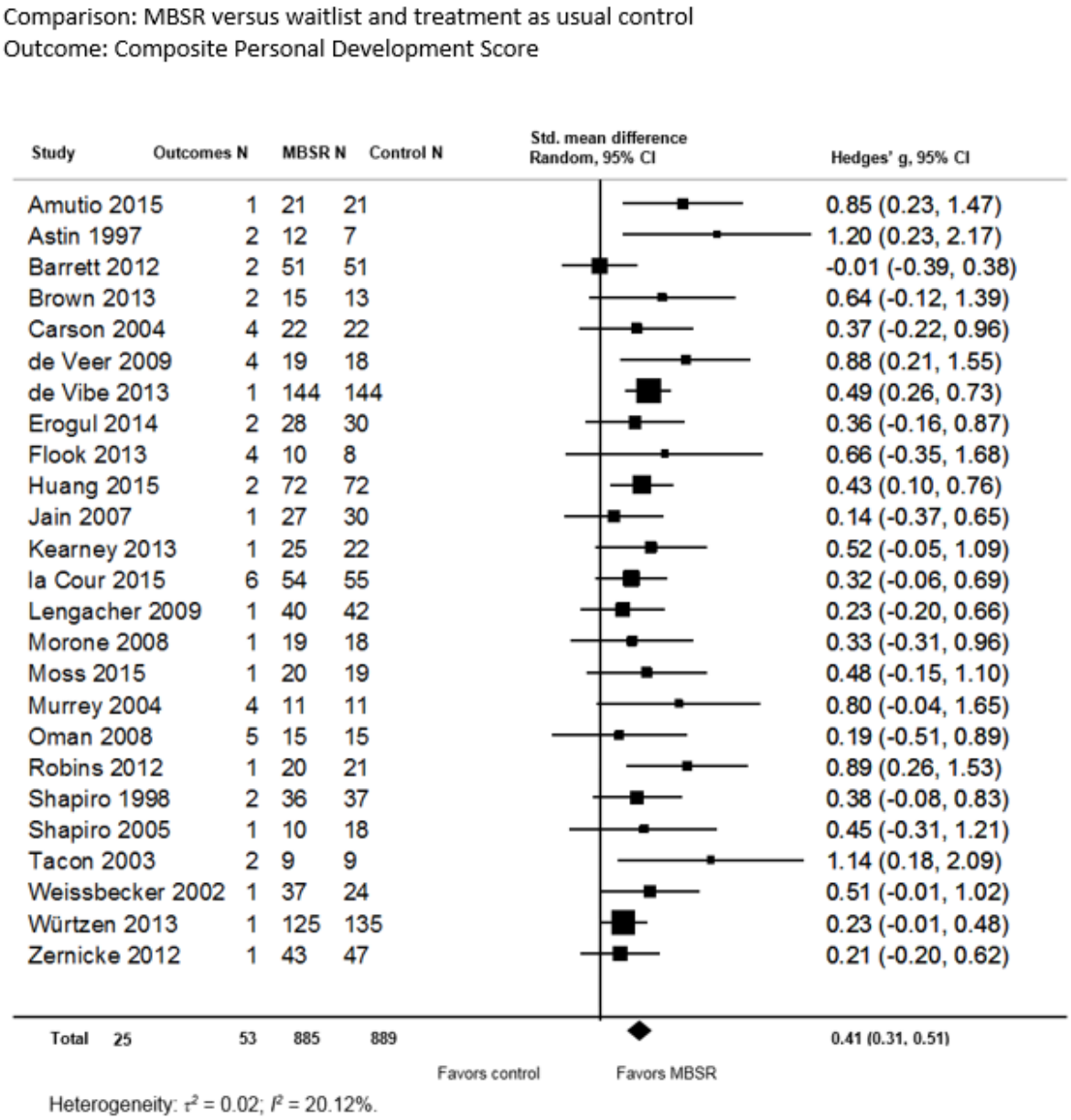

Figure 13: MBSR vs inactive controls. Composite Personal development outcome

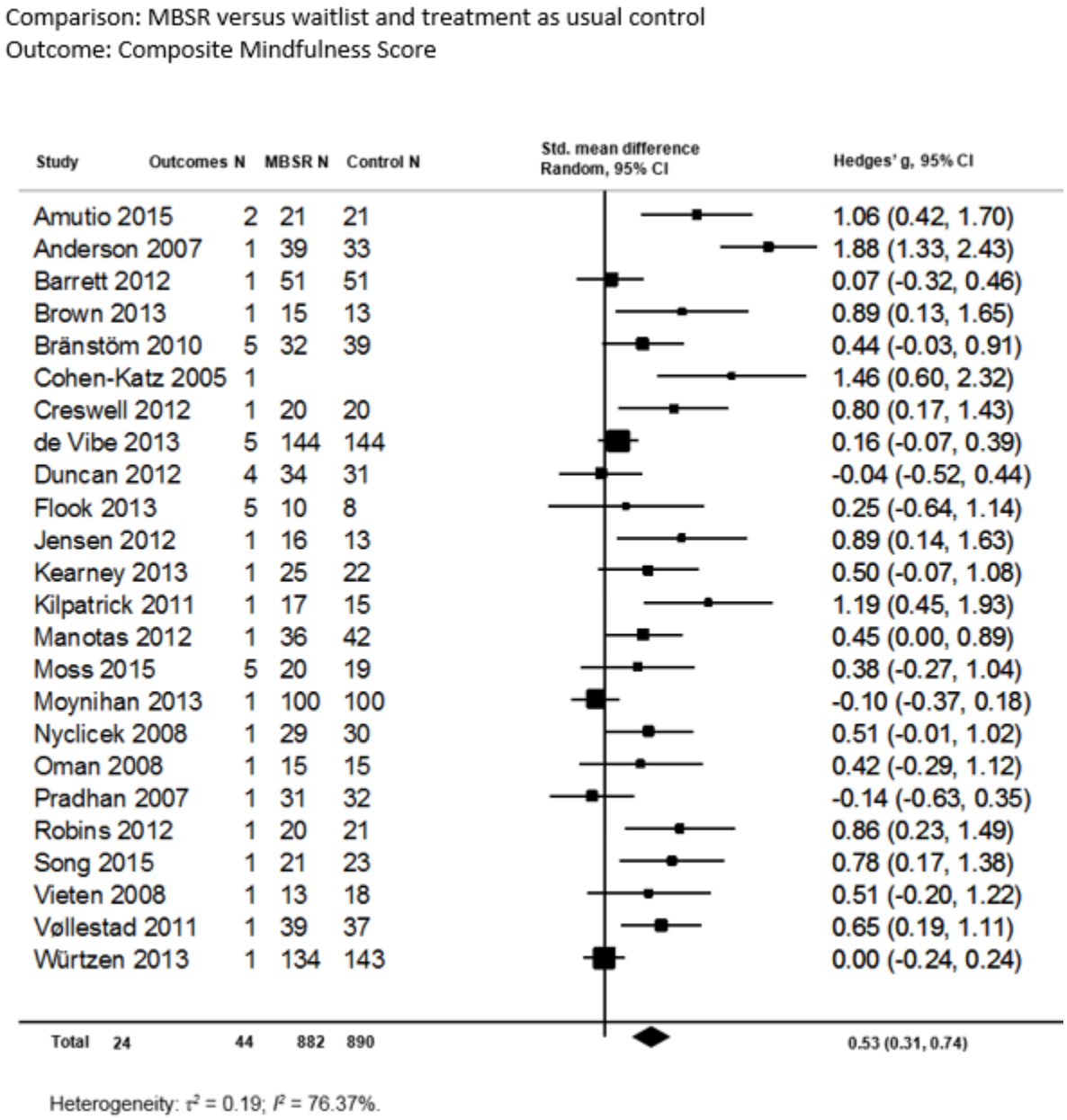

Figure 14: MBSR vs inactive controls. Composite Mindfulness outcome

4.3.1.3 Subgroup and sensitivity analyses

All subgroup analyses were done for the composite mental health outcome (Table 6), and the correlation matrix is shown in table 7.

Table 6: Subgroup analyses, MBSR vs inactive controls, composite mental health outcome, bivariate model

Comparisons	Study N	Effect size difference (95% CI), p-value
Non-clinical vs clinical groups	53	0.05 (-0.13, 0.24), p = .56
Clinical psychological vs clinical somatic target groups	30	-0.30 (-0.63, 0.04), p = .08

Studies without intention to treat (ITT) analysis vs studies with ITT analysis	53	0.17 (-0.01, 0.35), p = .06
Follow-up timing in months (from 0-34 months; only studies with follow-up)	21	-0.01 (-0.04, 0.01), p = .22
Risk of bias score	53	-0.09 (-0.17, -0.01), p = .03
MBSR course duration in hours	52	-0.01 (-0.02, 0.00), p = .14
MBSR attendance percentage (between 65% and 92%)	22	0.01 (-0.01, 0.02), p = .21
Minutes of MBSR practice (between 7 and 45 minutes/day)	20	0.00 (-0.01, 0.01), p = .76
Percentage of female participants	50	0.00 (-0.01, 0.01), p = .77

Table 7: Correlation matrix, MBSR vs Inactive controls

Mental health outcomes, MBSR vs Inactive control groups (WL + TAU)

	Clinical/ Nonclin.	Clin.Som/ Clin.Psych	ITT/ Non ITT	Risk of bias	MBSR hours	Attend. hours	Practice minutes	No of studies
Clinical/Nonclinical	1.00	Not Appl						53
Clin.Som/Clin.Psych	Not Appl	1.00						30
ITT/NonITT	.43	.14	1.00					53
Risk of bias	.30	.14	.50	1.00				53
MBSR hours	.20	.22	.20	.13	1.00			52
Attendance hours	.26	.12	.07	.12	.20	1.00		22
Practice minutes	.38	.30	.25	.23	.32	.40	1.00	20
Percent female	-.16	.25	-.04	.12	-.30	-.04	-.59	50

There were insignificant differences in effect sizes between studies with clinical versus non-clinical target groups. Likewise, studies of people with somatic problems as entry criteria reported on average a similar effect to those that recruited people with psychological difficulties. There were also insignificant differences in effect sizes in studies reporting per protocol data compared to studies reporting intention-to-treat data.
For the 21 studies with follow-up data the effect size was generally maintained; effect size difference -0.01 (95% CI -0.04, 0.01) at follow-up from one to 34 months.

There was a significant decrease in effect size with increased risk of bias; effect size difference -0.09 (95% CI-0.17, -0.01).

The effect size did not significantly change with increasing length of the intervention (52 studies), with increased attendance (between 65 and 92% in 22 studies), or increase in reported amount of home exercises (7-45 minutes per day in 20 studies).

There were no differences in effect size depending on gender distribution in the studies.

The results from the multivariable meta-regression model are shown in Table 8.

Table 8: Subgroup analyses, MBSR vs inactive controls, composite mental health outcome, multivariate model

Comparisons	b	95% CI, p-value
Non-clinical groups	-0.11	(-0.40, 0.19), p = .46
Studies without intention to treat (ITT) analysis	0.08	(-0.13, 0.30), p = .42
Risk of bias score	-0.09	(-0.18, -0.01), p = .03
MBSR course duration in hours	-0.01	(-0.03, 0.01), p = .21
Percentage of female participants	-0.00	(-0.01, 0.00), p = .47
Intercept	1.34	(0.26, 2.42), p = .02
N trials = 49, N effect sizes = 144, residual $\tau^2 = 0.12$		

The multivariate regression model yielded similar results to the bivariate models shown in Table 6. Namely, even after adjusting for the other variables in the model, there were insignificant associations between effect size magnitude and the clinical status of participants, the use of intention-to-treat analysis, the length of the intervention, and the percent of females in the sample. Risk of bias remained a statistically significant predictor of effect sizes (b= -0.09, 95% CI -0.18, -0.01), indicating that effect sizes were smaller in studies with higher risks of bias.

Mindfulness was measured in 24 studies and increased in 17 of these at post-intervention, while one study only showed an increase at four months follow-up (Pradhan, 2007). Four studies performed mediation analysis (Lengacher, 2014; Nyklicek, 2008; Robins, 2012; Vøllestad, 2011), suggesting that the effect on the outcomes were mediated by the increase in mindfulness scores.

Meta-regression of average mindfulness effects on average mental health effects at post-intervention for 22 studies with inactive controls showed an unstandardized regression coefficient of 1.20 (95% CI 0.80, 1.60, p < .001), indicating that the mental health effect sizes are positively correlated with the mindfulness effect sizes (a one-unit change in mindfulness effect size is associated with a 1.20 unit of change in the mental health effect size). This is consistent with the unweighted bivariate correlation (r = .59, p = .006) between the mental health and mindfulness effect sizes at post-intervention.

Re-analyses of effect sizes without outliers are shown in Table 9 and show minor reductions in effect sizes for anxiety, depression and other mental health outcomes.

Table 9: Sensitivity analysis, MBSR vs inactive controls, Composite Mental health outcome

	With Outliers included		With Outliers Excluded	
Outcomes	g	95% CI	g	95% CI
Anxiety	0.56	0.41-0.71	0.48	0.39-0.57
Depression	0.59	0.35-0.83	0.50	0.33-0.67
Stress/Distress	0.53	0.40-0.67	0.53	0.40-0.67
Other mental health	0.51	0.33-0.69	0.44	0.31-0.56
Any mental health	0.54	0.44-0.63	0.50	0.42-0.58
Personal development	0.41	0.31-0.51	0.41	0.31-0.51
Quality of life + cognitive & brain function	0.39	0.24-0.54	0.38	0.23-0.52
Mindfulness	0.53	0.31-0.74	0.53	0.31-0.74

Note: Effect sizes of 3*IQR above or below first/third quartile of effect distribution excluded

4.3.2 MBSR versus active interventions

4.3.2.1 Primary outcomes

There were smaller effects of MBSR versus active control groups (Table 10 and Figures 15-21). Table 10 shows which studies contributed to each outcome and Figures 15- 21 show the number of participants from each study that contributed to each outcome.

Table 10: Effect sizes of primary outcome groups, Anxiety, Depression, Stress, Other measures of mental health and composite Mental health, MBSR vs active controls

Outcomes	Studies	Measures	g	95% CI	Heterogeneity
Anxiety (12 studies, 22 outcomes)	Arch, Barrett, Gaylord, Goldin, Gross 2010, Gross 2011,Hoge, Hou, Jazaieri, Koszycki, Whitebird, Wong,	BAI, BSI-18 anx, CGI-S, CSR, HAM-A, LSAS-SR, MASQ-AAS, SIAS-S, SPS, SSPS, STAI	0.08	-0.05 -0.21	Tau^2: 0.00 I^2: 4.79%
Depression (11 studies, 11 outcomes)	Arch, Frisvold, Gaylord, Gross 2010, Gross 2011, Hou, Jazaieri, Koszycki, Polusny, Whitebird, Wong	BDI, CES-D, BSI-18 depr, PHQ-9 depr	0.22	0.11 - 0.34	Tau^2: 0.00 I^2: 0.00%

Stress/distress (16 studies, 19 outcomes)	Barrett, Frisvold, Garland, Gaylord, Hou, Jain, Jazaieri, Jensen, MacCoon, Pbert, Pipe, Rosenkranz, SeyedAlinaghi, Whitebird, Williams, Wong	BSI, C-SOSI, DSI, GSI, Pain-related distress, PSS, SCL-90, Subj. stress burden	0.18	0.02-0.35	Tau^2: 0.04 I^2: 43.24%
Other measures of mental health (14 studies, 35 outcomes)	Arch, Barrett, Frisvold, Garland, Goldin, Gross, Jain, Jazaieri, Koszycki, Moritz, Murphy, Polusny, Whitebird, Wong	Caregiver burden, CGI-Illness Severity, DASS, DER Rumination, IPSM, LSRDS, Neg Selfendors, NegSelf-focusResp, PANAS, PCL, POMS, Pos Selfendors, PSOM, PSWQ, RSES, Self-focus/negS-f, Social support, STAXI, Subjective demand burden, ULS-8	0.12	-0.10 -0.35	Tau^2: 0.11 I^2: 66.21%
Mental health (25 studies, 87 outcomes)	All studies in anxiety, depression, stress/distress and other mesures of mental health	All outcomes in anxiety, depression, stress/distress and other measures of mental health	0.18	0.05-0.30	Tau^2: 0.05 I^2: 50.71%

Note: Some scales reported outcomes in many subscales

Comparison: MBSR vs. Active Control
Outcome: Composite Anxiety Score

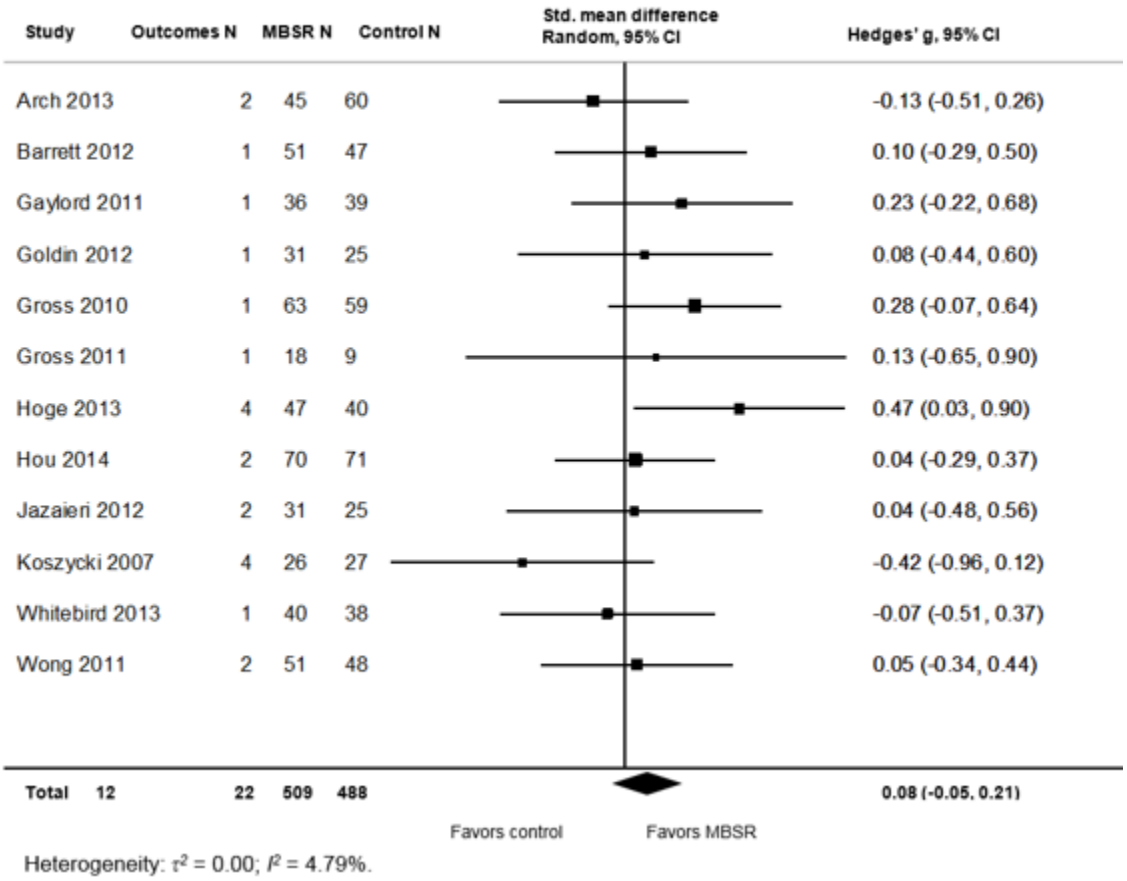

Figure 15: MBSR vs active control. Composite Anxiety outcome

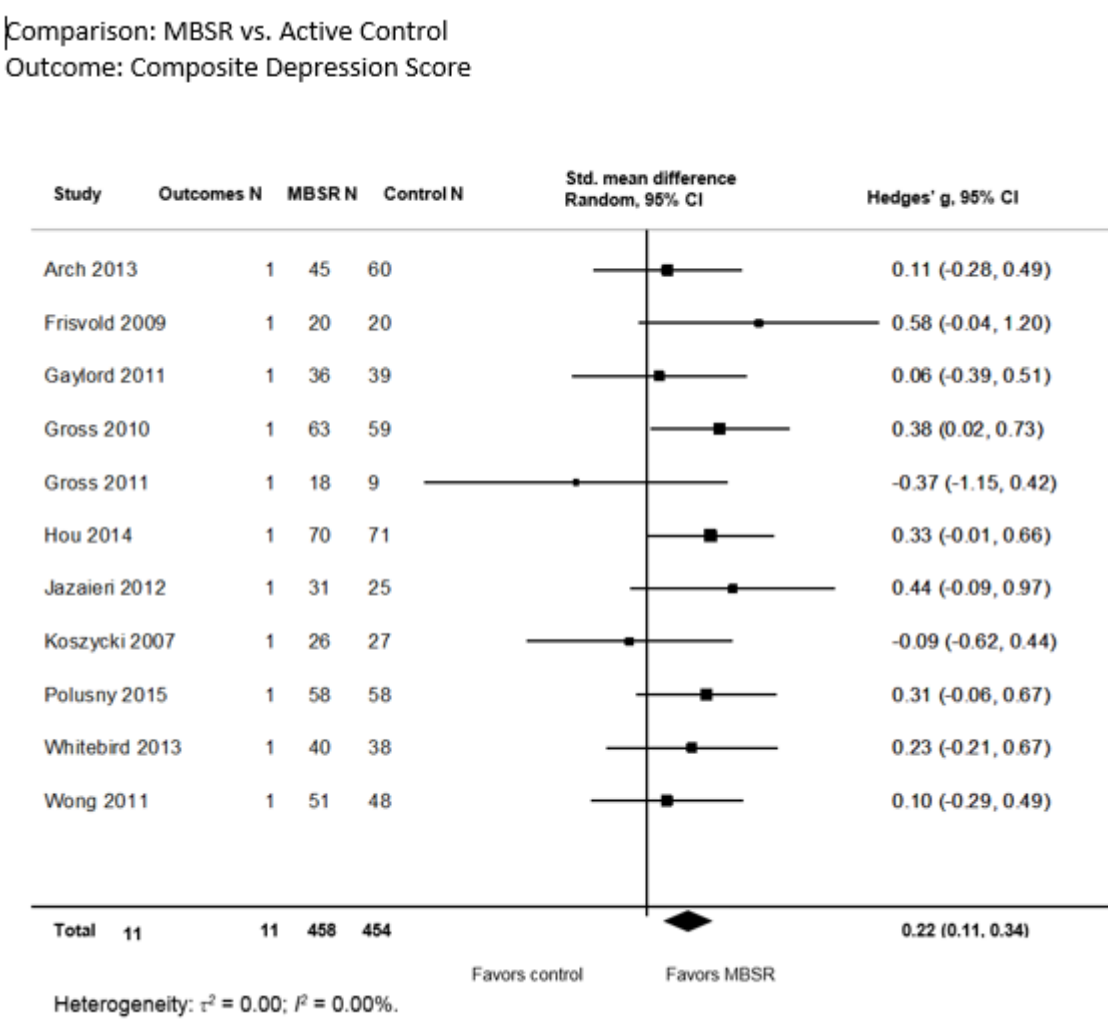

Figure 16: MBSR vs active control. Composite Depression outcome

Comparison: MBSR vs. Active Control
Outcome: Composite Stress/Distress Score

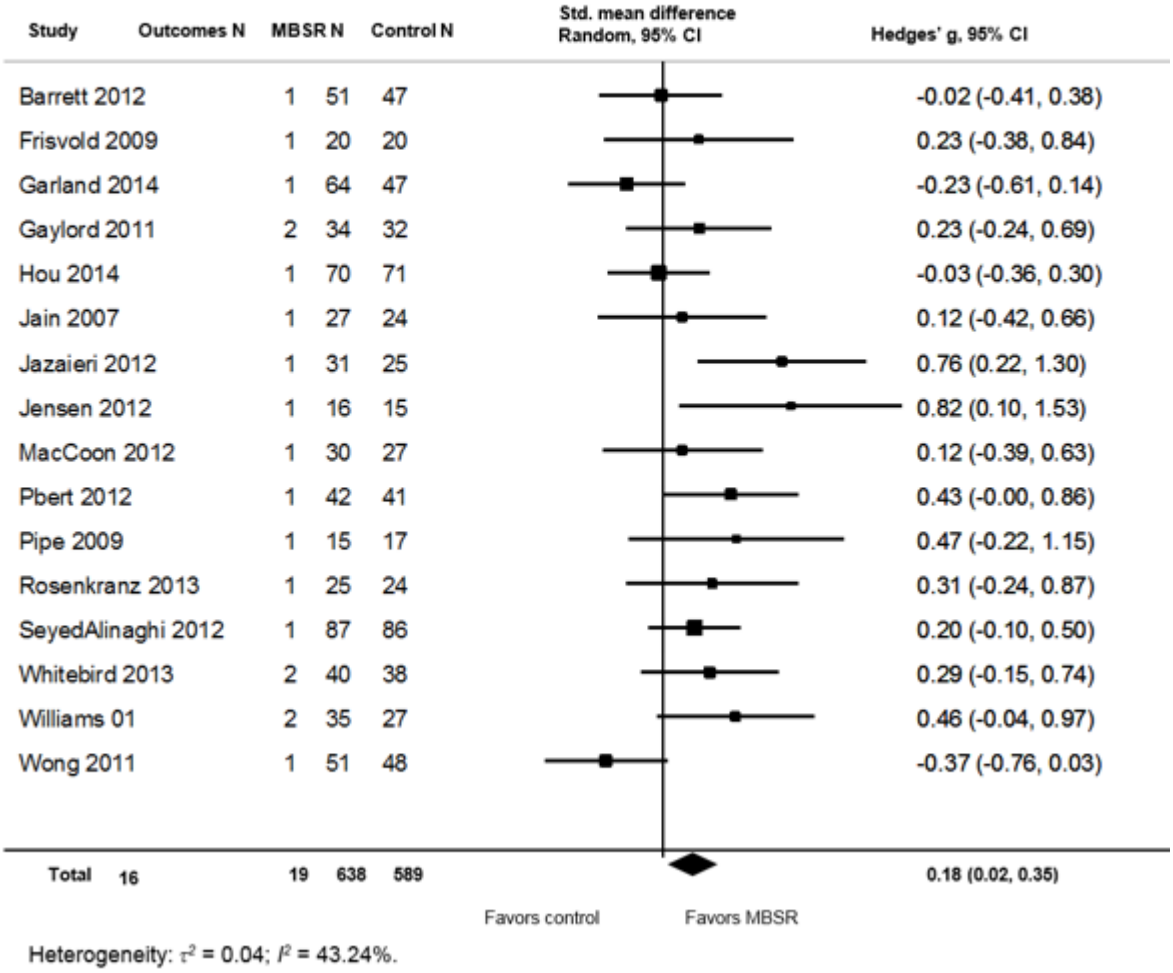

Figure 17: MBSR vs active control. Composite Stress/distress outcome

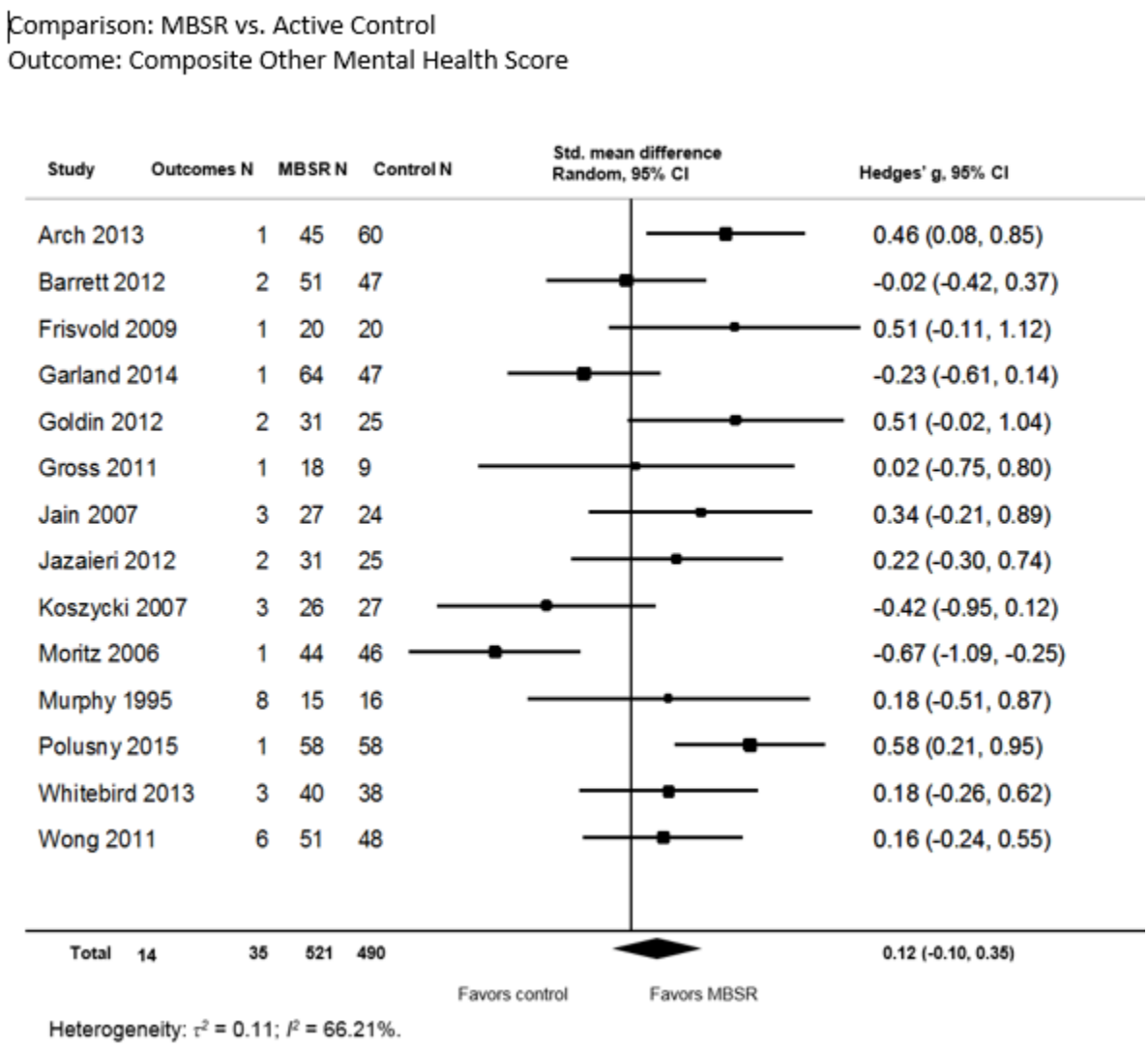

Figure 18: MBSR vs active control. Composite other Mental Health outcome

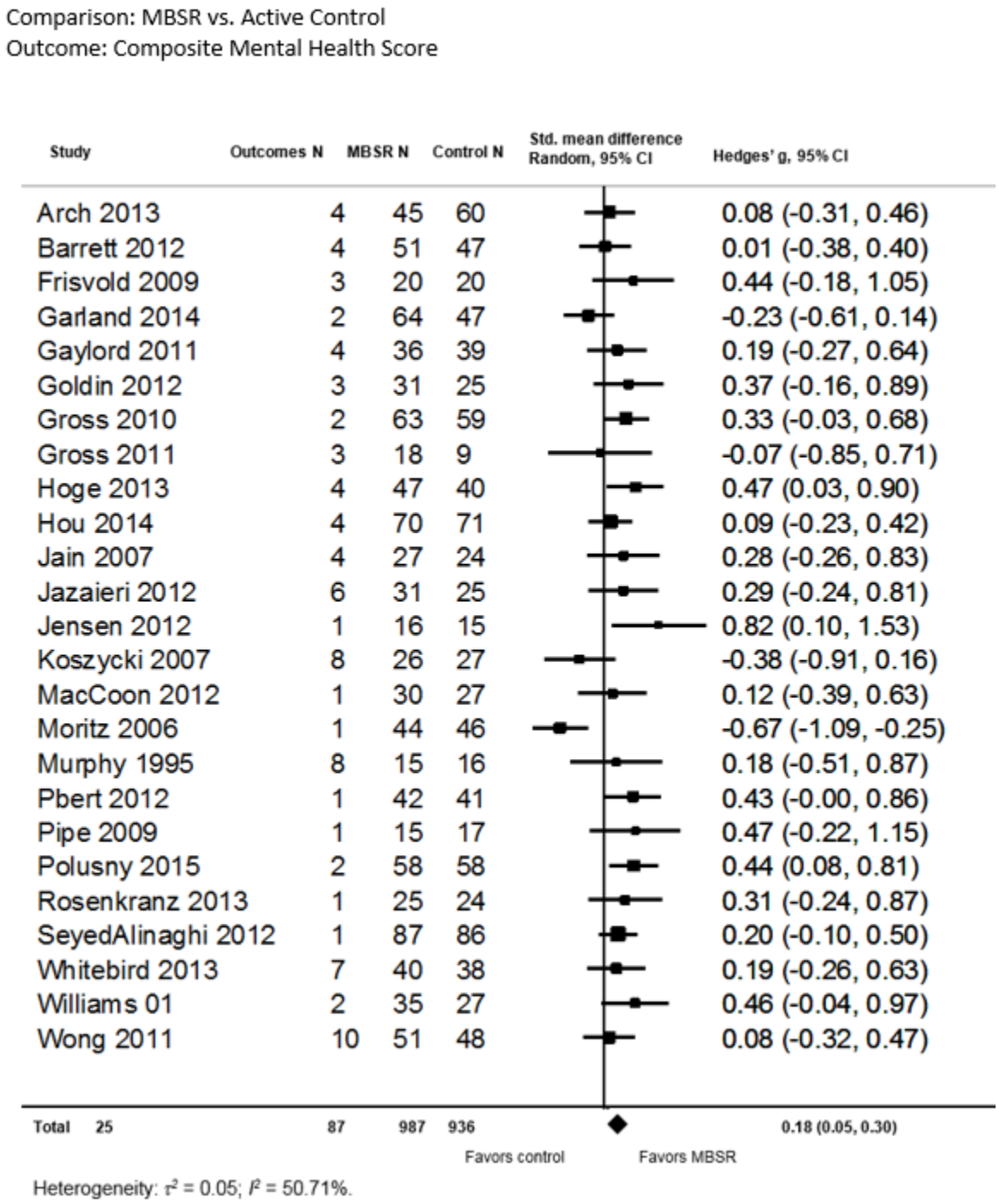

Figure 19: MBSR vs active control. Composite Mental Health outcome

There was a significant effect in favour of MBSR on outcomes of depression, stress/distress and composite mental health. Assuming that 50% of participants in the control group have a favourable outcome, an effect size of 0.18 for composite mental health means that 57% of the treatment group will score above the mean of the control group, and there is a 55% chance that a random person from the treatment group will have a higher score than a person picked up at random from the control group (probability of superiority). In order to have one more favourable outcome in the treatment group compared to the control group post-intervention we need to treat 14 people (95% CI 8, 50). Thus, if 100 people go through the treatment, 7

more people will have a favourable outcome compared to if they had received the control treatment.

There were no significant differences in the effects on measures of anxiety or other mental health outcome measures. Heterogeneity was low for all mental health outcome groups.

The results for quality of life including social function and somatic health are shown in Table 11 and Figures 20-21.

Table 11: Effect sizes of primary outcome groups, Quality of life and social function and Somatic health, MBSR vs active controls

Outcomes	Studies with active control groups	Measurement scales (some scales reported outcomes in many subscales)	g	95% CI	Heterogeneity
Quality of life + social function (15 studies, 27 outcomes)	Baker, Barrett, Gaylord, Goldin, Gross 2010, Gross 2011, Hou, Jazaieri, Koszycki, Moritz, Pbert, Plews-Ogan, Polusny, Whitebird, Wong	AQOL, BladderQO, HRQOL, IBS-QOL, QOL VAS, QoLI, SF-12, SF-36, SheehanDS, SWLS, WHOQOL-BREF, Sick leave	0.17	-0.02-0.35	Tau^2: 0.08 I^2: 60.13%
Physical health + cognitive and brain function (22 studies, 73 outcomes)	Baker, Barrett, Creswell 2009, Frisvold, Garland, Gaylord, Gross 2010, Gross 2011, Hoge, Hughes, Jensen, MacCoon, Malarkey, Murphy, Ong, Pbert, Plews-Ogan, Polusny, Rosenkranz, SeyedAlinaghi, Williams, Wong	24-hour Cortisol, A/Brisbane H1N1, H3N2, ACTH, Actigr SE, Actigr SOL, Actigr TST, Actigr TWT, Actigr WASO, AreaUTCseverity, AUC1, g, B/Brisbane, BMI, BSI-18 somatization, Calprotectin, CAPS, CD4+Tlymf, Cortisol AUC, Cortisol mean, Cortisol20/40min, 20/60, CRP, DBAS- Diary (SE, SOL, TST, TWT, WASO), Diast BP, FEV1, Flare size, Health VAS, IBS severity, IL-6, 8, 10, ISI, MSCL, Pain intensity, unpleasant, PEF, PSAS, PSG (SE, TST, TWT) PSQI, Short term medic., Sleep self-eff, Syst BP, Thermal pain, Total IE, TSST Cortisol, UIE, US-DAI, Visceral sensitivity, VSI, WT/Ibs	0.13	-0.08-0.34	Tau^2: 0.19 I^2: 76.34%

Note: Some scales reported outcomes in many subscales

Comparison: MBSR vs. Active Control
Outcome: Composite Quality of Life/Social Function Score

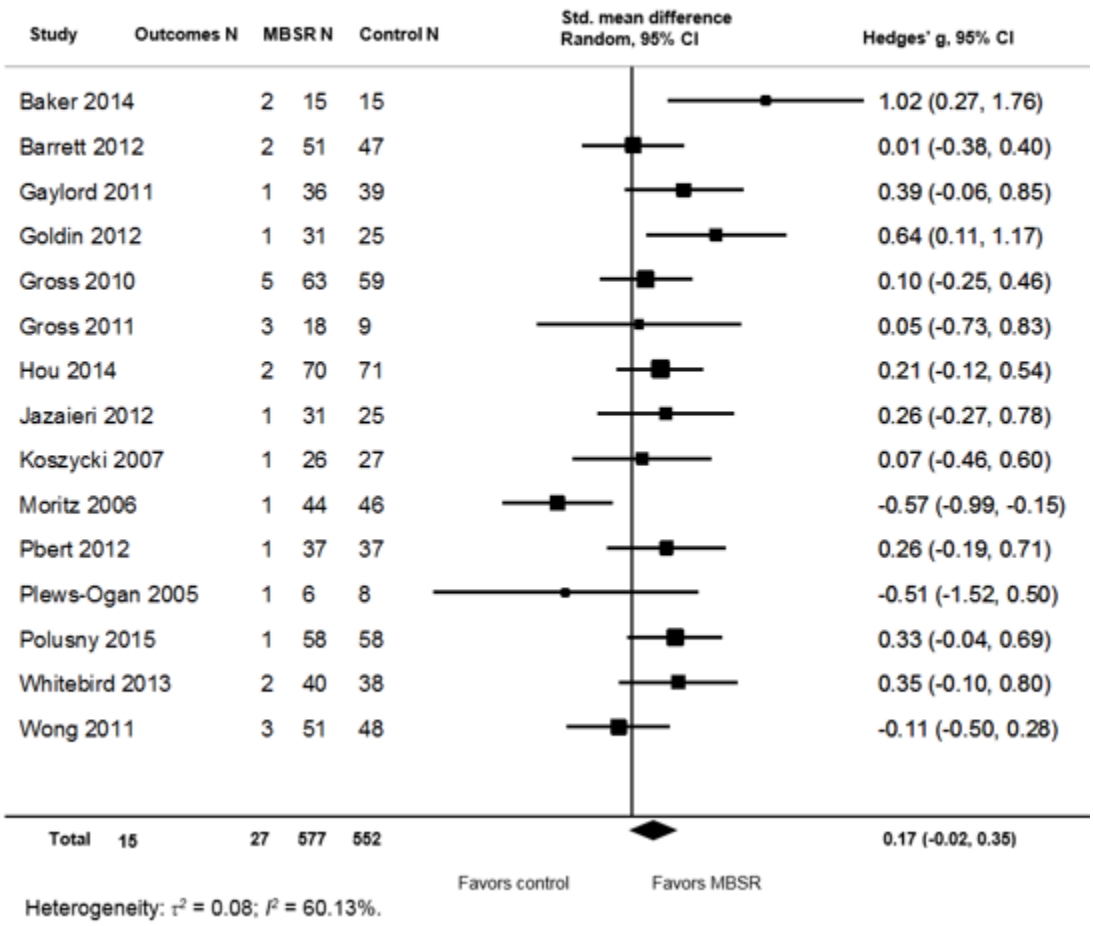

Figure 20: MBSR vs inactive controls, Composite Quality of life and social function outcome

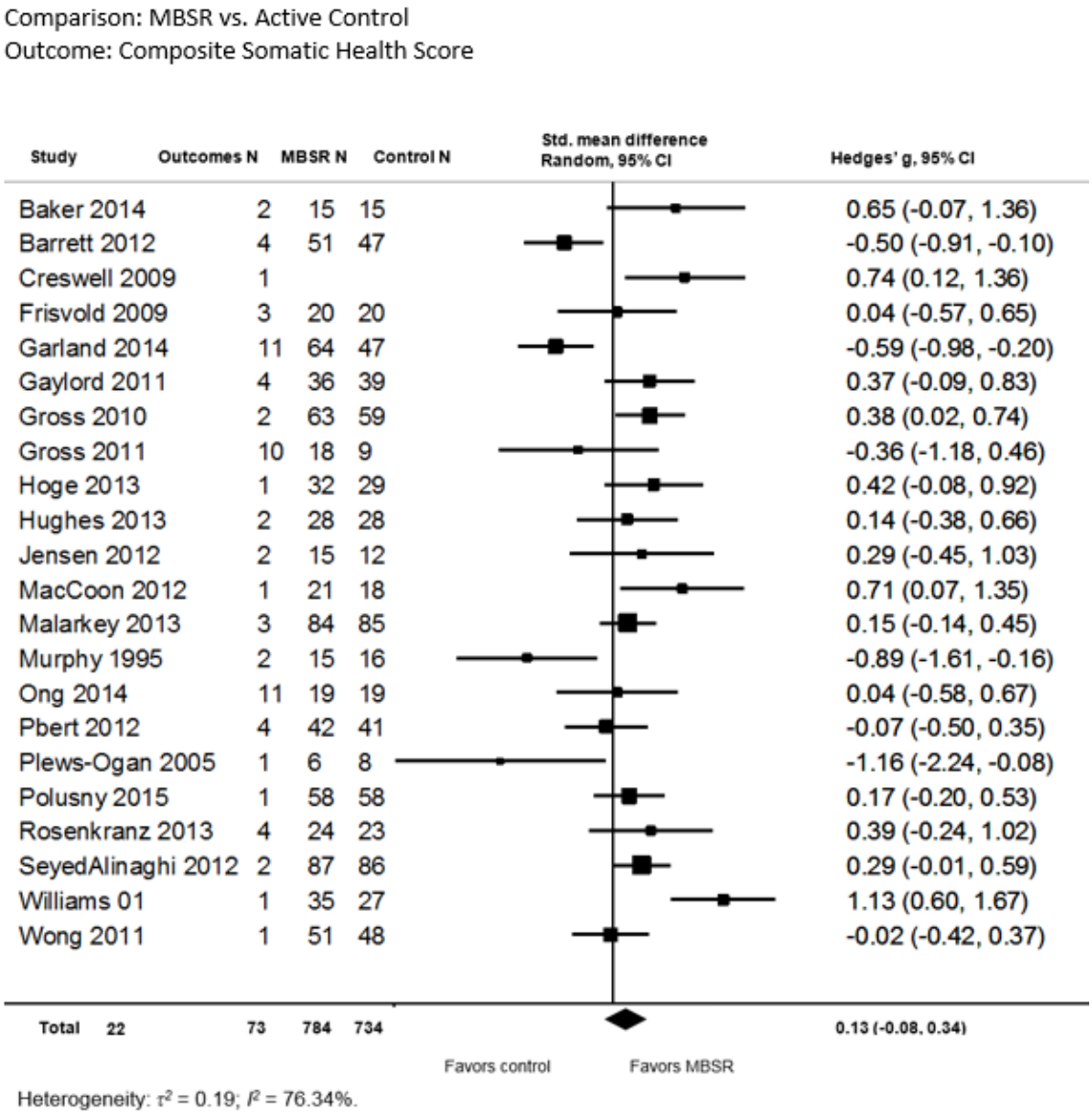

Figure 21: MBSR vs inactive controls, Composite Somatic Health outcome

There was a significant but very small effect on measures of quality of life and somatic health, which showed moderate and large heterogeneity respectively.

4.3.2.2 Secondary outcomes

The secondary outcome measures of personal development and mindfulness are shown in Table 12 and Figures 22-23.

Table 12: Effect sizes of secondary outcome groups, Personal development and Mindfulness, MBSR vs active controls

Outcomes	Studies	Measures	g	95% CI	Hetero geneity
Personal development (6 studies, 10 outcomes)	Barrett, Gaylord, Hou, Jain, Jazaieri, Pipe	Caring Efficacy Scale, CRSE, INSPIRIT, LO, Pain Catastroph, Reinterpreting pain, Ryff-PR, SCS	-0.09	-0.38-0.19	Tau²: 0.03 I²: 31.61%
Mindfulness (9 studies, 14 outcomes)	Barrett, Frisvold, Gaylord, Goldin, Hou, Jensen, Malarkey, Polusny, Schmidt,	CAM, FFMQ, FMI, KIMS, MAAS, TMS,	0.31	0.12-0.50	Tau²: 0.04 I²: 45.73%

Note: Some scales reported outcomes in many subscales

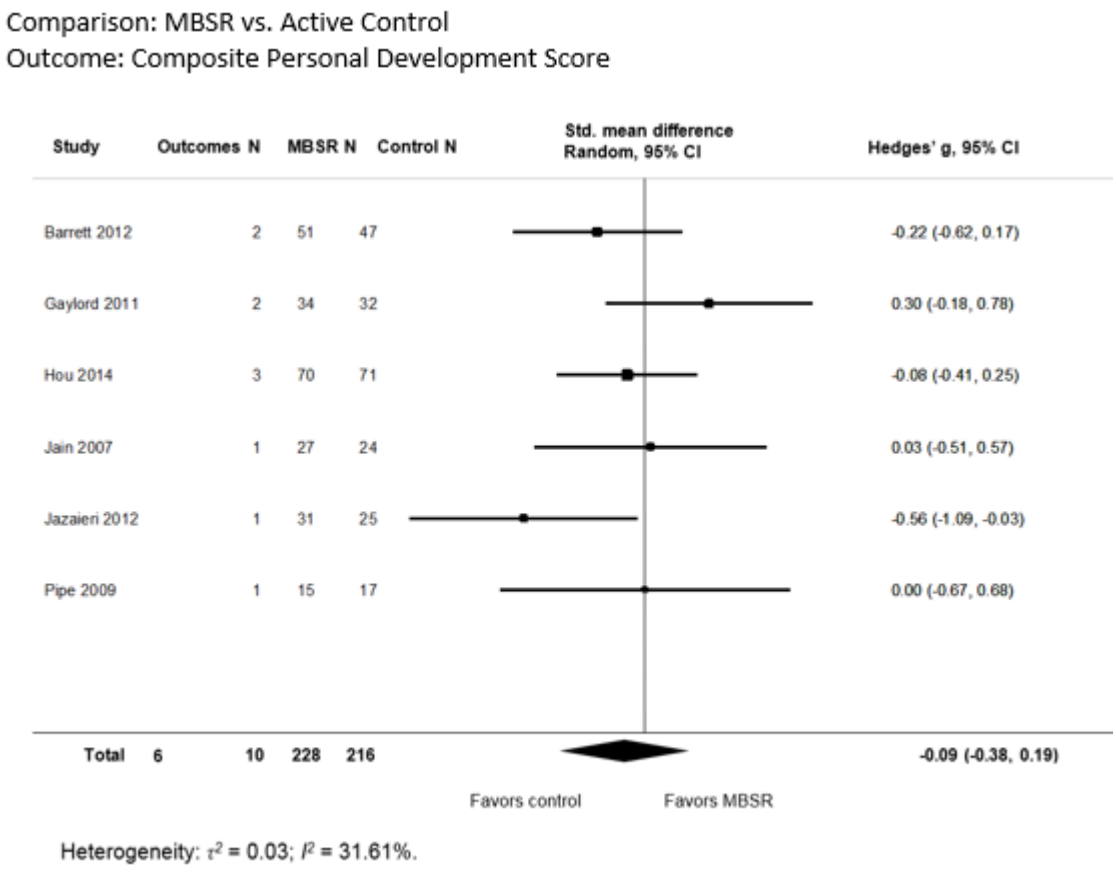

Figure 22: MBSR vs inactive controls. Composite Personal development outcome

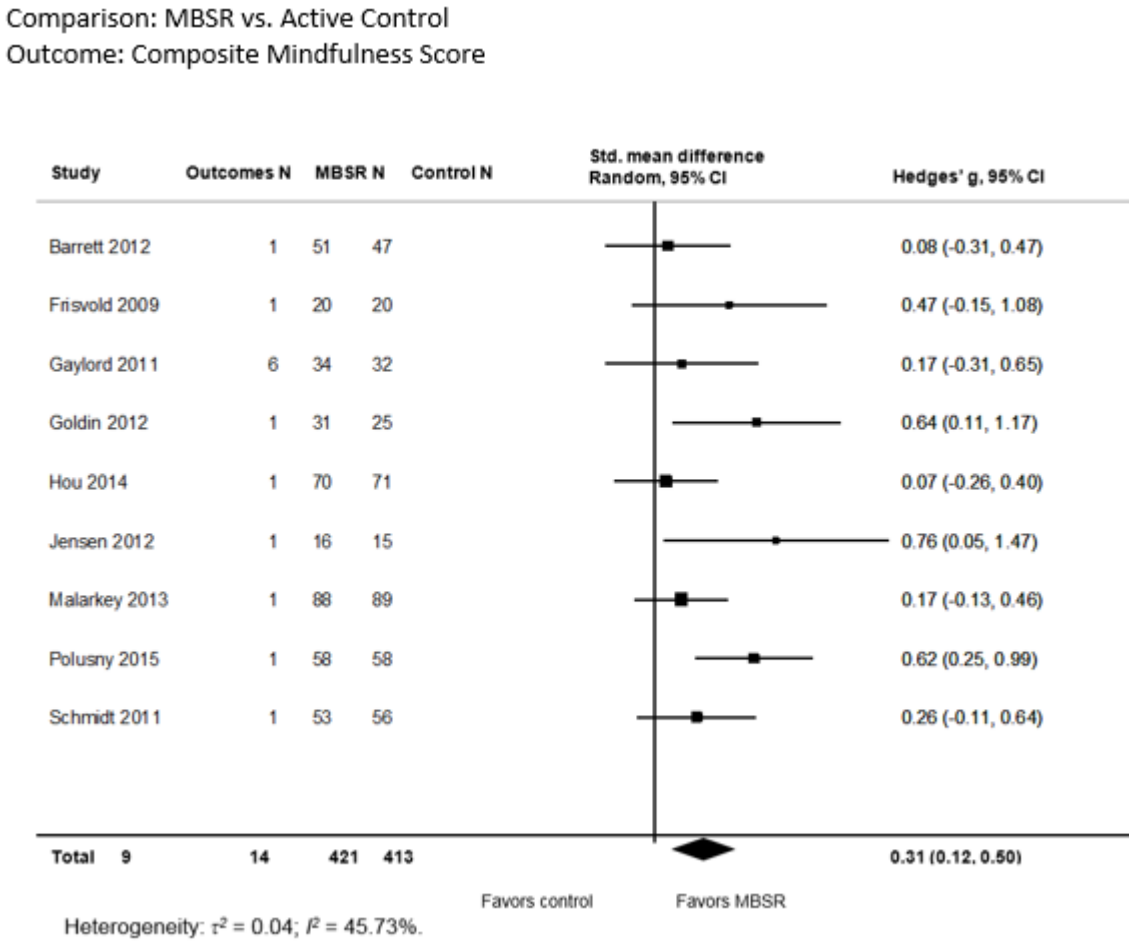

Figure 23: MBSR vs active controls. Composite Mindfulness outcome

There were no significant differences in the effects on measures of personal development, but a small and significant effect on mindfulness (Table 11 and Figures 22-23). Heterogeneity was low for both outcome groups.

4.3.2.3 Subgroup and sensitivity analyses

All subgroup analyses were done for the composite mental health outcome (Table 13). The corresponding correlation matrix is shown in Table 14.

For the 20 studies with follow-up data, the effect size was maintained (effect size difference=0.00, 95% CI -0.04, 0,04) at follow-up from one to 32 months. Studies using intention-to-treat analysis and studies with low risk of bias tended to show lower effect sizes, but the findings did not reach statistical significance using bivariate analyses.

Table 13: Subgroup analyses, MBSR vs active controls, composite mental health outcome, bivariate model

Comparisons	Study N	Effect size difference (95% CI), p-value
Non-clinical vs clinical target groups	25	0.13 (-0.17, 0.43), p = .35
Clinical psychological vs clinical somatic target groups	19	0.04 (-0.26, 0.33), p = .81
Studies without intention to treat (ITT) analysis vs studies with ITT analysis	25	0.23 (-0.01, 0.46), p = .06
Follow-up timing in months (from 0-32 months; only studies with follow-up)	20	0.00 (-0.04, 0.04), p = .81
Risk of bias score	25	-0.07 (-0.17, 0.03), p = .14
MBSR course duration in hours	25	0.02 (-0.01, 0.05), p = .24
MBSR attendance percentage (between 65% and 92%)	9	0.01 (-0.04, 0.07), p = .57
Minutes of MBSR practice (between 7 and 45 minutes/day)	8	0.03 (-0.16, 0.22), p = .40
Percentage of female participants	25	0.00 (-0.00, +0.00), p = .64

Table 14: Correlation matrix, MBSR vs active control groups

	Clinical/ Nonclin.	Clin.Som/ Clin.Psych	ITT/ Non ITT	Risk of bias	MBSR hours	Attend. hours	Practice minutes	No of studies
Clinical/Nonclinical	1.00	Not Appl						25
Clin.Som/Clin.Psych	Not Appl	1.00						19
ITT/NonITT	.54	-.23	1.00					25
Risk of bias	.37	.23	.46	1.00				25
MBSR hours	.16	.39	.02	-.24	1.00			25
Attendance hours	-.35	-.37	-.41	-.58	.60	1.00		9
Practice minutes	-.75	.15	-.41	-.18	-.14	Not applic.	1.00	8
Percent female	-.39	.20	-.14	-.06	.03	.20	.03	25

Again, the results from the multivariable meta-regression model (Table 15) yielded similar results to the bivariate models shown in Table 13. Namely, even after adjusting for the other variables in the model, there were insignificant associations between effect size magnitude and the clinical status of participants, the use of intention-to-treat analysis, risk of bias, the length of the intervention, and the percent of females in the sample.

Table 15: Subgroup analyses, MBSR vs active controls, composite mental health outcome, multivariate model

Comparisons	b	95% CI
Non-clinical groups	0.07	(-0.35, 0.48), p = .72
Studies without intention to treat (ITT) analysis	0.19	(-0.07, 0.45), p = .14
Risk of bias score	-0.01	(-0.12, 0.10), p = .84
MBSR course duration in hours	0.02	(-0.02, 0.05), p = .31
Percentage of female participants	-0.00	(-0.01, 0.00), p = .48
Intercept	-0.14	(-1.17, 0.90), p = .76

N trials = 25, N effect sizes = 87, residual $\tau^2 = 0.05$

Meta-regression of average mindfulness effects on average mental health effects at post-intervention for 8 studies with active controls showed an unstandardized regression coefficient of 1.35 (95% CI 0.66, 2.04, p = .008), which indicates that the mental health effect sizes are positively correlated with the mindfulness effect sizes (a one unit change in the mindfulness effect size is associated with a 1.35 unit change in the mental health effect size). This is consistent with the unweighted bivariate correlation (r = .93, p = .002) between mental health and mindfulness effect sizes at post-intervention.

Re-analyses of effect sizes without outliers showed no changes in effect sizes (Table 16).

Table 16: Sensitivity analyses, MBSR vs active control groups

	With Outliers included		With Outliers Excluded	
Outcomes	g	95% CI	g	95% CI
Anxiety	0.08	-0.05-0.21	0.08	-0.05-0.21
Depression	0.22	0.11-0.34	0.22	0.11-0.34
Stress/Distress	0.18	0.02-0.35	0.18	0.02-0.35
Other mental health	0.12	-0.10-0.35	0.12	-0.10-0.35
Any mental health	0.18	0.05-0.30	0.18	0.05-0.30
Personal development	-0.09	-0.38-0.19	-0.09	-0.38-0.19
Quality of life + cognitive & brain function	0.17	0.02-0.35	0.17	0.02-0.35
Mindfulness	0.13	-0.08-0.34	0.16	-0.03-0.35

Note: Effect sizes of 3*IQR above or below first/third quartile of effect distribution excluded

4.3.3 Studies where data could not be used in meta-analyses

Alterman (2004) compared the effect of an eight-week MBSR course (23 hours) with treatment as usual for 31 substance-abuse recovery inpatients at post-intervention and at five months follow-up. The data were analysed using repeated measures analysis of variance across three time points. While the intervention group improved more than the control group

regarding medical problems, no significant group differences were found on measures of psychological health.

Corsica (2014) carried out a 3-armed RCT and compared the effect of a 6 session MBSR course with a 6-session stress eating intervention and a combination of MBSR and a stress eating intervention in 53 overweight patients. All three interventions reduced perceived stress and stress eating, but the combined intervention resulted in greater reductions and also produced a moderate effect on short term weight loss.

Dykens (2014) compared the effect of MBSR to a positive psychology course for 243 mothers of children with autism. Using slopes as outcomes, they found that both interventions led to significant reductions in stress, anxiety and depression, and improved sleep and life satisfaction. The mothers in the MBSR group had greater improvements in anxiety, depression, sleep and well-being. Results were maintained at six months follow-up.

MacCoon (2014) presented data from the MacCoon (2012) study on the effect of MBSR and a comparable non-mindfulness intervention (Health Enhancement Program - HEP) on sustained attention. They did not find that attentional sensitivity was affected by MBSR, and findings regarding the effect on the vigilance aspect of attention were unclear.

Oman (2008) compared MBSR with another mindfulness intervention and found similar effects, but data for this comparison was not given.

Lengacher (2014) compared the effect of a 6-week MBSR course versus usual care on telomer length and activity in 142 patients treated for breast cancer. They showed no differential influence of MBSR on telomer length, but a significant positive effect on telomer activity measured at 6 and 12-week follow-up.

Wells (2014) compared the effect of a standard MBSR course versus usual care for 19 patients with episodic migraines. They showed a non-significant reduction in length and frequency of migraine attacks per month after the intervention ended, and a significant improvement in migraine disability assessment, headache impact, self-efficacy and mindfulness in the MBSR group, relative to the control group.

4.3.4 Quality of the evidence

We used the grading of evidence system (Guyatt, 2008) that classifies evidence as high, moderate, low or very low. The grading of the primary outcome groups with reasons for down-grading from high (RCTs start in the high category) is presented in Table 17-18.

Mindfulness Based Stress Reduction (MBSR) for improving health, quality of life and social function in adults

Patient or population: both patients and healthy people
Settings: All settings, **Intervention:** MBSR; **Comparison:** Wait-list or TAU

Outcomes	Hedges´ g	Hedges´ g (95% CI)	No of Participants	Quality of the evidence (GRADE)
Mental Health Outcome Pooled estimate of 159 mental health outcomes in 53 studies using robust SE	0.54	(0.44, 0.63)	4001	⊕⊕⊕⊕ **moderate**[1,2,3,4,5]
Stress Outcome Pooled estimate of 62 stress outcomes in 40 studies using robust SE	0.53	(0.40, 0.67)	2961	⊕⊕⊕⊕ **moderate**[1,2,3,4,5]
Anxiety Outcome Pooled estimate of 24 anxiety outcomes in 20 studies using robust SE	0.56	(0.41, 0.71)	1320	⊕⊕⊕⊖ **moderate**[1,2,3,4,5]
Depression Outcome Pooled estimate of 20 depression outcomes in 20 studies using standard SE	0.59	(0.35, 0.83)	1590	⊕⊕⊕⊖ **moderate**[1,2,3,4,5]
Somatic Health Outcome Pooled estimate of 142 somatic health outcomes in 38 studies using robust SE	0.31	(0.10, 0.52)	2605	⊕⊕⊕⊖ **low**[1,2,3,4,5,6]
Quality of Life and Social function Outcome Pooled estimate of 44 quality of life outcomes in 25 studies using robust SE	0.44	(0.31, 0.56)	1765	⊕⊕⊖⊖ **moderate**[1,2,3,4,5]

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] 27 studies did not specify sequence generation. 44 studies did not specify whether concealment of allocation was adequate. 48 studies did not report on blinding. 7 studies had inadequate reporting. Not rated down as there was little difference in estimated effect sizes in studies with different risk of bias scores. [2] Results consistent across studies using different populations and different lengths of MBSR intervention, thus not rated down. [3] $\tau^2 = 0.10$ and $I^2 = 65\%$ for mental health, 0.11 and 67% for stress, 0.06 and 48% for anxiety, 0.15 and 73% for depression, 0.19 and 76% for somatic health and 0.06 and 51% for quality of life, showing heterogeneity, therefore rated down. [4] 69 of 72 included studies entered data in the meta-analysis, [5] Some small studies, but effect sizes adjusted for sample size, robust SE used in meta-analysis and CI acceptable, thus not rated down. [6] Many different somatic outcomes used, and more studies with similar outcomes necessary to assess differential effect across different domains of somatic health, thus rated down.

Table 17: Grading of the quality of evidence of MBSR vs inactive control conditions

Mindfulness Based Stress Reduction (MBSR) for improving health, quality of life and social function in adults

Patient or population: both patients and healthy people
Settings: All settings, **Intervention:** MBSR; **Comparison:** Active control

Outcomes	Hedges´ g	Hedges´ g (95% CI)	No of Participants	Quality of the evidence (GRADE)
Mental Health Outcome Pooled estimate of 87 mental health outcomes in 25 studies using robust SE	0.18	(0.05, 0.30)	1943	⊕⊕⊕⊕ **moderate**[1,2,3,4,5]
Stress Outcome Pooled estimate of 19 stress outcomes in 16 studies using robust SE	0.18	(0.02, 0.35)	1245	⊕⊕⊕⊕ **moderate**[1,2,3,4,5]
Anxiety Outcome Pooled estimate of 22 anxiety outcomes in 12 studies using robust SE	0.08	(-0.05, 0.21)	997	⊕⊕⊕⊖ **moderate**[1,2,3,4,5]
Depression Outcome Pooled estimate of 11 depression outcomes in 11 studies using standard SE	0.22	(0.11, 0.34)	912	⊕⊕⊕⊖ **moderate**[1,2,3,4,5]
Somatic Health Outcome Pooled estimate of 73 somatic health outcomes in 22 studies using robust SE	0.13	(-0.08, 0.34)	1518	⊕⊕⊕⊖ **low**[1,2,4,5,6]
Quality of Life and social function Outcome Pooled estimate of 27 quality of life outcomes in 15 studies using robust SE	0.17	(-0.02, 0.35)	1129	⊕⊕⊖⊖ **moderate**[1,2,4,5]

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] 9 studies did not specify sequence generation. 15 studies did not specify whether concealment of allocation was adequate. 12 did not report on blinding. 4 studies had inadequate reporting. Not rated down as there was only a small reduction in effect size with increasing risk of bias. [2] Results consistent across studies using different populations and different lengths of the MBSR intervention, but very many different active control group interventions, therefore rated down. [3] Low heterogeneity: $\tau^2 = 0.05$ and $I^2 = 50\%$ for mental health, 0.04 and 43% for stress, 0.00 and 5% for anxiety, 0.00 and 0% for depression, and $\tau^2 = 0.08$ and $I^2 = 60\%$ for quality of life, and not rated down. [4] 34 of 36 studies in the meta-analysis entered data, [5] Some small studies, but effect sizes adjusted for sample size, robust SE used in meta-analysis and CI acceptable. [6] Heterogeneity moderate for somatic health ($\tau^2 = 0.19$ and $I^2 = 76\%$), and very different somatic outcomes used. More studies with similar outcomes necessary to assess differential effect across different domains of somatic health, thus rated down.

Table 18: Grading of the quality of evidence of MBSR vs active control conditions

The grading shows that for most of the outcomes the evidence was moderate, meaning that new studies could potentially influence our confidence in the effect estimate. For outcome measures of somatic health, the evidence is low, and further research is very likely to impact on the estimate of effect, possibly depending on type of somatic outcomes and active control interventions used.

4.3.5 Adverse events

There were no reports of adverse events or reports on costs in any of the 101 studies in the review.

5. Discussion

5.1 Summary of main results

It is encouraging to see the increased number of randomized controlled trials that have studied this mind-body intervention. We identified 70 new trials since the last literature search in 2010, bringing the total number to 101 RCTs with 8,135 participants. Recent studies more often included an active control group, had a study protocol registered, and carried a lower risk of bias compared to the studies included in the first review.

Since the measure of mental health includes outcomes from a larger proportion of the included studies compared to somatic health or quality of life, it is a more robust measure for the effect of the MBSR intervention. It is therefore treated as the main primary outcome for the meta-analyses. The overall effect size for mental health was moderately large (Hedges' g = 0.54, 95% CI 0.44, 0.63) for studies with inactive control groups, and the effect size was similar across a range of different mental health outcomes, with only small changes compared to the effect sizes reported in the first version of this review. However, we now found moderate heterogeneity, compared to low in 2010, and there was some funnel-plot asymmetry indicating a small study bias. The moderate heterogeneity indicates that the studies have differences that make comparisons across studies less certain. This could arise from differences in the populations, the intervention, the outcome measures or methodological differences between the studies. In addition, there was substantial risk of bias in many studies, and these study features should caution us when drawing conclusions. A fairly robust NNT between 4 and 6 at post-intervention indicates that the effect found is on par with other mental health interventions for mild to moderate mental health problems, and arguably also with many interventions for physical health problems (Arroll 2009, Wright 2009). The effect generally held up at follow-up (up to 34 months in 41 studies).

We also found small but significant effects on overall mental health (Hedges' g = 0.18, 95% CI 0.05, 0.30) for studies with active control groups. The studies in this comparison showed no funnel plot asymmetry, and risk of bias and heterogeneity was lower, increasing our confidence in the result. This is an interesting finding, given that not all traditional treatments hold up when put to the same test. However, there were no differences in effects for quality of life (including social function), or physical health.

Subgroup analyses for both studies with inactive and active control groups revealed similar effect sizes across a range of target groups, intervention lengths, length of follow-up, gender, and various degrees of compliance. The effects of the intervention decreased with increased risk of bias for studies with inactive control groups but not for studies with active control

groups. Sensitivity analyses after removing outliers had a minor impact on the effect sizes for the different outcome groups. Meta-regression revealed a strong correlation between mindfulness and mental health outcomes at post-intervention.

Most of the included studies reported a number of outcome measurements that clearly were interdependent. Failure to account for those dependencies results in erroneous standard errors and compromises all the inferential statistics generated. To pick only one outcome measure to include in a meta-analysis, on the other hand, can be quite problematic. Similarly, there are statistical dependencies in follow-up measures after post-test. We therefore estimated robust standard errors in such situations, making it possible to use more information in the dataset than traditionally has been the case (Hedges, 2010).

5.2 Overall completeness and applicability of evidence

This is the largest review as yet of controlled MBSR trials. While the first version of this review did not find many studies using active interventions, such studies now comprise a third of the included trials. The 101 included studies cover a range of different target groups, both patients and members of the public, and more studies have follow-up measurements beyond a few months. The studies come from countries in America, Europe, Asia and Australia, increasing the applicability of the evidence.

The review did not include studies that implemented major modifications to the standard MBSR protocol, nor did we include non-randomized controlled trials of MBSR. Both might have influenced our results. However, we accepted studies with varying length of the intervention if researchers adhered to the principles set out by Kabat-Zinn (1990). Thus, we cannot generalize our findings to other mindfulness based interventions or other study designs.

There were several inaccuracies regarding whether the control group was a treatment as usual group or whether it in fact was a waitlist control group. Some studies stated that they used a treatment as usual design, but also wrote that the control group was offered the MBSR intervention after the completion of the study without specifying whether this was known to the control group from the onset of the trial. Furthermore, what treatment as usual entailed was seldom described. Because of these uncertainties, we chose to group together the studies using waitlist and treatment as usual. Another reason for doing this was to gain statistical strength to assess effects across different groups of outcomes. Thus, we cannot differentiate the differential effects depending on whether a waitlist or treatment as usual is used as the control condition.

Unfortunately, only four trials provided data on social function separately from measuring it as part of quality of life measures. The effect on work ability could therefore not be assessed. Neither were there reports of possible adverse effects or costs. Both types of information should be addressed in future trials. The composite outcome measure labelled somatic health included a wide variety of outcomes, from self-reported physical health measures to

laboratory data on physical, attention and brain functions. It is therefore not surprising that the heterogeneity of effect sizes in this outcome group is high. It may well be that different aspects of physical health respond differentially to an MBSR intervention.

5.3 Quality of the evidence

The quality of the studies varied and the overall risk of bias was considerable for many trials. Encouragingly, we found a decrease in average risk of bias from the first edition of this review. The data also indicate that trials with active control groups had a lower risk of bias than trials with inactive controls. Effect sizes showed a trend towards decreasing with increasing risk of bias, although this was only significant for trials with inactive controls. There were relatively few studies that reported compliance accurately and the relationship between attendance, home practice and outcome could therefore only be assessed for a minority of studies. This should be explored further. Overall, there is ample opportunity for trialists to improve methods.

The level of heterogeneity was generally moderate across studies in some analyses. This indicates that studies differ in ways that make the meta-analytic results less certain. The differences in populations, outcomes, and ways of analysing the results could contribute to this. Ten of the excluded articles were unattainable and two of these were written in Chinese. In addition, some studies presented some of the non-significant results in such a way that they could not be entered into the meta-analyses. These factors might also have influenced the results.

There were few studies that had registered their trials beforehand, although newer studies, and particularly newer studies with active controls, increasingly seem to comply with this recommendation. This is important in order for reviewers to be able to assess whether reporting of outcomes is accurate. A recent study of 124 controlled mindfulness trials (Coronado-Montoya et al., 2016) indicated that positive results have been reported more often than expected. Indeed, our finding of a funnel-plot asymmetry indicate a possible lack of small studies without effect, emphasizing the need for researchers to publish and editors to accept for publication such 'negative studies'. It is therefore possible that the effect sizes reported in this review for MBSR versus inactive controls are somewhat inflated.

Judgments about evidence and recommendations in healthcare are complex. The GRADE system has been developed to improve on judgments about the quality of the evidence (Guyatt, 2008). Grading of the evidence led us to believe that the quality is moderate for most comparisons and low for somatic health (Tables 17-18). This means that new research might change the effect estimates. Although the findings in this review are remarkably similar to what we found in the first version of the review based on the first 31 trials, we would want to see a GRADE profile that corresponds to high quality removing residual uncertainty about the confidence in the results.

5.4 Potential biases in the review process

Several of the reviewers are themselves mindfulness practitioners and this represents a possible bias in the review process. The first author of the review is also first author of two included studies. These were assessed by other members of the team.

Estimation of effects by the robust variance estimation typically resulted in similar effect size estimates as the conventional method, but with more narrow confidence intervals. It is encouraging to be able make use of most of the data in the studies and to avoid the often haphazard choice of which outcome to select for meta-analysis when several measures of the same construct are presented in a primary study. We anticipate that this method will become more of a standard technique in meta-analysis.

5.5 Agreements and disagreements with other studies or reviews

A large number of systematic reviews on mindfulness-based interventions have been published since we put forward our first review. Most of them concentrated on particular target groups such as patients with chronic pain (Bawa et al., 2015), sleep in cancer patients (Chiu et al., 2014), or healthy individuals (Sharma & Rush, 2014), and most of them included different mindfulness-based interventions. Three systematic reviews and meta-analyses of all types of mindfulness-based interventions have recently been published. One review with 209 individual trials (Khoury, 2013) included 38 controlled studies and found a post-intervention combined effect size of g = 0.52 and 0.33 comparing MBSR to wait-list control and to active control groups respectively. A second review (Goyal, 2014) included 41 controlled trials with different meditation programs: 26 were mindfulness-based interventions and 16 of these were MBSR programs. There were not enough trials with active controls to perform comparative effect analyses but the comparison of 26 mindfulness-based interventions to inactive controls demonstrated an effect size on anxiety, depression, and pain of Cohen's d = 0.40, 0.32, and 0.33 respectively. The third review (Gotink, 2016) was an overview of systematic reviews and meta-analyses of mindfulness-based interventions. It included 23 reviews covering 115 RCTs that had included 8,683 unique individuals. Compared to inactive controls, MBSR and MBCT (Mindfulness-Based Cognitive Therapy) significantly improved depressive symptoms, anxiety, and stress with a Cohen's effect size of d = 0.37, 0.49, and 0.51, while the effect on quality of life and physical functioning were estimated to be d = 0.39 and 0.27 respectively. Our results are in general agreement with these reviews.

Based on the assumption that many of the self-report mental health outcome measures tap similar aspects of mental functions, we created a composite measure of mental health from the outcomes for anxiety, depression, stress/distress, and other mental health outcomes (measures of emotional disturbance and regulation, anger, worry, rumination, and relaxation). The mental health measure captured data from three quarters of the studies. A couple of other reviews have also measured mental health as one construct, reporting figures in the same range as we did (Baer, 2003; Grossman, Niemann, & Schmidt, 2004, Carmody & Baer, 2009).

5.6 Subgroup analyses

All subgroup analyses were carried out with the composite mental health outcome measure as the dependent variable. The hypotheses had been revised based on the findings from the first edition of this review. In agreement with the hypotheses, the review found a similar effect size among patient samples as with non-clinical groups, and studies including persons with psychological problems reported about the same effects as those recruiting people with physical health issues. A possible explanation is that all studies include participants on a basis of self-selection and the MBSR intervention is a well-known intervention for stress-related problems. Hence, people included in the studies might be more similar with respect to the level of mental health problems than the inclusion labels indicate. Only a few studies included patients with diagnosed mental problems.

The effect size on mental health outcomes was maintained at follow-up both for studies comparing MBSR to inactive and active controls. There were only 41 studies with such data, and hopefully future trials will add to this number and enable us to verify this promising finding.

It was unexpected that attendance and home practice hardly influenced the effect size. Accordingly, the 'dosage' of mindfulness training that is necessary to have an effect is still unknown. The effect may come through moments of insight leading to a change in the way one views oneself and the world. This may happen as much from a readiness to change as from the length of the MBSR course. In a more detailed analysis of dose-response, Carmody (2009) did not find a significant effect of length of the MBSR course or assigned home practice. We do not know of course anything about the quality of practice that was reported; 30 minutes routine daily practice without paying much attention may be less effective than learning to be mindful in everyday life, something which is much more difficult to measure. Furthermore, different types of practice may have different effects on different outcomes, as shown in a pre-post study of 174 participants assigned to different types of MBSR classes (Carmody & Baer, 2008). When analysed on the basis of more careful recording, Rosenzweig et al. (2010) showed that the effect varied both as a function of clinical condition and compliance. A different perspective was provided by an uncontrolled study showing that home practice predicted not only reductions in self-reported stress, but also changes in brain grey matter density in the right amygdala, an area involved in stress reactions (Hölzel, 2010).

Only a quarter of the studies reported accurately on compliance, and this makes it difficult to assess the relationship between compliance and effect. The meta-regression of the effect size of mindfulness on mental health outcome at post-intervention both for inactive and active control groups does, however, may indicate that training in mindfulness is important for the reported outcomes. This is in line with findings in a recent systematic review of mindfulness mediation studies (Gu, Strauss, Bond, & Cavanagh, 2015).

The studies reporting intention-to-treat data did not differ significantly in effect on mental health outcome from studies reporting per-protocol data, although there was a trend towards

lower effect sizes in studies with intent-to-treat analyses for both inactive and active control groups. On the whole attrition was low (ca. 15%), which could explain this result.

The average mental health effect size decreased significantly with increased risk of bias for inactive groups b = -0.09 (-0.18, -0.01), but not for active groups. This underlines the importance of following the guidelines for registering, conducting and reporting of randomized controlled trials which were all of higher quality in the trials using active control groups.

6. Authors' conclusions

6.1 Implications for practice and policy

Compared to inactive controls, MBSR seems to have a moderately large positive effect on outcomes of mental health; the quality of evidence being graded as moderate. The intervention also improved quality of life, including social function, and positive effects were found also for outcome measures of somatic health, personal development like empathy, coping and sense of coherence, and mindfulness. Heterogeneity was moderate for most outcome groups, and this, in addition to publication and reporting bias, may have inflated the results somewhat.

Compared to active control groups, MBSR seems to have an additional small positive effect on outcome measures of mental health, depression, stress and mindfulness. This may indicate that MBSR has an effect in addition to the effects of common factors (such as group support, attention from the teacher, and knowing that one is doing something to promote health), which one is trying to control for by using active control interventions. MBSR had a similar effect to other psychosocial interventions on anxiety, personal development and physical health. Heterogeneity was low except for somatic health and quality of life where it was high and moderate, respectively.

Consistent effects were found across different target groups and intervention forms. While the Program alleviated symptoms of stress and mental health more broadly defined, MBSR also had positive effects on measures of personal development, and quality of life including social function. MBSR might be an attractive option for anyone interested in improving the way they handle stress and cope with illness and the strains of life. In times that value action, perfection, and always being available, mindfulness offers a different perspective that allows one to learn to appreciate life as it is just now, and opening up to the resources available within us and in our surroundings. Although MBSR is often tried out in therapeutic settings, it is a general method for strengthening our resources and ability to self-regulate mind and body functions. It is low-cost and group-based, and it can also be delivered by non-medical personnel with sufficient training and experience in teaching and practicing mindfulness.

6.2 Implications for research

Further studies should improve and innovate the MBSR Program in order to achieve a possibly stronger effect. In particular, it might be time for combining MBSR with other treatment modalities such as exercise, different forms of psychotherapy, or educational programs. As more trials with active control conditions are published, future reviews could

compare the effects of MBSR to different types of active interventions, such as educational programs and group therapy programs. Studies with mixed designs might be of value to provide insights into how participants can strengthen the effects of the intervention, and systematic reviews of qualitative studies might be timely. There is no need for more uncontrolled studies and it is strongly recommended that all randomized trials be pre-registered, performed, and reported according to current standards. It might be worth exploring further the effects of the length of the intervention, reported home practice, teacher qualifications, and the variation in outcomes among study participants in well-designed primary studies.

The field is rapidly evolving and more trials are embedding investigations of changes in the brain and in bodily functions, possibly shedding light on mechanisms of change. All new trials should include measures of mindfulness and explore moderators and mediators of effect. In addition, it would be valuable to use other methods for measuring mindfulness than self-report measures, since these may measure skills in self-reporting rather than mindfulness per se (Davidson & Kaszniak, 2015).

More accurate ways to monitor fidelity and compliance may help us to assess the correct relationship between the intervention and the outcomes, both by video assessment of sessions and through more direct monitoring of home practice, for example by using smart phones or physiological monitoring of heart rate variability during practice. It may also be useful to include ecological momentary assessment om mind-wandering and not just retrospective questionnaires assessing mindfulness (Davidson, 2015).

Another important issue in research is a more detailed description of the MBSR program delivered, and how this has been adapted to the population in question (Davidson, 2015).

All trialists should attempt to share data, as many topics related to mechanisms may only be properly explored in individual patient data meta-analysis.

7. References

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8.2 Roles and responsibilities

Arild Bjørndal suggested the update of this review. Michael de Vibe wrote the first draft of the review. Karianne Hammerstrøm, who is a research librarian, developed the search strategies. Arild Bjørndal wrote the methods sections of the protocol and Krystyna Kowalski designed the forms. Karianne Hammerstrøm and Brynhildur Axelsdottir carried out the searches. Michael de Vibe, Arild Bjørndal, Sabina Fattah, Gunvor M Dyrdal, Even Halland and Toril Eide selected studies and extracted data. Emily Tanner-Smith, Michael de Vibe, and Arild Bjørndal did the data analyses. Michael de Vibe and Arild Bjørndal wrote the review. All authors have commented on different versions of the manuscript.

8.3 Sources of support

This study was supported by the Norwegian Institute of Public Health and The Centre for Child and Adolescent Mental Health, Eastern and Southern Norway.

8.4 Declarations of interest

Michael de Vibe has carried out a research project on MBSR in Norwegian family practice that was published in the Norwegian Medical Journal in 2006 and is a MBSR instructor. He completed his doctorate based on a RCT trying out MBSR among students with Arild Bjørndal as his mentor. Michael de Vibe did not assess or extract data from his own studies, nor did Arild Bjørndal. Sabina Fattah, Gunvor M Dyrdal and Even Halland are MBSR instructors. None of the authors stand to gain financially from a positive or negative evaluation of MBSR.

8.5 Plans for updating the review

Arild Bjørndal will be responsible for updating this review within the next five years.

9. Tables

9.1 Characteristics of studies tables

9.1.1 Characteristics of included studies

Alterman2004

Methods	RCT
Participants	Drug-abusers in resident treatment > two months, Exclusion criteria: Schizophrenia and borderline, AIDS, hepatitis, regular mind-body practice last two months
Interventions	MBSR vs treatment-as-usual MBSR: 8 x 2 hours per week + 7 hour all day session. 30-45 minutes of daily practice in a group
Outcomes	Semi-structured psychiatric interview measured problems in seven areas: medical, employment, alcohol, drug, legal, family-social and psychiatric, in addition to spirituality, optimism, positive and negative mood, vitality, physical and mental health, drug and alcohol use and meditation practice
Key conclusions	Addiction severity index indicated greater improvement in MBSR group in medical problems over a 5 months follow-up and a trend on psychological problems, but no other group differences and no difference in urine toxicology
Notes	Analysis by repeated measures of variance to look for group x time interaction. Because low statistical power, effect sizes for group differences were also given

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random number sequence

Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	High risk	University technicians administered interview at post-intervention and follow-up but not at baseline.
Incomplete outcome data (attrition bias)	Low risk	Only three people dropped out in each group
Selective reporting (reporting bias)	High risk	No SD given
Other bias	High risk	Treatment staff administered interview at baseline and technical staff at other times

Amutio 2015

Methods	RCT
Participants	42 physicians
Interventions	MBSR (8x2,5 + 8h) vs WL
Outcomes	FFMQ, SRSI-3, Heart rate
Key conclusions	Significant improvements at post-intervention for FFMQ and SRSI-3 in the MBSR group vs WL, and significant reduction within MBSR group of heartrate, all measured after the intervention.
Notes	At post-intervention the control group received the intervention and both groups received 2.5 hours per month for one year, which maintained the post-intervention gains at one year

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer program
Allocation concealment (selection bias)	Unclear risk	not described
Blinding (performance bias and detection bias)	Unclear risk	not described
Incomplete outcome data (attrition bias)	Low risk	low attrition
Selective reporting (reporting bias)	Low risk	all outcomes reported
Other bias	Low risk	

Anderson 2007

Methods	RCT
Participants	86 healthy adults
Interventions	MBSR vs wait-list control MBSR: 8 x 2 hours per week, no all day retreat
Outcomes	Attentional control, depression, affect, anxiety , anger, rumination, worry, mindfulness and 4 attention tasks
Key conclusions	MBSR did not affect attentional control, but was associated with improvements ($p<0.01$) in emotional well-being (as measured by depression, anxiety, anger, positive affect, general rumination, anger rumination and anger sensitivity) and mindfulness. Changes in mindfulness predicted changes in emotional well-being in the MBSR group, and improved mindfulness enhanced awareness of present experience
Notes	Intention to treat analysis not conducted as the number of dropouts in each group were equal (n=7). Greater negative affect, depression and anger rumination in MBSR group at baseline. Therefore done multivariate ANOVA using baseline differences as covariates

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Unclear risk	Not specified
Incomplete outcome data (attrition bias)	Low risk	The number of dropouts in each group were equal (n=7) and hence the most conservative estimation of post-test scores would not have affected group mean-differences at post-test
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Arch 2013

Methods	RCT
Participants	105 veterans (83 % male). Inclusion criteria: 18-75 years old, English speaking, a principal (or dual principal) DSM-IV diagnosis of panic disorder with or without agoraphobia (PD/A), generalized anxiety disorder (GAD), social anxiety disorder (SAD), specific phobia (SP), obsessive-compulsive disorder (OCD) or civilian post-traumatic stress disorder (PTSD) (e.g., non combat or military sexual trauma related) on the MINI International Neuropsychiatric Interview (MINI) for DSM-IV.
	Exclusion criteria: principal military-related PTSD, active suicidal ideation, active substance use disorders within the past 3 months, or current participation in other CBT or adapted MBSR treatments for anxiety disorders.
Interventions	MBSR vs CBT (Cognitive behavioral therapy. 10 x 90 minutes per week.) Both groups received workbooks with didactic handouts, did homework and in-session exercises.)
	MBSR: 9 x 90 minutes per week, 3 hours retreat.
Outcomes	Primary: diagnostic severity, worry, anxiety arousal. Secondary: depression.
Key conclusions	CBT and MBSR were both effective at reducing principal diagnosis severity and somewhat effective at reducing self-reported anxiety symptoms. CBT was more effective at reducing anxiety arousal, MBSR more effective at reducing worry and comorbid disorders.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	computer generated
Allocation concealment (selection bias)	Low risk	Allocation not known to blind assessors
Blinding (performance bias and detection bias)	Low risk	Blinding of assessors
Incomplete outcome data (attrition bias)	Low risk	All data reported
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Arefnasab 2013

Methods	RCT
Participants	40 male pulmonary injured veterans, mean age 49. Inclusion criteria: Caucasian, inhabitants of Teheran, mild to moderate pulmonary problems. Exclusion criteria: History of acute psychotic disorder/ psychosis, negative history of psychiatric drug consumption/ chronic medical problem (except sequels of chemical injuries).
Interventions	MBSR vs wait-list control. MBSR: 8 x 2 hours per week, no retreat. One hour daily home practice.
Outcomes	Physical and social functioning, role limitations due to physical/ social problems, wellbeing and three pulmonary function tests.
Key conclusions	MBSR can improve quality of life, but not lung function in chemically injured veterans.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computerized number generator
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Unclear risk	Not specified
Incomplete outcome data (attrition bias)	Unclear risk	Not specified
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Unclear risk	Insufficient information

Astin 1997

Methods	RCT
Participants	Students
Interventions	MBSR vs wait-list control MBSR: 8 x 2 hours per week, no all day retreat
Outcomes	Psychological distress, control and spiritual experience
Key conclusions	MBSR significantly reduced psychological distress $p<0.002$, representing a 64% reduction in the MBSR group vs 14 % in the

	control group. Increased overall sense of control (p<0.02), and using more accepting/ yielding mode of control p<0.03, and increase on measure of self as source of control p<0.008. Increased scores on spiritual experiences p<0.03
Notes	ITT (intention to treat analysis) not reported. ANOVA analysis was performed using change shores as dependant variable and baseline values as covariates. Written to author to get more data but this was not available.

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Coin flip (on request to author)
Allocation concealment (selection bias)	Unclear risk	Not specified who did the coin flip
Blinding (performance bias and detection bias)	High risk	Most likely not blinded, as the researcher was acting as both instructor and data collector
Incomplete outcome data (attrition bias)	Unclear risk	Large dropout from control group
Selective reporting (reporting bias)	High risk	Missing raw data from all facets of SCI (sense of control index)
Other bias	Low risk	No other bias detected

Baker 2014

Methods	30 community-dwelling women with urge-predominant urinary incontinence, 22 – 79 years old. Inclusion criteria: 5 or more urinary urge incontinence (UUI) episodes, with urge predominance during three days. Exclusion criteria: anticholinergic medication, past non-pharmacologic treatment of UUI, past diagnosis of painful bladder, interstitial cystitis and/ or neurological disorder.
Participants	MBSR vs Yoga (8 weeks. Program included education and self-massage, but no breathing techniques) MBSR: 8 x 2, 5 hours per week + 7 hour all-day session. Recording of formal and informal home-practice.
Interventions	Incontinence episodes, urge incontinence episodes, bladder quality of life and health related quality of life.

Outcomes	MBSR seems to be a promising treatment of urinary incontinence. The results support larger scale trials.
Key conclusions	At all follow-up tests, the participants in the MBSR program showed greater percent change from the baseline in UIE, but statistically significant only at 8 weeks.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Shuffled sealed envelopes
Allocation concealment (selection bias)	Low risk	Sealed envelopes
Blinding (performance bias and detection bias)	Unclear risk	Not specified
Incomplete outcome data (attrition bias)	Low risk	Last observation carried forward
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Unclear risk	The quality of the yoga / MBSR instructor unclear

Banth 2015

Methods	RCT
Participants	88 female patients with non-specific chronic low back pain
Interventions	8 w x 90 min MBSR + TAU vs TAU
Outcomes	Pain (McGill Pain Q), Quality of life by SF-12
Key conclusions	Significant lowering of pain and increased QOL after the intervention
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Method not described

Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias)	Unclear risk	Not described
Incomplete outcome data (attrition bias)	High risk	High attrition
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Unclear risk	Insufficient description of method

Barrett 2012

Methods	RCT
Participants	149 community-recruited adults (82 % female). Inclusion criteria: 50 years and older, willingness to undertake any of the 3 randomization outcomes, reporting either 2 or more colds in the last 12 months or an average of 1 or more cold per year. Exclusion criteria: previous training or current practice of meditation, moderate exercise at least 2 times a week or vigorous exercise at least 1 time a week, and a score of less than 24 points on the Folstein Mini-Mental State Examination 21 or more than 14 points on the 9-item Patient Health Questionnaire (PHQ-9) depression screen22; immunodeficiency, autoimmune, or malignant disease; or prior allergic reaction to influenza vaccine or egg allergy.
Interventions	MBSR vs exercise (structure equivalent to the MBSR-intervention) vs control. MBSR: 8 x 2,5 hours per week, 45 minutes per day home practice.
Outcomes	Main: ARI illness (number of participants, number om episodes, severity, number of days), health care visits, sick days, biomarkers. Secondary: Exercise (metabolic equivalent task/ mindfulness score). Physical health, mental health, positive emotion, optimism, social support, sleep quality, perceived stress, negative emotion and anxiety.
Key conclusions	Training in meditation or exercise may be effective in reducing ARI illness burden.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**

Random sequence generation (selection bias)	Low risk	Computer-generated randomization
Allocation concealment (selection bias)	Low risk	Concealed envelopes
Blinding (performance bias and detection bias)	Unclear risk	Not specified
Incomplete outcome data (attrition bias)	Low risk	Using imputation
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	

Blom 2014

Methods	RCT
Participants	101 adults with unmedicated stage 1 hypertension
Interventions	8 w MBSR vs WL
Outcomes	Change in awake and 24-hour ambulatory BP from baseline to week 12
Key conclusions	No between group difference in BP. Secondary within-group analysis found a small reduction in BP after MBSR limited to females
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Permuted block design
Allocation concealment (selection bias)	Low risk	Sealed envelopes
Blinding (performance bias and detection bias)	Unclear risk	Unclear description
Incomplete outcome data (attrition bias)	Unclear risk	All randomized not used in analyses
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Brown 2013

Methods	RCT
Participants	28 patients with chronic pain. (21 women/ 7 men) Inclusion criteria: being right-handed, any type of musculoskeletal pain. Exclusion criteria: a history of neurological or cardiovascular disease. A history of psychiatric disease: major depression, bipolar disorder, anxiety disorders (obsessive compulsive disorder, panic, phobias, generalized anxiety disorders) and schizophrenia. (Patients were expected to have a mild to moderate levels of anxiety and/or depression.)
Interventions	MBPS (mindfulness-based pain management program) vs control/ treatment as usual. MBPS: 8 x 2,5 hours weekly. Homework not specified.
Outcomes	Self-report: mental and physical health, engagement, contemplation, perceived control over pain, sensory pain, affective pain, laser pain and mindfulness.
Key conclusions	The study supports the hypothesis that mindfulness training provides a cognitive strategy for improving pain management, which has positive consequences for mental health.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	not described
Allocation concealment (selection bias)	Unclear risk	not described
Blinding (performance bias and detection bias)	Unclear risk	not described
Incomplete outcome data (attrition bias)	High risk	high attrition for unexplained reasons
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Bränström 2010

Methods	RCT
Participants	71 Patients with varying cancer diagnoses who were not undergoing current radiation or chemotherapy treatment

Interventions	MBSR vs wait-list control MBSR: 8 x 2 hours per week, minus all day session
Outcomes	Stress, anxiety and depression, impact on event scale, mood states and mindfulness. Home practice of meditation, all measured before and 1 month after completion of MBSR
Key conclusions	Significant decrease in stress, post-traumatic avoidance symptoms and increased profile of mood states. Significant increase in mindfulness, and this mediated the effects.
Notes	Written to author who confirmed that numbers in table two are from ITT - intention to treat analysis (32 and 39)

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Software random selection procedure
Allocation concealment (selection bias)	Low risk	
Blinding (performance bias and detection bias)	Unclear risk	No blinding of group assignment.
Incomplete outcome data (attrition bias)	Low risk	ITT
Selective reporting (reporting bias)	Low risk	All reported, 6 month follow up to be reported later
Other bias	Low risk	

Carmody 2011

Methods	RCT
Participants	110 late perimenopausal and early postmenopausal women. Inclusion criteria: women in late menopausal transition and early post-menopause experiencing an average of ≥5 moderate or severe hot flashes (including night sweats)/day during the past week, willingness to keep a daily diary of the time and intensity and bother from hot flashes, and endeavoring to maintain present exercise, dietary pattern, and dosage of any soy supplements or menopausal remedies (including isoflavone intake).
Interventions	MBSR vs wait-list control. MBSR: 8 x 2,5 hours per week, one all-day class, 45 minutes 6 days/ week home practice.

Outcomes	Main outcome: the degree of bother from hot flashes and night sweats. Secondary outcomes: hot flash intensity, quality of life, subjective sleep quality, anxiety, perceived stress and treatment adherence.
Key conclusions	MBSR may be a clinically significant resource in reducing the degree of bother and distress women experience from hot flashes and night sweats.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Stata´s ralloc command, blocks of 4 and 6
Allocation concealment (selection bias)	Low risk	All personnel blinded to allocation.
Blinding (performance bias and detection bias)	Low risk	Data entry personnel ad instructors blinded
Incomplete outcome data (attrition bias)	Low risk	Last observation carried forward
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	

Carson 2004

Methods	RCT
Participants	White couples, married or cohabitating > two years, non-distressed (<58 on the global marital satisfaction inventory and <65 on the brief symptom inventory), and not practicing yoga or meditation regularly
Interventions	MBSR vs wait-list control MBSR: 8 x 2,5 hours per week + 7 hours all day session, couple focus in the exercises
Outcomes	Global marital satisfaction inventory, brief symptom inventory, relationship satisfaction, autonomy, closeness, acceptance of partner, optimism, spirituality, individual relaxation index
Key conclusions	Favorable impact on relationship satisfaction, autonomy, relatedness, closeness, acceptance and relationship distress, same on individual optimism, spirituality, relaxation and distress, and

	results maintained at three months follow-up. Those who practiced had better outcome
Notes	Sessions videotaped and rated for fidelity, daily practice diaries, experienced MBSR teachers

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not specified, randomisation stratified for couples
Allocation concealment (selection bias)	Unclear risk	Not specified, written to author
Blinding (performance bias and detection bias)	Unclear risk	Not specified, written to author
Incomplete outcome data (attrition bias)	Low risk	Equal drop-out in both groups, and differences between completers and dropouts analysed
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Cohen-Katz 2005

Methods	RCT
Participants	27 hospital staff, mainly nurses.
Interventions	MBSR vs wait-list control MBSR: 8 x 2,5 hours per week + 6 hour all day session.
Outcomes	Burnout, distress and mindfulness
Key conclusions	Significant increase in mindfulness, significant decrease in emotional exhaustion (p=0.05) and increase in personal accomplishment (p=0.014) and trend for depersonalization (p=0.063), but no significant difference in distress
Notes	More people with elevated distress in control group (7/13) than MBSR (3/12) at pre-intervention

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**

Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Unclear risk	Not specified
Incomplete outcome data (attrition bias)	High risk	Missing data for the two drop-outs in the intervention group not accounted for
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Unclear risk	Big baseline difference in distress between intervention and treatment group not analysed

Corsica 2014

Methods	RCT
Participants	53 participants with stress and problem eating behaviour and MBI>23
Interventions	MBSR (50x6) vs Stress-eating intervention vs MBSR+SEI and BMI
Outcomes	PSS, EADES
Key conclusions	All interventions significantly reduced stress and stress-eating, with best effect for the combined intervention which also showed a moderate effect on short-term weight-loss
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	not described
Allocation concealment (selection bias)	Unclear risk	not described
Blinding (performance bias and detection bias)	Unclear risk	not described
Incomplete outcome data (attrition bias)	Low risk	ITT
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Creswell 2009

Methods	RCT
Participants	HIV-infected adults with psychological distress
Interventions	MBSR vs one day MBSR control MBSR: 8 x 2 hours per week, six hours all day session
Outcomes	Blood CD4+ T lymphocyte levels and concentrations of HIV-1 RNA
Key conclusions	MBSR can buffer CD4+ T lymphocyte declines in HIV-1 infected adults, independent of ARV (anti-retroviral) treatment status. Attendance in class predicted outcome, and accounted for 2/3 of effect on CD4+T lymphocytes
Notes	Intention to treat analysis conducted

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	unclear sequence generation, reported use of "2:1 randomisation schedule"
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Low risk	Study assessment personnel were blind to participant condition
Incomplete outcome data (attrition bias)	Low risk	ITT conducted
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Creswell 2012

Methods	RCT
Participants	40 healthy older adults, loneliness and pro-inflammatory gene expression, mean age 65, 33 women. Inclusion criteria: English-speaking, not currently practicing any mind-body therapies more than once per week, non-smokers, mentally/ physically healthy (last three months), not currently taking medication that affect immune, cardiovascular, endocrine or psychiatric functioning. Exclusion criteria: being left handed, non-removable metal implants, weight above 3000 lbs, cognitive impairment.
Interventions	MBSR vs wail-list control

	MBSR: 8 x 2 hours, full day retreat. 30 minutes of ascribed daily home practice.
Outcomes	Mindfulness skills, loneliness, C-reactive protein (CRP) and interleukin-6.
Key conclusions	MBSR may be a novel treatment approach for reducing loneliness and related pro-inflammatory gene expression in older adults.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computerized number generator
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Low risk	Blinding performed (study staff)
Incomplete outcome data (attrition bias)	Unclear risk	Not specified
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	

Davidson 2003

Methods	RCT
Participants	41 right-handed employees in a biotechnology cooperation
Interventions	MBSR vs wait-list control MBSR: 8 x 2 hours per week, six hours all day session
Outcomes	Anxiety, positive and negative affect, EEG brain changes, antibody titre after influenza vaccination
Key conclusions	Significant increase in left-sided anterior cortical activation on EEG in MBSR group, and significant increase in antibody titre rise. Magnitude of Cortical change predicted magnitude of antibody response
Notes	Insufficient reporting on psychometric data

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**

Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Unclear risk	Not reported
Selective reporting (reporting bias)	High risk	Data on anxiety outcome for T3 is missing
Other bias	Unclear risk	Possible contamination as all participants came from same firm

de Veer 2009

Methods	RCT, matched for age, gender and education
Participants	46 persons entered, 37 persons (29 males and 8 females) who stutter completed the program
Interventions	MBSR vs wait-list control MBSR: 8 x 2,5 hours per week
Outcomes	Stress, anxiety about speech situations, self-efficacy, coping, locus of control and attitude towards speech situations
Key conclusions	MBSR group showed less suffering from stress and related tension and fatigue, less anxiety about speech situations and more confidence in approaching speech situations, they felt more in control and used more problem-focused coping
Notes	Follow-up data cannot be used in meta-analysis because follow-up parallel with the wait-list group receiving MBSR. written to author and got additional information. Attendance recorded, not practice time

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Coin tossing by main experimenter
Allocation concealment (selection bias)	High risk	coin tossing

Blinding (performance bias and detection bias)	Low risk	Questionnaires received anonymously in sealed envelopes by second investigator
Incomplete outcome data (attrition bias)	High risk	Uneven attrition in intervention and control group
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	High risk	Not intention to treat analysis and no analysis of dropouts

de Vibe 2006

Methods	RCT
Participants	144 people with stress and chronic illnesses
Interventions	MBSR vs wait-list control MBSR: 8 x 2.5 hours per week, six hours all day session
Outcomes	Psychological distress, subjective health complaints and quality of life
Key conclusions	MBSR group showed reduced distress and health complaints and increased quality of life. Significant effect of amount of practice on quality of life measures at follow-up. Same trend on subjective health complaints
Notes	Follow-up after cross-over of wait-list control group who then received MBSR and they showed same results after 6 months follow-up as the intervention group. Follow-up results therefore not included in our analyses

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Dice
Allocation concealment (selection bias)	High risk	Allocation done by main investigator
Blinding (performance bias and detection bias)	High risk	Data collected by main investigator
Incomplete outcome data (attrition bias)	Low risk	No dropouts in control group, 10% dropout in intervention group accounted for
Selective reporting (reporting bias)	Low risk	All outcomes reported

Other bias	Unclear risk	Baseline data gathered at inclusion to study but groups started at different times after inclusion

de Vibe 2013

Methods	RCT
Participants	288 medical and psychology students
Interventions	MBSR vs. Control (study as usual) MBSR: 6 weekly sessions of 1.5 hrs each, a 6-hour session in week seven, and 30 min. of daily mindfulness practice.
Outcomes	Mental distress (General health questionnaire, GHQ12), student burnout (Maslach burnout inventory, MBI), study stress (perceived medical school stress, PMSS), subjective well being (SWB), mindfulness (five facet mindfulness questionnaire, FFMQ), student compliance (attendance and self-reported home-based mindfulness practice).
Key conclusions	The MANCOVA analysis (mental distress, student burnout, study stress and subjective well-being) revealed a significant overall effect on the main outcome measures on the intervention compared with the control group. The ANCOVA analysis showed a significant effect of the intervention on mental distress and well-being. For the latter analysis, the intervention did not significantly reduce student stress or student burnout. For the outcome of mindfulness, the results showed an overall significant effect in favour of the intervention group.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Using computerized random number generator
Allocation concealment (selection bias)	Low risk	Information on allocation emailed to participants one week prior to start of intervention
Blinding (performance bias and detection bias)	Low risk	Blinding performed
Incomplete outcome data (attrition bias)	Low risk	Addressed

Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Unclear risk	Contamination of data due to intervention and control group in same med / psych class?

Duncan 2012

Methods	RCT
Participants	76 HIV-patients taking antiretroviral therapy (ART). 84% / 64 male.
Interventions	MBSR vs wait-list control standard care MBSR: 8 x 2, 5- 3 hours per week, one all-day retreat, 45 minutes formal practice + 5-15 minutes informal practice at home six days per week.
Outcomes	CD4 count, side effect checklist. Secondary: medication/ART adherence and psychological functioning (perceived stress, depression, positive and negative affect, and mindfulness)
Key conclusions	MBSR is a promising approach for reducing HIV treatment-related side effects.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomization using SAS system´s PLAN procedure
Allocation concealment (selection bias)	Low risk	Allocation by participant IDs and randomization key
Blinding (performance bias and detection bias)	Unclear risk	Insufficient information
Incomplete outcome data (attrition bias)	Low risk	Missing data dropped in analyses
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	

Dykens 2014

Methods	RCT
Participants	243 mothers of children with disabilities. Incl. Willingness to be randomized. No previous training in mindfulness or

	positive psychology practices.
Interventions	MBSR or Positive Adult Development (positive psychology practice). 6 x 1,5 hours of both interventions
Outcomes	Using slopes-as-outcomes, mixed random effects models, both treatments led to significant reductions in stress, depression, and anxiety, and improved sleep and life satisfaction, with large effects in depression and anxiety. Mothers in Mindfulness-Based Stress Reduction versus Positive Adult Development had greater improvements in anxiety, depression, sleep, and well-being. Mothers of children with autism spectrum disorder improved less in anxiety, but did not otherwise differ from their counterparts
Key conclusions	Future studies are warranted on how trained mentors and professionals can address the unmet mental health needs of mothers of children with developmental disabilities. Doing so improves maternal wellbeing and furthers their long-term caregiving of children with complex developmental, physical, and behavioral needs.
Notes	Must be described as results are given as regression slopes

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	**Clearly randomized**
Allocation concealment (selection bias)	Low risk	**By computer**
Blinding (performance bias and detection bias)	Unclear risk	**No blinding**
Incomplete outcome data (attrition bias)	Low risk	**202/243 is good**
Selective reporting (reporting bias)	Low risk	**No**
Other bias	Low risk	**No**

Erogul 2014

Methods	RCT
Participants	58 1st-year medical students, mean age 23,5, 45,6 % women. Inclusion criteria: Attendance at minimum 7 sessions and the retreat.
Interventions	MBSR vs control.

	MBSR: 8 x 75 minutes per week + five hour retreat. Suggested 20 minutes meditation at home per day. (realized: 40,7 minutes per week)
Outcomes	Perceived stress, resilience and self-compassion.
Key conclusions	An abridged MBSR intervention improves perceived stress and self-compassion in 1st-year medical students and may be a valuable curricular tool to enhance wellness and professional development.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random number generator
Allocation concealment (selection bias)	Low risk	Blind allocation
Blinding (performance bias and detection bias)	Unclear risk	No blinding
Incomplete outcome data (attrition bias)	Unclear risk	Not specified
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	

Esmer 2010

Methods	RCT
Participants	25 patients with failed back surgery syndrome (FBSS). (11 women/ 14 men). Inclusion criteria: persistent leg pain, back pain, or both despite a history of lumbosacral spinal surgery within the previous 2 years. Exclusion criteria: pregnancy, cognitive impairment, relapsed chemical dependency, and lack of effective transportation.
Interventions	MBSR vs control group. (Both groups received standard care.)
	MBSR: 8 x 1, 5- 2, 5 hours per week, one 6-hour session, 45 minutes home practice six days a week.
Outcomes	Level of pain, acceptance of pain, quality of life, pain-related functionality, medication consumption, and sleep quality.
Key conclusions	The results suggest that MBSR can be a useful clinical intervention for patients with FBSS.
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information
Allocation concealment (selection bias)	Unclear risk	Insufficient information
Blinding (performance bias and detection bias)	Low risk	Blinding used
Incomplete outcome data (attrition bias)	Unclear risk	Not specified
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	

Farb 2013

Methods	RCT
Participants	36 right-handed adults, mean age 44, 75 % women. Exclusion criteria: suicidal ideation, substance abuse and mental health problems.
Interventions	MBRS vs waitlist MBSR: Weekly for eight weeks (session time not specified), one full day of silent meditation, instructions to practice 40 minutes a day.
Outcomes	Respiration frequency/ volume, IA recruitment ant gyrus and IA recruitment insula brain region.
Key conclusions	We examined whether interoceptive cortical representations demonstrate functional plasticity following 8 weeks of interoceptive monitoring practice. Secondary representations of interoceptive information demonstrated enhanced activity during IA, and greater homework compliance was associated with greater selectivity of primary cortex for interoceptive signals. MBSR may enhance these signals' cortical propagation during attention toward distinct sensory features of the breath. Such enhancement may allow attention to more readily select features of the interoceptive signals, integrating them into a broader contextual representation of present-moment sensation.
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement

Random sequence generation (selection bias)	Unclear risk	Insufficient information
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Unclear risk	Not specified
Incomplete outcome data (attrition bias)	Unclear risk	Not specified
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	

Flook 2013

Methods	RCT
Participants	18 public elementary school teachers
Interventions	MBSR (8x2,5 + 6h) vs WL
Outcomes	SCL=Symptom Checklist, GSI=Global Severity Index; FFMQ=Five-Facet Mindfulness Questionnaire; SCS=Self-Compassion Scale, PersAcc=Personal Accomplishment; CLASS=Observer-rated teacher classroom behavior, Sustained Attention tasks
Key conclusions	Significant reductions in psychological symptoms and burnout, improvements in observer-rated classroom organization and performance on a computer task of affective attentional bias, and increases in self-compassion. In contrast, control group participants showed declines in cortisol functioning over time and marginally significant increases in burnout. Furthermore, changes in mindfulness were correlated in the expected direction with changes across several outcomes (psychological symptoms, burnout, and sustained attention) in the intervention group.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	not described
Allocation concealment (selection bias)	Unclear risk	not described

Blinding (performance bias and detection bias)	Low risk	Blinding of assessors of classroom behavior
Incomplete outcome data (attrition bias)	Low risk	low attrition
Selective reporting (reporting bias)	Low risk	all data reported
Other bias	Unclear risk	not described how the subsample of participants were selected that was assessed for classroom behavior

Fogarty 2015

Methods	RCT
Participants	51 patients with rheumatoid arthritis, Excl major psych illness, active alcohol or drug dependency, scheduled for surgery or previous meditation practice
Interventions	8 w MBSR vs WL
Outcomes	Disease Activity Score (DAS28-CRP) at post-intervention and 2 and 4 months follow-up
Key conclusions	MBSR group showed greater improvement in morning stiffness and pain at post-intervention and at follow up but no effect on swollen joints or CRP
Notes	Full text of study received from author upon request

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	computer randomization stratified for gender
Allocation concealment (selection bias)	Unclear risk	not described
Blinding (performance bias and detection bias)	Low risk	The research assistant conducting the clinical assessments was blinded for treatment allocation and participants were instructed not to discuss their treatment condition during the clinical assessment.

Incomplete outcome data (attrition bias)	Low risk	Missing data were imputed using a standard carry forward analysis
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Frisvold 2009

Methods	Randomized, stratified by BMI
Participants	Forty nurses, aged 39 -57 yrs
Interventions	MBSR (8x2, 5h + 6h dayl) or perimenopausal education (8x 1h) , 95% completion rate
Outcomes	DASS, PSS, CES-D, PSQI, CAM, SCS, Wt and BMI
Key conclusions	Both groups had improvement on all of the variables tested. There was a reduction from Baseline to Week 16 on weight, BMI, perceived stress, depressive symptoms, anxiety, and improvements in sleep quality and mindfulness. The main difference between the two groups was the pattern of change in these variables over time.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Drawing numbers from a hat
Allocation concealment (selection bias)	Unclear risk	not described
Blinding (performance bias and detection bias)	Unclear risk	not described
Incomplete outcome data (attrition bias)	Low risk	low attrition
Selective reporting (reporting bias)	Low risk	all data reported
Other bias	Low risk	

Garland 2014

Methods	RCT
Participants	111 adults with a non-metastatic cancer diagnosis, having completed chemotherapy and radiation treatments at least 1 month before study entry.

Interventions	MBSR vs. Cognitive behavioral therapy for insomnia (CBT-I) CBT-I: 8 weeks x 90 min. sessions MBSR: 8 weeks x 90 min. sessions + one 6h weekend intensive silent retreat
Outcomes	Severity of sleep onset and sleep maintenance difficulties, etc. with The Insomnia Severity Index (ISI), as well as secondary outcomes such as subjective and objective sleep quality and psychological outcomes.
Key conclusions	Assessments were conducted at baseline, after the program, and after 3 months of follow-up. MBSR showed to be inferior to CBT-I for improving insomnia severity immediately after the program, but demonstrated non-inferiority at follow-up. Sleep onset latency was reduced by 22 minutes in the CBT-I group and by 14 minutes in the MBSR group at follow up. The study claims that CBT-I remains the best choice of non-pharmacologic treatment of insomnia.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	computer randomization
Allocation concealment (selection bias)	Low risk	sealed envelopes
Blinding (performance bias and detection bias)	Low risk	primary investigators blinded to allocation and study hypothesis
Incomplete outcome data (attrition bias)	Low risk	ITT
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Gaylord 2011

Methods	RCT
Participants	Seventy-five female IBS patients. Incl. Rome II criteria and physician diagnosis. Female. 18-75 ys. English speaking. Excl. Psychosis. Inpatient admission for psychiatric disorder last 2 ys. Current inflammatory bowel disease or GI cancer. Active liver or pancreas disease. Abdominal trauma or surgery involving GI resection. Pregnancy.

Interventions	MBSR or Support Group (8ws x 2hs + half-day intensive)
Outcomes	IBS severity scale (primary outcome), IBS-quality of life, BSI-18, visceral sensitivity index, treatment credibility scale, and FFMQ after treatment and 3-m f-up.
Key conclusions	Mindfulness training has a substantial therapeutic effect on bowel symptom severity, improves health-related quality of life, and reduces distress. The beneficial effects persist for at least 3 months after group training
Notes	Participants ' ratings of the credibility of their assigned interventions, measured after the first group session, were not different between groups.

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer program
Allocation concealment (selection bias)	Low risk	As above
Blinding (performance bias and detection bias)	Low risk	Blinding of data collection and management
Incomplete outcome data (attrition bias)	Low risk	ITT and LOCF
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	No

Gayner 2011

Methods	RCT
Participants	117 gay men living with HIV. Inclusion criteria: being mal, age 18-70, living within 1 hour of the hospital and having a diagnosis of HIV. Exclusion criteria: active current major depression, substance abuse or significant cognitive deficit. Current treatment (psychotropic pharmacological or psychosocial interventions) for a period of at least 2 months was acceptable, however subjects were asked not to initiate new treatment following recruitment into the study.
Interventions	MBSR vs treatment as usual MBSR: 8 x 3 hours per week, a daylong retreat, an hour or more of homework per day, 6 days per week.

Outcomes	HIV-specific distress, anxiety and depressive symptoms. Secondary outcomes: positive/ negative affect, mindfulness.
Key conclusions	Increase in mindfulness was significantly correlated with reduction in avoidance, higher positive affect and improvement in depression at 6 months. MBSR has specific and clinically meaningful effects in this population.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	computer program
Allocation concealment (selection bias)	Low risk	study staff not aware of group allocation until assignment was completed
Blinding (performance bias and detection bias)	Unclear risk	not described
Incomplete outcome data (attrition bias)	Low risk	ITT
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Goldin 2012

Methods	RCT
Participants	56 adult patients with generalized social anxiety disorder (SAD), mean age 32,88, 52 % women. Inclusion criteria: unmedicated patients (for the last six months) seeking treatment for SAD who met DMS-IV criteria for generalized SAD. Exclusion criteria: psychotherapy last six months, current psychological treatment, history of mental disorder or head trauma, thought disorders, bipolar disorder, alcohol/ drug dependency, a completed MBSR course or regular meditation practice/ AE regime.
Interventions	MBSR vs AE (Aerobic exercise: a minimum of two individual and one group AE session weekly, for two months.) MBSR: 8 x 2, 5 hours per week, 1-day retreat and daily home practice.
Outcomes	Social anxiety, social anxiety related disability, mindfulness and positive/ negative self-endorsement.

Key conclusions	The results suggest that MBSR attenuates maladaptive habitual self-views. Furthermore, MBSR may enhance more adaptive social self-referential processes in patients with SAD.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Coin randomization procedure
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Unclear risk	Not specified
Incomplete outcome data (attrition bias)	Unclear risk	Only analysed complete data
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	

Gross 2010

Methods	RCT
Participants	138 recipients of kidney, kidney/pancreas, liver, heart or lung transplants. (55% men). Inclusion criteria: a functioning solid-organ transplant (kidney, kidney/pancreas, pancreas, lung, liver, heart or heart-lung), 18 years or older, being able to read/ write English, willingness to attend classes and at least 6 months since transplant. Exclusion criteria: being medically unstable, on dialysis, having serious pre-existing mental health issues, or having previously taken MBSR.
Interventions	137/138 recipients of kidney, kidney/pancreas, liver, heart or lung transplants. (55% men). Inclusion criteria: a functioning solid-organ transplant (kidney, kidney/pancreas, pancreas, lung, liver, heart or heart-lung), 18 years or older, being able to read/ write English, willingness to attend classes and at least 6 months since transplant. Exclusion criteria: being medically unstable, on dialysis, having serious pre-existing mental health issues, or having previously taken MBSR.
Outcomes	Primary: anxiety, depression, sleep quality. Secondary: quality of life, perceived health, Key conclusions: MBSR reduced distressing symptoms of anxiety, depression and poor sleep and improved quality of life. Benefits

	were sustained over 1 year. A health education program provided fewer benefits, and effects were not as durable. Increased mindfulness, measured by the MAAS, was strongly correlated with improvements in sleep, anxiety, depression, mental health, vitality and quality of life (correlation coefficients = .4 to .7, Ps<0.01, all) among those who completed MBSR.
Key conclusions	
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer generated
Allocation concealment (selection bias)	Low risk	kept by study statistician
Blinding (performance bias and detection bias)	High risk	unblinded
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Gross 2011

Methods	RCT
Participants	30 adults with primary chronic insomnia based on DSM-IV-TR criteria. 22 women.
Interventions	MBSR vs pharmacotherapy (PCT: 3 mg of eszopiclone (LUNESTA™) nightly for 8 weeks followed by 3 months of use as needed.) Both interventions: a 10-minute sleep hygiene presentation. MBSR: 8 x 2,5 hours per week, one day-long retreat. Home practice expectations were 45 minutes of meditation per day at least 6 days a week for 8 weeks, followed by 20 minutes per day for 3 months.
Outcomes	Insomnia severity, sleep quality and quantity (total sleep time (TST), sleep onset latency (SOL), wake after sleep onset (WASO), and sleep efficiency (SE, time asleep divided by time in bed)). Secondary: anxiety, depression, health-related quality of life, and activity limitation.
Key conclusions	This study provides initial evidence for the efficacy of MBSR as a viable treatment for chronic insomnia as measured by: sleep diary,

	actigraphy, well-validated sleep scales and measures of remission and clinical recovery.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	computer generated
Allocation concealment (selection bias)	Low risk	study coordinator notified by email and notified the participants when starting the intervention
Blinding (performance bias and detection bias)	Unclear risk	not described
Incomplete outcome data (attrition bias)	Low risk	low attrition
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Grossman 2010

Methods	RCT, randomised in blocks of 4-6
Participants	150 patients with mild to moderate MS (multiple sclerosis)
Interventions	MBSR vs usual care MBSR: 8 weeks x 2,5 hours per week, seven hour all day session
Outcomes	Quality of life, depression, fatigue and anxiety
Key conclusions	Significant decrease on all effect parameters, but not on disease specific function of limbs noted at post-intervention and 6 months later. A lessening of effect at 6 months follow-up but still significant, When groups with depression, fatigue and anxiety at pre-intervention (using clinical cut-off points) were analysed separately, considerably higher effect sizes were found, indication a floor effect. Improvements in quality of life, depression and anxiety correlated with practice
Notes	High compliance and attendance, and low attrition in MBSR group. ITT (intention to treat) analysis

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Block randomisation using random event generator
Allocation concealment (selection bias)	Low risk	done by principal investigator blinded to all patient information
Blinding (performance bias and detection bias)	Low risk	outcome measures entered database by personnel blinded to group assignment
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Hartmann 2012

Methods	RCT
Participants	110 patients with type 2 diabetes and microalbuminuria. 86 males.
	Inclusion criteria: Albuminuria (>20mg/l in two separated spot urines), Age 30 - 70 Exclusion criteria: Diabetes duration < 3 years, pre-existing non-diabetic kidney disease, psychiatric disorders, alcohol or drug abuse, malignant tumors or hematologic disorders, heart failure NYHA III-IV, acute coronary syndrome.
Interventions	MBSR vs treatment as usual control. MBSR: 8 week program, booster session after 6 months.
Outcomes	Psychosocial distress (i. e. depression, psychosocial stress), progression of nephropathy (i.e., albuminuria) and subjective health status.
Key conclusions	MBSR group showed lower depression and improved health. No difference in albuminuria
Notes	separate results in the article by Kopf

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	method not mentioned
Allocation concealment (selection bias)	Unclear risk	not described

Blinding (performance bias and detection bias)	Unclear risk	not described
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Henderson 2012

Methods	RCT
Participants	172 women, aged 20-65, with stage 1 or 2 breast cancer
Interventions	MBSR vs. Nutrition education program (NEP) and usual supportive care (UC). MBSR: 7 weeks x 2.5-3.5 hrs-sessions + one 7.5 hr intensive silent retreat in the 6th week
Outcomes	Cancer-specific QOL; coping mechanisms; emotional distress as well as personality and coping dimensions (including depressive symptoms, anxiety symptoms, general distress, self-esteem, subjective social support, etc.)
Key conclusions	Those who were enrolled in MBSR experienced a significant improvement in the primary measures of QOL and coping outcomes compared to the NEP, UC or both. The MBSR group showed greater improvements for meaningfulness, depression, paranoid ideation, hostility, anxiety, unhappiness, and emotional control after 4 months. The MBSR intervention appears to benefit psychosocial adjustment in cancer patients, over and above the effects of usual care or a credible control condition.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Block randomization
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Unclear risk	Not specified
Incomplete outcome data (attrition bias)	Low risk	Addressed
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	

Hoffman 2012

Methods	RCT
Participants	229 BC 0-III stage, 49 ys. Inclusion: 18-80 ys, completed treatment (2-24ms). Exclusion criteria: BC stage IV, men, not English speaking, psychosis, intellectual impairment, substance abuse, suicidal thoughts.
Interventions	MBSR vs WL MBSR: 8 x 2 (2,25 1st session)+ 6h day. Weekly logs 21 min formal practice/day at T2 (not measured at T3). Attendance 6,26 sessions on average (78%).
Outcomes	Primary: POMS, Secondary: Disease specific QOL and endocrine symptoms (FACT-B and FACT-ES). WHO-5 QOL, all measured at pre-intervention (-2-0ws - T1), post-intervention (8-12ws - T2) and follow-up (12-14ws – T3).
Key conclusions	MBSR improved mood and QOL and results persisted at one month follow-up. Increased formal exercise assoc with increased response at T2 and T3.
Notes	Unclear whether T1 protocols were filled out before allocation to group was known to the participants

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Balanced block (4) computer based randomisation
Allocation concealment (selection bias)	Low risk	Se above
Blinding (performance bias and detection bias)	Low risk	Blinding of those who collected data
Incomplete outcome data (attrition bias)	Low risk	Low attrition, but not all those randomized were analysed, thus not strictly a ITT analyses
Selective reporting (reporting bias)	Low risk	All outcome data reported
Other bias	Low risk	Different N in tables 2 and 3, but small differences

Hoge 2013

Methods	RCT

Participants	89 individuals with DSM-IV-diagnosed general anxiety disorder, mean age 39, 51 % women. Inclusion criteria: Adults who met DSM-IV criteria for current primary GAD and designated GAD as the primary problem, and scored 20 or above on the Hamilton Anxiety scale (HAM-A). Exclusion criteria: (1) a lifetime history of schizophrenia or any other psychosis, mental retardation, organic medical disorders, bipolar disorder, post-traumatic stress disorder or obsessive compulsive disorder, (2) alcohol or substance abuse or dependence within the past 6 months, (3) significant suicidal ideation or behaviors within past 6 months, (4) if on medication, on a stable dose for less than 4 weeks, or unwilling to remain on that dose throughout the study, (5) serious medical illness or instability, (6) concurrent psychotherapy directed toward GAD, (7) more than 4 classes of meditation training and practice (including yoga and tai-chi) in the past 2 years; (8) pregnancy or lactation, and (9) significant personality disorder likely to interfere with study participation.
Interventions	MBSR vs SME (Stress management education consisting of 8 x two hours per week, 20 minutes of homework, (frequency not specified) and a four-hour retreat.) MBSR: 8 x two hours per week, 20 minutes of homework, (frequency not specified) and a four-hour retreat.)
Outcomes	Anxiety and stress.
Key conclusions	MBSR may have a beneficial effect on anxiety symptoms and stress reactivity/ coping as measured in a laboratory stress challenge. Both interventions led to significant reduction on the Hamilton anxiety scale.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Low risk	Blinding performed
Incomplete outcome data (attrition bias)	Low risk	Last observation carried forward
Selective reporting (reporting bias)	Low risk	All data reported

Other bias	Low risk	

Hou 2014

Methods	RCT
Participants	141 adult (>18y) caregivers of persons with chronic conditions
Interventions	MBSR or self-help control group MBSR: 8 week x 2hr. Sessions + home practice Control: self-help booklet with 8 chapters on health education
Outcomes	Clinically relevant depressive symptoms were measured by the Chinese Center for Epidemiologic Studies Depression Scale. Well established questionnaires (translated to Chinese) such as the State-Trait Anxiety Inventory, the Perceived Stress Scale, the short form of the Health Survey and the Five Facets Mindfulness Questionnaire - used to measure anxiety, perceived stress, quality of life, and levels of mindfulness.
Key conclusions	Participants in the MBSR group had a greater decrease in depressive symptoms at post intervention and at 3 months post-intervention. The improvement in state anxiety symptoms was greater within the MBSR-group at post-intervention, whilst not statistically significant at the 3 month follow up. Also the MBSR-group showed greater increase in self-efficacy and mindfulness at the 3 month intervention. No statistically significant group effects (MBSR vs. control) were found in perceived stress, quality of life or self-compassion.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random number generator (excel)
Allocation concealment (selection bias)	Low risk	Yes
Blinding (performance bias and detection bias)	Low risk	Yes
Incomplete outcome data (attrition bias)	Unclear risk	Insufficient information; Lower attrition in control group
Selective reporting (reporting bias)	Low risk	All data reported

Other bias	Low risk	

Huang 2015

Methods	RCT
Participants	144 manufacturing workers. Incl. Poor mental health (psychological distress and job strain): in the top tertile for psychological distress and job demands, and bottom tertile for job control.
Interventions	MBSR (8 x 2hs) vs WL
Outcomes	Measurements at five time points. Chinese Health Questionnaire (CHQ-12), Checklist Individual Strength questionnaire (CIS) for fatigue, PSS, Job Content Questionnaire (JCQ),
Key conclusions	The intervention group were significantly lower on psychological distress, prolonged fatigue, and perceived stress. No effect on job strain or job demand.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Block randomization with a block size of four (ICIC design)
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias)	Unclear risk	Data kept from leader of intervention; otherwise no blinding
Incomplete outcome data (attrition bias)	Low risk	ITT
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	

Hughes 2013

Methods	RCT
Participants	56 adults with unmedicated blood pressure (BP) in the prehypertensive range, mean age 50,3, 57% women. Inclusion criteria: Healthy individuals, 30-60 years, unmedicated BP in the prehypertensive range. Exclusion criteria: Antihypertensive medication, experience with meditation practises, current smoking, diseases + medication that could affect BP.

Interventions	MBSR vs PMR (Progressive muscle relaxation, consisting of 8 x 2,5 hours per week, instructions to practice at home 45 minutes a day/ six days per week.) MBSR: 8 x 2, 5 hours per week, instructions to practice at home 45 minutes a day/ six days per week.
Outcomes	Clinic systolic/ diastolic BP and ambulatory systolic/ diastolic BP.
Key conclusions	MBSR reduced systolic BP and diastolic BP compared with PMR.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random number generator
Allocation concealment (selection bias)	Low risk	Yes
Blinding (performance bias and detection bias)	Low risk	Yes
Incomplete outcome data (attrition bias)	Low risk	Addressed
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	

Jain 2007

Methods	RCT
Participants	104 health care/medical students
Interventions	MBSR vs waiting list control vs relaxation training MBSR: 4 x 1,5 hours per week, six hour all day session
Outcomes	Mental distress, positive mood, distraction, rumination and spiritual experiences
Key conclusions	Both MBSR and relaxation training reduced psychological distress and increased positive mood, but MBSR reduced distractive and ruminative thoughts and behaviours and effect on distress was mediated through this. No effect on spiritual experiences. Effect of amount of hours of practice on outcome for distress and positive mood
Notes	ITT performed

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer program stratifying participants for sex and student status
Allocation concealment (selection bias)	Low risk	Computerized generation
Blinding (performance bias and detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Low risk	All outcomes addressed
Selective reporting (reporting bias)	Low risk	Intention to treat analysis performed
Other bias	Low risk	No other bias detected

Jazaieri 2012

Methods	RCT
Participants	56 generalized Social Anxiety Disorder (SAD) patients diagnosed by trained clinical psychologist, mean age 32.8, 52% female. Exclusion criteria: Current pharmaco- or psychotherapy, medical disorders or head trauma, current other psychiatric disorder, previous MBSR course, or regular meditation practice or exercise practice
Interventions	MBSR vs Aerobic exercise
	MBSR: 8 x 2 ½ + 7 hour session in addition to weekly phone calls to monitor practice and address obstacles to med. practice. 212 minutes/wk practice. AE: 8 weeks in gym, 2 indiv AE and 1 group per week in addition to weekly phone calls to monitor practice and address obstacles to med. practice. 196 minutes/wk. Attendance unknown for both groups.
Outcomes	Self-report at baseline, post-intervention and 3 ms follow-up. Clinical: Liebowitz Social Anxiety Scale-Self Report (LSAS-SR), Social Interaction Anxiety Scale Straightforward Scale (SIAS-S), Beck Depression Inventory-II (BDI-II), Perceived Stress Scale (PSS-4)*.
	Well-being: Rosenberg Self-Esteem Scale (RSES), Satisfaction with Life Scale (SWLS), Self-Compassion Scale (SCS), UCLA-8 Loneliness scale (ULS-8)*
	Kentucky Inventory of Mindfulness Skills (KIMS)*
	*not adm at 3 ms follow-up

Key conclusions	No difference between the interventions. Both showed reductions in social anxiety, depression and increased well-being after the intervention and at follow-up when compared to a non-randomized untreated group and by pre-post within-group analyses. One quarter demonstrated clinically significant changes on social anxiety symptoms after the interventions. Both groups improved equally on KIMS mindfulness scale
Notes	Amount of group experience and exposure may be a key factor. Possibly different mechanisms of effect and both interventions could be tried out combined.

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Efron's biased coin randomization
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Unclear risk	Those delivering MBSR courses were blinded to the diagnoses of those participating. Blinding otherwise not described
Incomplete outcome data (attrition bias)	Low risk	ITT used with LOCF to impute missing data, but data presented are completer analyses data and no sign difference between ITT and completer analyses. The difference between groups in drop out was not significant. The difference between groups in completion of post-treatment assessment was not significant. The difference between groups in completion of 3-month follow-up assessments was not significant.
Selective reporting (reporting bias)	Low risk	All data reported, except pre-post means and SD of KIMS
Other bias	Low risk	More woman (61% MBSR) vs 40% in AE, but diff. not sign.

Jedel 2015

Methods	RCT

Participants	55 patients with severe ulcerative colitis in remission
Interventions	MBSR (8x2,5h) vs Educational support group (8 x slightly shorter than 2,5h)
Outcomes	Primary outcome: disease status (UCDAI), Secondary: Calprotectin in stools, Cytokins, IBDQ, time to flare-up and severity of flare-up, ACTH, CRP, Cortisol, PSQ, BDI, STAI MAAS, PHCS
Key conclusions	MBSR did not affect the rate or severity of flare-ups in UC patients in remission. However, MBSR might be effective for those with high stress reactivity (high perceived stress and urinary cortisol) during remission. MBSR appears to improve QOL in UC patients by minimizing the negative impact of flare-ups on QOL.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer
Allocation concealment (selection bias)	Low risk	sealed envelopes
Blinding (performance bias and detection bias)	Low risk	patients blinded to study hypothesis, clinical outcome assessors blinded to group allocation
Incomplete outcome data (attrition bias)	Low risk	ITT
Selective reporting (reporting bias)	Low risk	all reported
Other bias	Low risk	

Jensen 2012

Methods	RCT
Participants	48, (94%) were healthy psychology students. 66% females. 20-36 ys. All meditation and yoga novices.
Interventions	MBSR vs NMSR vs Inactive controls MBSR: 8 x 2 ½ + 7 hour session. 45 min assigned homework. NMSR: yoga, relaxation and training without meditation and training in non-judgemental attitude, aimed at increasing body-consciousness and relaxation.

	Compliance measured with practice diaries and course attendance. Attendance 7.6 of 9 in MBSR and 7.0 in NMSR. Fidelity not measured. Experienced instructor and psychologist gave MBSR and psychomotrician gave NMSR
Outcomes	Self-report (MAAS and PSS) and morning cortisol at baseline and post-intervention, and attentional tasks (excluded from meta-analyses, but reported in review).
Key conclusions	MBSR reduced cortisol secretion and perceived stress as compared to inactive control groups, but not compared to active stress-reduction intervention. MBSR improved mindfulness as compared to the inactive control group.
	Attentional tasks susceptible to test effort, but selective attention and visual working memory capacity increased in MBSR group. Effects unrelated to compliance.
Notes	There seem to be an overlap in the active change mechanisms in the MBSR and the active control group. Active control group included yoga, grounding exercises and circulatory training to increase body consciousness. Both yoga (in the non-mindfulness stress reduction) and MBSR can be considered forms of attentional training. Low sample size and high number of attentional measures and statistical tests, introduce risk.

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Method of randomization not described
Allocation concealment (selection bias)	Unclear risk	not described
Blinding (performance bias and detection bias)	Low risk	Blinding of outcome assessor described
Incomplete outcome data (attrition bias)	Low risk	96% complete data
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Unclear risk	Creation of 3 balanced groups prior to randomisation, method not described

Johansson 2012

Methods	RCT

Participants	26 stroke or traumatic brain injury (TBI) victims, mean age 55, 58% women. Inclusion criteria: subjects who, >12 months earlier, suffered a stroke/ TBI, age 30-65, moderate disability (Glasgow outcome scale) or a score indicating a higher level of recovery, a score of 10 or higher on self-assessment questionnaire for mental fatigue. Exclusion criteria: significant co-morbidity (including psychiatric/ neurological disorder), history of alcohol or drug abuse, significant cognitive impairment.
Interventions	MBSR vs wait-list control. MBSR: 8 x 2, 5 hours per week + one day-long silent retreat. 45 minutes home practice, six days a week.
Outcomes	Mental fatigue, depression and anxiety. Neuropsychological tests.
Key conclusions	MBSR may be a promising non-pharmacological treatment for mental fatigue after a stroke or TBI.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Unclear risk	Not specified
Incomplete outcome data (attrition bias)	Unclear risk	Not specified
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	

Johns 2015

Methods	RCT
Participants	35 cancer survivors with clinically significant cancer-related fatigue (CRF), Inclusion criteria: 18 years or older, earlier cancer diagnosis, report of experiencing persistent CRF for minimum the last 8 weeks and clinically significant CRF at the time of eligibility screening. Exclusion criteria: cancer treatment in the prior three months, enrolment in hospice care, severe hearing impairment, severe depression, previously participation in mindfulness meditation class or not understanding English.

Interventions	MBSR vs wait-list control MBSR: 7 x 2 hours per week. No retreat. 20 minutes home practice.
Outcomes	Fatigue interference/ measures, vitality, disability, depression, anxiety, insomnia/ sleep disturbance,
Key conclusions	MBSR is a promising treatment for CRF and associated symptoms.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Coin toss, blocks of 4
Allocation concealment (selection bias)	Low risk	Sealed envelopes
Blinding (performance bias and detection bias)	Low risk	Yes
Incomplete outcome data (attrition bias)	Unclear risk	Insufficient information
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	

Kang 2009

Methods	RCT
Participants	41 nursing students
Interventions	8 x 1,5-2h MBSR vs study as usual
Outcomes	Stress (Psychosocial wellbeing index-short form PWI-SF), anxiety (STAI) and depression (BDI)
Key conclusions	Significant post-intervention effect for MBSR on stress and anxiety, but not on depression
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Drawing even or uneven numbers
Allocation concealment (selection bias)	Unclear risk	not described

Blinding (performance bias and detection bias)	Low risk	Blinding of assessors
Incomplete outcome data (attrition bias)	High risk	high attrition
Selective reporting (reporting bias)	Low risk	
Other bias	Unclear risk	Inequality in MBSR and control group

Kearney 2013

Methods	RCT
Participants	47 veterans with PTSD diagnosed from medical records, mean age 52, 81% male. Exclusion criteria: Current or past psychosis, mania or poorly controlled bipolar disorder, borderline or schizoaffective personality disorder, current suicidal or homicidal ideation, active substance abuse or dependence disorder.
Interventions	MBSR + TAU vs TAU MBSR: 8 x 2 ½ + 7 hour session. 45 min assigned homework. No compliance or fidelity measures. Experienced instructors
Outcomes	Self-report at baseline, post-intervention and 4 ms follow-up. PTSD symptoms: PTSD Checklist-Civilian version (PCL), traumatic life events checklist (LEC), Patient health Questionnaire-9 (PHQ-9), The Short Form-8 (HRQOL). FFMQ. Behavioral Activation for Depression Scale (BADS)
Key conclusions	ITT analyses found no effect on PTSD or depression. Mental HRQOL improved posttreatment but no effect at 4 ms. At 4 ms more veterans in MBSR had clinically meaningful change in mental HRQOL, and in both mental HRQOL and PSTD symptoms. Completer analyses (> 4 classes attended) showed median to large between group effect sizes for depression, HRQOL and mindfulness.
Notes	Amount of group experience may be a key factor. Possibly different mechanisms of effect and could be tried combined.

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Method of randomization not described
Allocation concealment (selection bias)	Low risk	“using concealed allocation” but method not described

Blinding (performance bias and detection bias)	Unclear risk	Blinding not described
Incomplete outcome data (attrition bias)	Low risk	ITT, but imputation method data not described
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	Benzodiazepin use differed at baseline

Kilpatrick 2011

Methods	RCT
Participants	32 healthy meditation naïve women, age 34. Exclusion criteria: medical or psychiatric disorders.
Interventions	MBSR vs WL MBSR: 8 x 2 ½ + 7 hour session. 30 min assigned, 2716 minutes/8 wk practice. 10x9 times, 3x7, 2x6.
Outcomes	Self-report at baseline, post-intervention MAAS and STAI pre-intervention. Functional connectivity on fMRI in 5 areas pre- and post-intervention
Key conclusions	Sign difference in MAAS post-intervention, and functional connectivity on fMRI in 5 areas.
Notes	STAI post-intervention not given

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Method not described
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Unclear risk	Blinding not described
Incomplete outcome data (attrition bias)	Low risk	3 missing MAAS data in control group?? May be not of importance as mixed model analyses used
Selective reporting (reporting bias)	Low risk	All data not reported fully

Other bias	Low risk	

Klatt 2008

Methods	RCT
Participants	48 university faculty & staff
Interventions	MBSR vs wait-list control MBSR: 6 x 1 hour per week, 20" home practice
Outcomes	Stress, sleep, mindfulness, salivary cortisol
Key conclusions	The MBSR group experienced a significant reduction of stress, and an increase in mindfulness, in spite of low dose MBSR. No effect on salivary cortisol
Notes	ITT (intention to treat analysis) not reported

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Not specified
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	High risk	MBSR group data was collected at MBSR meetings
Incomplete outcome data (attrition bias)	Low risk	Small number of missing data
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Koszycki 2007

Methods	RCT
Participants	58 patients with generalized social anxiety
Interventions	MBSR vs GBCT (12 weeks group based cognitive therapy) vs control MBSR: 8 x 2,5 hours per week, seven and a half hour all day session
Outcomes	Anxiety, illness severity, social interaction and interpersonal sensitivity, self-rated disability, depression, quality of life

Key conclusions	Patients in both MBSR and GBCT improved, but GBCT had better effect on social anxiety, while equal effect on improving mood, functionality and quality of life
Notes	For those with serious problems 12 week intervention was too short

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomisation procedure not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias)	Low risk	Assessors on clinician-rated instruments blinded
Incomplete outcome data (attrition bias)	Low risk	Two analyses performed. ITT - intention to treat and analysis of completer sample (including patients who completed and attended at least 80% of sessions). Expectation maximation method used to impute missing values
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

la Cour 2015

Methods	RCT
Participants	109 patients with chronic pain treated in a pain clinic. Excl was unstable clinical situation, mental disabilities and poor Danish
Interventions	MBSR (8 x 3hours + 4,5 day and a follow-up session after 2 ms) vs WL
Outcomes	Primary SF36 Vitality, Secondary: Pain measures. Catastrophic thinking, control over pain and pain acceptance, HADS. SF physical and mental function. All taken at post-intervention and at 6ms follow-up
Key conclusions	Significant effect on all measures except pain measures which were maintained at follow-up.

Notes	WL received MBSR after 8 ws and follow-up data cannot be used in MA.

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Drawing sealed envelopes with group assignment
Allocation concealment (selection bias)	Low risk	as above
Blinding (performance bias and detection bias)	High risk	No blinding
Incomplete outcome data (attrition bias)	Low risk	ITT analyses and completer analyses
Selective reporting (reporting bias)	Low risk	
Other bias	Unclear risk	Differences between groups at baseline

Lengacher 2009

Methods	RCT
Participants	84 women over 21 ys diagnosed with breast cancer stage 0-III who had undergone surgery and received adjuvant radiation and/or chemotherapy and who had completed treatment within prior 10 months
Interventions	MBSR vs wait-list control MBSR: 6 x 2hours per week, adapted for breast cancer survivors. Attendance and home practice measured. 70% considered compliant, 1 of 7 groups had 5 sessions due to tropical storm.
Outcomes	Concerns about recurrence, anxiety, depression, life orientation, stress, spirituality, symptoms
Key conclusions	MBSR sign improved psych distress, fear of recurrence and QOL. Extent of practice influences overall benefit, Attendance alone favourable effect on psych status
Notes	Adjusted means given, written to author to get unadjusted means and SD, Symptoms measured by MDASI - not reported in study

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	1:1 ratio stratified for cancer stage
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias)	High risk	Outcome assessors not blinded to follow-up from baseline
Incomplete outcome data (attrition bias)	Low risk	One drop out from each group not likely to introduce bias
Selective reporting (reporting bias)	Unclear risk	They mention that they did not report symptoms from MSASI, but not why
Other bias	High risk	Did not use correction for use of large number of outcomes published in several different articles

Lengacher 2014

Methods	RCT
Participants	142 breast cancer survivors, stages 0-3 who had completed adjuvant treatment
Interventions	MBSR vs. WL MBSR: 6 weeks x 2-h weekly sessions + daily practice of meditation as well as recording the progress in a diary
Outcomes	Telomere length (TL) and Telomere Activity (TA). Concerns about Recurrence Scale. CED-S for depression. STAI for anxiety. PSS for stress. Cognitive and Affective Mindfulness Scale.
Key conclusions	Adjusted for baseline TA and psychological status, TA in peripheral blood mononuclear cells increased steadily in MBSR group (17%) compared to no increase in the WL group. No between group difference in TL.
Notes	Results given as median values and study not included in meta-analyses.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	not described

Allocation concealment (selection bias)	Unclear risk	not described
Blinding (performance bias and detection bias)	Unclear risk	not described
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Lengacher 2014a

Methods	RCT
Participants	79 Breast cancer patients stage 0-III
Interventions	MBSR (6
Outcomes	
Key conclusions	
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	random number generator
Allocation concealment (selection bias)	Low risk	opaque sealed envelopes
Blinding (performance bias and detection bias)	Unclear risk	blinding of study assignment until after baseline assessment, otherwise not mentioned
Incomplete outcome data (attrition bias)	Low risk	ITT
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

MacCoon 2012

Methods	63 participants, healthy adults, mean age 46, 82 % women.
	Inclusion criteria: Able to lie still for 90 minutes, meets MRI safety standards, weight < 300 pounds, 18–65 years old, right-handed, no previous experience with meditation, no daily practice, speak English, and see without glasses.

	Exclusion criteria: Diabetes, peripheral vascular/ arterial disease, diagnosed circulatory disorders. BMI below 18.5, involuntary motor disorders, allergic to adhesive tape, a history of problems of any kind during blood draws or needle phobia.
	2 or more of the following: Diagnosed hypertension, hyperlipidemia, high cholesterol, obesity, smoke cigarettes, family history of coronary or atherosclerotic disease. Medical disorders that might make interpretation of scan data difficult, problem with alcohol or non-prescription drugs, currently uses/ plans to start medications that affect CNS function, including psychotropics, opiate medication or corticosteroids, during the last 3 months. Takes inhaled steroids for asthma or any corticosteroids. Night shift workers, Temporal Mandibular Joint disorder or other problems with biting/chewing, previous training in meditation, currently meditates on a regular basis, daily yoga/ tai-chi/ Qigong practice. Engagement in moderate sport and recreational activities more than 5 times a week, engagement in vigorous sport and recreational activities more than 4 times a week. Not able to attend an informational session, all class meetings, and all clinic visits.
Participants	MBSR vs HEP (Health enhancement program consisting of 8 x 2, 5 hours per week + one all-day session. Home-practice: 45 minutes, 6 of 7 days each week.)
	MBSR: 8 x 2,5 hours per week + one all-day session. Home-practice: 45 minutes, 6 of 7 days each week.
Interventions	Terminal pain, psychological distress, depression, anxiety, hostility and medical symptoms.
Outcomes	MBSR is as efficacious – but not more efficacious – than another active intervention (HEP) when applied to a typical MBSR population when our participant-reported outcomes are used.
Key conclusions	
Notes	The article from 2014 from the same study cannot be included in MA due to the way the data are presented

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random number generator
Allocation concealment (selection bias)	Low risk	Performed by logistical staff member

Blinding (performance bias and detection bias)	Low risk	Yes
Incomplete outcome data (attrition bias)	Unclear risk	Analysed only complete data
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Unclear risk	Intervention group had stronger preference for MBSR.

Majid 2012

Methods	RCT
Participants	33 (in abstract 31) male Generalized anxiety disorder (GAD) patients diagnosed by structured interview, mean age 32. Exclusion criteria: Substance abuse and/or dependence, suicidal/homicidal ideation and past participation in MBSR group
Interventions	MBSR vs control (not specified) MBSR: 8 x 2 hs. 30 min assigned daily practice, daily logs, but not published. Attendance not given
Outcomes	Self-report at baseline, post-intervention. Beck Depression Inventory-II (BDI-II), Beck Anxiety Inventory (BAI), Penn State Worry Questionnaire (PSWQ).
Key conclusions	Significant between group difference on all 3 measures.
Notes	Small sample, in abstract N given as 31 (16 + 15) but in article N = 33

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Unclear risk	not described

Incomplete outcome data (attrition bias)	Unclear risk	Not specified regarding missing data
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Unclear risk	Compliance not reported, and little detailed info on how study was run. Group difference in baseline outcome values and demographics not analysed

Malarkey 2013

Methods	RCT
Participants	186 Faculty and staff at Ohio State University, 88% female, mean age 50, with CRP> 3mg/ml. Exclusion criteria: CRP >10, Current psychiatric disorder other than depression, major life stress in last 2 months, pregnancy, > 2 drinks daily. > ½ packet of tobacco daily, drug use, vaccination last 2 ms, illness last mth, BMI > 40, previous mind-body relaxation practice, exercise>1/2 h/day
Interventions	MBI-id vs Lifestyle education group
	MBSR: 7 x 1h + 1 x 2h, 20 min daily exercise. Music used in background. Teleform diaries filled in every day to track informal and formal home practice. Actual practice 15 min/day. Leg: 7 x 1h + 1 x 2 h, 30 min home readings. Attendance recorded but not reported.
Outcomes	CRP, IL-6 and salivary corticol. Secondary self-report at baseline, post-intervention and 4 ms and 10 ms follow-up. PSS, CES-D, PSQI, TMS
	Others: BP, pulse rate, BMI and leptin collected but not referred to as primary or secondary outcomes
Key conclusions	No difference between the interventions on primary outcomes, trend towards higher CRP drop I MBI at 2 ms. Sign. difference in TMS at post, 4 and 12 ms f-up. No sign change in PSS, PSQI and CES-D. No association between practice and outcome CRP level.
Notes	For those with BMI<30 much bigger CRP effect than in those > 30

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Blocks of 6, stratified for BMI group

Allocation concealment (selection bias)	Low risk	Research team blinded to group allocation
Blinding (performance bias and detection bias)	Low risk	Group concealed to all but instructors And concealed to participants until the day of the intervention Assessors and those analysing were blinded
Incomplete outcome data (attrition bias)	Low risk	Baseline values used as dependent to reduce missing data bias, LOCF used to impute missing data, Non-ITT
Selective reporting (reporting bias)	High risk	Subj measures not given, but results mentioned, must write to authors
Other bias	Low risk	Low attrition and equal in groups

Manotas 2012

Methods	RCT
Participants	82 healthcare employees (74 women). Inclusion criteria: Healthcare professionals employed by La Fundacion Santa Fe de Bogota, and willingness to participate. Exclusion criteria: Administrative professionals.
Interventions	MBSR vs wait-list control MBSR: 4 x 2 hours per week. No retreat.
Outcomes	Psychological distress, emotional style, mindfulness, psychological flexibility and perceived stress.
Key conclusions	The 4-week version of MBSR may be an effective means of improving wellbeing among busy working professionals.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Unclear risk	Not specified
Incomplete outcome data (attrition bias)	Unclear risk	Not specified
Selective reporting (reporting bias)	Low risk	All data reported

Other bias	Low risk	

Moritz 2006

Methods	RCT
Participants	165 people with emotional distress measured on POMS
Interventions	MBSR vs home-based spirituality program (8 x 1,5 hours audiotape per week + 45" audiotape practice daily) vs wait-list control MBSR: 8 x 1,5 hours per week, 45" daily practice to audiotapes
Outcomes	Profile of mood state and health related quality of life
Key conclusions	At postintervention significant effect of both interventions and significantly more for spirituality group than MBSR. At 4 weeks postintervention effect of MBSR maintained, both interventions effects now equal but still significantly different from wait-list
Notes	Baseline differences (not significant) with more mental distress in spirituality group. Adherence and practice bigger in spiritual group

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer Program
Allocation concealment (selection bias)	Low risk	Done by biostatistician. The list of allocation only available to an administrator not involved in the study
Blinding (performance bias and detection bias)	Low risk	All data collection forms mailed out and returned by post
Incomplete outcome data (attrition bias)	Low risk	Intention to treat analysis performed
Selective reporting (reporting bias)	High risk	Subscale scores for SF36 at 4 weeks postintervention not reported
Other bias	Low risk	No other bias detected

Morone 2008

Methods	RCT
Participants	37 >65ys with chronic low back pain
Interventions	MBSR vs wait-list control MBSR: 8 x 1,5 hours per week

Outcomes	Pain and pain acceptance, physical function, physical health, global health and mental health
Key conclusions	Significant improvement in pain acceptance, and physical function
Notes	Follow-up after crossover of control group

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer software
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes
Blinding (performance bias and detection bias)	Low risk	Outcome assessor masked to group assignment
Incomplete outcome data (attrition bias)	Low risk	Intention to treat analysis with last value carried forward method
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Moss 2015

Methods	RCT
Participants	39 old people living in a continuing care community
Interventions	MBSR (8 x 2hs) vs WL
Outcomes	SF-36, Psych flexibility, SCS and FFMQ
Key conclusions	Increased acceptance, psych flexibility and less role limitation due to physical health.
Notes	Adapted with chair yoga and 30 min home practice, also qualitative interviews

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random selection from pool of 41 possible numbers
Allocation concealment (selection bias)	Low risk	Sealed envelopes

Blinding (performance bias and detection bias)	Low risk	Those performing the study and collecting the data blinded to group assignment
Incomplete outcome data (attrition bias)	Low risk	Mixed effects model consistent with ITT
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Unclear risk	50 participants recruited, but only 39 randomized

Moynihan 2013

Methods	RCT
Participants	201 older adults
Interventions	MBSR vs. Waiting list control MBSR: 8 week x 120 min. sessions + one all day intensive session.
Outcomes	The Trail Making Test part B/A ratio (a measure of executive function), changes in left frontal alpha asymmetry, positive emotions, depression, mindfulness, stress, immunoglobulin G response to a protein antigen, adaptive immunity.
Key conclusions	MBSR produced small but significant changes in executive function, mindfulness and sustained left frontal alpha asymmetry.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Excel function
Allocation concealment (selection bias)	Unclear risk	not described
Blinding (performance bias and detection bias)	Unclear risk	not described
Incomplete outcome data (attrition bias)	Unclear risk	not fully described
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Murphy 1994

Methods	RCT
Participants	31 male inmates with a history of alcohol abuse and aggression

Interventions	MBSR vs progressive relaxation training (PRT - 6 x 2 hours over 5 weeks) MBSR: 6 x 2 hours given over 5 weeks
Outcomes	Egocentrism, anger, impulsivity and stress reactivity by measuring saliva cortisol after stress test
Key conclusions	Small reductions in self-reported anger in both groups. No change in impulsivity. Significant within-group post-stressor reduction in cortisol in PRT group. A significant between group difference favouring MBSR on sub-measure of egocentrism called negative self-focused attention. At one month follow-up a slight decrease in aggressive responding in MBSR and a slight increase in PRT group
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias)	Unclear risk	Not described
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Murray 2004

Methods	RCT
Participants	27 male students using sex as a coping strategy
Interventions	MBSR vs wait list control MBSR: 8 x 1,5 hours per week
Outcomes	Coping using sex strategies, regulation of negative affect, general mood
Key conclusions	MBSR increased effectiveness of handling negative mood states, and decreased avoidant coping strategies, but did not alter approach coping strategies
Notes	Intention to treat analysis not conducted

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	High risk	Partly; research assistant collected most of the data, but PANAS was collected by co-therapist
Incomplete outcome data (attrition bias)	High risk	Equal drop-out from each group, reasons for drop-out addressed
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Neece 2014

Methods	RCT
Participants	46 parents, mean age 35, 78% female, with a child 2.5-5ys with developmental delay (DD) determined by a regional centre, parents reported > 10 child behaviour problems, parents not receiving psych treatment. Exclusion: having children with debilitating disability
Interventions	MBSR vs WL. MBSR: 8 x 2h + 6. Music used in background. Actual practice recorded weekly and used in growth model analysis. Attendance not reported.
Outcomes	PSI-SF (parental distress subscale used). FIQ (2 subscales used giving a negative impact score), CES-D, SWLS, CBCL, SUDS
Key conclusions	Significantly less parent stress and depression and higher QOL after intervention. Children had fewer behaviour problems in area of attention and ADHD symptomatology
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Parents drew a paper out of box showing group allocation
Allocation concealment (selection bias)	Unclear risk	Not reported

Blinding (performance bias and detection bias)	Unclear risk	Not described
Incomplete outcome data (attrition bias)	Low risk	Low attrition
Selective reporting (reporting bias)	Unclear risk	All reported, although information on mindfulness analysed post-hoc and referred to in discussion
Other bias	Low risk	Low attrition and equal in groups

Nyklicek 2008

Methods	RCT
Participants	60 people experiencing regular distress
Interventions	MBSR vs wait-list control MBSR: 8 x 2.5 hours per week, six hours all day session, 40" home practice
Outcomes	Perceived stress, exhaustion, positive and negative affect, quality of life, mindfulness
Key conclusions	MBSR decreased distress, exhaustion and negative affect and increased to a lesser degree QoL. Changes partially mediated by increase in measured mindfulness
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer software
Allocation concealment (selection bias)	Low risk	Allocators were blinded
Blinding (performance bias and detection bias)	Low risk	Questionnaires sent to participants
Incomplete outcome data (attrition bias)	Low risk	Last values carried forward
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Nyklicek 2013

Methods	RCT

Participants	88 adults reporting elevated stress levels
Interventions	MBSR vs. Waiting list control MBSR: 8 week x 120 min. sessions
Outcomes	Heart (period, rate and variability), Blood Pressure (Syst and Diast), salivary Cortisol
Key conclusions	MBSR group had larger decreases in BP post-intervention and exhibited smaller stress-related changes in BP. No other physiological effects were found
Notes	Separate part of the Nyklicek 2008 study

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer software
Allocation concealment (selection bias)	Low risk	Allocators were blinded
Blinding (performance bias and detection bias)	Low risk	Questionnaires sent to participants
Incomplete outcome data (attrition bias)	Low risk	Last values carried forward
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Oman 2008

Methods	RCT
Participants	54 Undergraduate college students
Interventions	MBSR vs EPP (Easwaran´s Eight-Point Program - 8 x 1,5 hours per week) vs wait-list control MBSR: 8 x 1,5 hours per week
Outcomes	Perceived stress, rumination, forgiveness of others, hope
Key conclusions	MBSR and EPP same significant effect on stress, forgiveness and trend on reducing rumination. No effect on hope
Notes	Authors state that they did intention to treat analysis, but all randomised participants not included (only 44)

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer software
Allocation concealment (selection bias)	Low risk	Computer Program used
Blinding (performance bias and detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Low risk	Reported that four drop-outs were not significantly associated with pre-test values or co-variates on any outcome
Selective reporting (reporting bias)	Low risk	No other bias detected
Other bias	High risk	EPP and MBSR groups analysed together. Five participants crossed over between intervention and control groups after randomisation.

Ong 2014

Methods	RCT
Participants	54 adults with chronic insomnia, mean age 43, 74 % women. Inclusion criteria: adults over 21 years, diagnosed with an insomnia disorder. Exclusion criteria: uncontrolled medical or psychiatric condition requiring treatment, comorbid sleep disorders, use of hypnotic/ sedating medication for the purpose of insomnia or inadequate proficiency in English.
Interventions	MBSR vs MBTI (eight-week mindfulness-based therapy for insomnia) vs SM (eight-week self-monitoring). Participants in both mindfulness groups were instructed to practice at home for 30-45 minutes six days a week. MBRS: 8 x 2,5 hours per week + one 6-hour meditation retreat.
Outcomes	Subjective and objective measures related to sleep.
Key conclusions	Mindfulness meditation appears to be a viable treatment option for adults with chronic insomnia, and could provide an alternative to traditional treatment for insomnia.
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomization in sequential cohorts; unclear sequence generation
Allocation concealment (selection bias)	Low risk	Allocation concealed
Blinding (performance bias and detection bias)	Low risk	Blinding performed
Incomplete outcome data (attrition bias)	Low risk	No imputation for missing data
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	

Pbert 2012

Methods	RCT
Participants	83 physician documented mild, moderate and severe asthma. 27 men 67.4% women, 53 ys Exclusion criteria: intermittent asthma, smoked in past year, other lung disease, CVS disease, post tb test, past MBSR course or reg med practice
Interventions	MBSR: 8 x 2 ½ h + 6h, 30 min designated practice, mean attendance 5.64, unknown compliance with home practice, quality of instructors and program fidelity, Each MBSR group consisted of 2 study participants and 28 non-study participants. Vs healthy living course 8x 2 ½ h 30 min homework
Outcomes	Primary: AQOL and lung function, Secondary: PSS, asthma control measures, days off work/school, rescue medication (short and long-term),
Key conclusions	Sign difference between the interventions on AQOL and PSS at 12 months follow-up but not for lung function, no diff in percentage of well controlled asthma, days off work/school and asthma exacerbations, but in use of short term rescue medication.
Notes	Attendance 5 of nine in MBSR, so shorter course could be sufficient

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Blocks of 4 and 6,

Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias)	Low risk	Blinding of outcome assessors
Incomplete outcome data (attrition bias)	Low risk	ITT? virtually, because of low attrition
Selective reporting (reporting bias)	Low risk	All reported, except full data on days off work/school
Other bias	Low risk	

Pickut 2013

Methods	RCT
Participants	30 Parkinson Disease (PD) patients, mean age 61.8, 48% female. Inclusion: Clinical diagnosis, stage I-III, optimally treated, stable drug regimen for 30 ds, commitment to attend, Exclusion :not atypical P features, no drugs causing parkinsonism, no cognitive dysfunction, no unstable og life threatening disease, no contradiction for MRI
Interventions	MBSR vs WL MBSR: 8 x 2 ½ h. 55 min daily practice recorded, Attendance 97 %
Outcomes	MRI assessments before and after intervention
Key conclusions	Sign increased grey matter density in MBI group in neural networks postulated to play an important part in PD (hippocampus and amygdala) and these areas have also been indicated in functional networks mediating the benefits of meditation
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomization by blinded investigator but method not specified
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Unclear risk	All patient-reported outcome measures entered database by personnel blinded to group assignment, but such outcomes not reported?

Incomplete outcome data (attrition bias)	Low risk	Very low attrition and nearly equal in both groups
Selective reporting (reporting bias)	Low risk	Subjective outcomes not reported, but not included in hypothesis
Other bias	Low risk	

Pipe 2009

Methods	RCT
Participants	33 nurse leaders
Interventions	MBSR 5x2 hs vs 5 x2 stress education program
Outcomes	SCL90 and coping pre-post
Key conclusions	Sign more improvement in MBSR group
Notes	Planned 12ms follow up stopped because of big difference in effect and intervention offered to control group

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	computer program
Allocation concealment (selection bias)	Unclear risk	not described
Blinding (performance bias and detection bias)	Unclear risk	not described
Incomplete outcome data (attrition bias)	Low risk	low attrition
Selective reporting (reporting bias)	Low risk	All reported
Other bias	High risk	stopping trial early and small sample

Plews-Ogan 2005

Methods	RCT
Participants	30 patients with chronic musculoskeletal pain
Interventions	MBSR vs massage (one hour weekly for 8 weeks) vs treatment as usual
	MBSR: 8 x 2,5 hours per week

Outcomes	Pain sensation, pain unpleasantness, global physical and mental health
Key conclusions	Massage group showed an effect on pain and mental health after intervention but not at follow-up, while MBSR had no effect on pain outcomes, but had significant effect on mental health at follow-up.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer generated random number sequence used
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias)	High risk	Not reported
Incomplete outcome data (attrition bias)	High risk	Incomplete data on drop-outs in MBSR group
Selective reporting (reporting bias)	High risk	Incomplete outcome data on physical health and pain sensation
Other bias	Low risk	No other bias detected

Polusny 2015

Methods	RCT
Participants	116 Veterans with PTSD
Interventions	MBSR (8x2,5 + 6,5 h) vs Patient centred group therapy (9x1,5h)
Outcomes	PTSD checklist (PCL), CAPS, PHQ9, WHOQOL-BREF, FFMQ, Credibility scale and rating tool for fidelity
Key conclusions	greater change in PCL in MBSR group. At two months f-up no diff in loss of diagnosis of PTSD
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	computer block randomization

Allocation concealment (selection bias)	Low risk	Randomization procedure performed by assistant
Blinding (performance bias and detection bias)	Low risk	Independent assessors
Incomplete outcome data (attrition bias)	Low risk	ITT
Selective reporting (reporting bias)	Low risk	all reported
Other bias	Low risk	

Pradhan 2007

Methods	RCT
Participants	63 Reumatoid Arthritis patients not in remission
Interventions	MBSR vs wait-list control MBSR: 8 x 2,5 hours per week, six hour all day session. Three refresher classes in the follow-up period
Outcomes	Psychological distress, depression, well-being, disease activity, mindfulness
Key conclusions	No significant results after intervention, but significant reduction in distress and increased well-being and mindfulness at four months follow-up
Notes	Post-intervention, frequency of practice (but not time spent) was related to outcome, but not at six months follow-up. Better results with one of three instructors (the most experienced)

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer generated randomisation
Allocation concealment (selection bias)	Low risk	Carried out by research director who had no direct patient contact (using Mienert clinical trials assignment procedure)
Blinding (performance bias and detection bias)	Low risk	Rheumatoid Arthritis disease activity assessors and lab personnel blinded

Incomplete outcome data (attrition bias)	Low risk	Intention to treat analysis using all available data. Last value carried forward to impute missing data. Results for imputed and non-imputed data were reported as similar, final analyses based on non-imputed data.
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Reich 2014

Methods	RCT
Participants	41 Breast Cancer survivors with Stage 0, I, II, or III breast cancer, who had undergone surgery (lumpectomy) and received adjuvant RT or RT and CT. Excl.(a) Stage IV breast cancer, (b) treated for a breast cancer recurrence, (c) undergone mastectomy, or (d) severe psychiatric problems
Interventions	MBSR (8 x 2hs) vs WL
Outcomes	M. D. Anderson Symptom Inventory, lymphocyte analyses
Key conclusions	Symptom cluster scores tended to go down across both UC and MBSR(BC) groups, but significant only in the MBSR(BC) group for the fatigue cluster (p = .003) and in the GI cluster (p = .035). Symptom improvement was associated with increased immune activity at baseline.
Notes	Adapted with 15–45 min daily practice recommendations

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Stratified by stage of cancer (0, I, II, or III) and type of treatment (RT alone or RT and CT)
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias)	Unclear risk	Not described
Incomplete outcome data (attrition bias)	Unclear risk	Attrition not reported
Selective reporting (reporting bias)	Low risk	All data reported

Other bias	Low risk	No

Robins 2012

Methods	RCT
Participants	56 normal pop, mean age 46. 84% female. Inclusion: >18 ys Exclusion :no regular meditation practice or prior MBSR, current psychosis, suicidal ideation, psychiatric hospitalisation past 6 ms, commitment to attend and practice
Interventions	MBSR vs WL MBSR: 8 x 2 ½ + 7 hour session. Designated 45" 6 days a week home practice. Attendance and home practice not reported
Outcomes	Awareness: FFMQ, Absent mindedness (CFQ), Emotional reg. scales: DERS, ACS, RRS, PSWQ, SAES, SCS, Social desirability: M-CSDS at baseline
Key conclusions	Sign difference in mindfulness, absent-mindedness, self-compassion, fear of emotion, suppression of anger, anger expression, worry and difficulties regulating emotions. No sign diff in ruminative response scale and 5 of the subscales in DERS and 2 subscales in ACS
Notes	Only postintervention measures can be used

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Unclear risk	Blinding not described
Incomplete outcome data (attrition bias)	Low risk	Equal drop-out in both groups, no difference between completers and dropouts in either group, no imputing of missing data, not ITT
Selective reporting (reporting bias)	Low risk	Subscales of SCS not reported
Other bias	Low risk	More mindfulness experience in MBSR group, but controlled for in analyses

Rosenkranz 2013

Methods	RCT
Participants	49 community volunteers, mean age 45, 10 men. 80% women. Exclusion criteria: Current pharmaco- or psychotherapy, medical disorders or head trauma, current other psychiatric disorder, previous night-shift work, diabetes, per. Vasc disease or other diseases affecting circulation, needle phobia, pregnancy, smoking, alcohol or drug dependency. practice, mind-body practice or exercise practice, inability to walk, use of psychotropic or steroid drugs,
Interventions	MBSR vs HEP training (health enhancement program)
	MBSR: 8 x 2 ½ + 7 hour session. 236 minutes/wk practice. HEP: 8 weeks in gym, 2 indiv AE and 1 group per week, 212 minutes/wk
Outcomes	Self-report at baseline, post-intervention and 4 ms follow-up. SCL-90, MSC, TNF-alfa, IL-8, capsaicin-induced flare size, cortisol in saliva
Key conclusions	No difference between the interventions. Except for smaller flare response in MBSR group in spite of similar corticol response.
Notes	Part of larger study with other outcomes, reported elsewhere???

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Unclear risk	not described
Incomplete outcome data (attrition bias)	Unclear risk	Not described
Selective reporting (reporting bias)	High risk	Incomplete report of mean and SD
Other bias	Unclear risk	Data may have been more fully reported elsewhere

Schmidt 2011

Methods	RCT
Participants	177 female adults (18-70 years old)

Interventions	MBSR, active control group or wait list MBSR: 8 week structured program with 2.5 hr session every week + 7h all day session Active control: aimed at equating the nonspecific features of MBSR, referred to as "relaxation group"
Outcomes	Primary outcomes: Health-related quality of life 2 months post treatment. Secondary outcomes: disorder-specific quality of life, depression, pain, anxiety, somatic complaints, and a proposed index of mindfulness.
Key conclusions	No significant differences between groups on primary outcome, but patients within the MBSR group showed overall improvement in health-related quality of life.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Block randomization using computer algorithm
Allocation concealment (selection bias)	Low risk	Allocation concealed
Blinding (performance bias and detection bias)	Low risk	Blinding performed
Incomplete outcome data (attrition bias)	Low risk	Addressed
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Unclear risk	Appx. 20% of participants volunteered information on allocation

SeyedAlinaghi 2012

Methods	RCT
Participants	245 HIV patients >18, mean 35ys,31% female. Exclusion criteria: Current substance addiction, psychosis, PTSD. Clinically symptomatic, CD4<250.
Interventions	MBSR vs Brief education support MBSR: 8 x 2 ½ + 7h. BES: 2 hs Attendance and home work not reported

Outcomes	Outcomes at pre-post, 3, 6, 9 and 12 ms after start. CD4, MSCL, SCL-90R
Key conclusions	Treatment adherent sample CD4 increased until 9 ms and then returned to baseline in MBSR. MSCL improved until 12 ms, and SCL-90 until 6 ms. In the BES group these values remained unchanged
Notes	Significant difference in CD4 count at baseline

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomized by staff blinded to treatment condition
Allocation concealment (selection bias)	Low risk	Se above
Blinding (performance bias and detection bias)	Unclear risk	No blinding of outcome assessors
Incomplete outcome data (attrition bias)	High risk	Of those who attended > 75% of the classes, there were few missing data, Many participants excluded from analyses (25%) because of low attendance
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	

Shapiro 1998

Methods	RCT (author confirmed this)
Participants	78 medical and premedical students
Interventions	MBSR vs wait-list control MBSR: 7 x 2,5 hours per week
Outcomes	Empathy, psychological distress, depression, anxiety and spirituality
Key conclusions	MBSR group experienced reduced state and trait anxiety, distress and depression, increased empathy and spiritual experiences. Result replicated in wait-list control group, with different experimenters. Results measured at exam time
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias)	Low risk	Outcome assessor masked to group assignment
Incomplete outcome data (attrition bias)	Unclear risk	Large number of dropouts in MBSR group
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Shapiro 2005

Methods	RCT
Participants	38 health care professionals
Interventions	MBSR vs wait-list control MBSR: 8 x 2 hours per week
Outcomes	Psychological distress, burnout, perceived stress, life satisfaction, self-compassion
Key conclusions	MBSR group reported decreased perceived stress and greater self-compassion compared to controls. Changes in self-compassion significantly predicted positive changes in perceived stress but not changes in satisfaction with life.
Notes	Intention to treat analysis not conducted, big dropout (44%) in intervention group

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	High risk	Data collected by research assistant but also by co-therapist

Incomplete outcome data (attrition bias)	Unclear risk	Large drop-out rate, no intention to treat analysis
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Song 2015

Methods	RCT
Participants	44 nursing students, mean age 19, 6, 81% women. Inclusion criteria: no regular medication/ yoga practice last 6 months, no current psychiatric symptoms and no contraindications to exercise.
Interventions	MBSR vs wait-list control MBSR: 8 x 2 hours per week. No retreat. Amount of home practice not specified.
Outcomes	Depression, anxiety, stress and mindfulness.
Key conclusions	MBSR was effective in reducing measures of depression, anxiety and stress, and increasing mindful awareness.
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Unclear risk	Not specified
Incomplete outcome data (attrition bias)	Unclear risk	Not specified
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Unclear risk	Small and non-representative sample

Speca 2000

Methods	RCT
Participants	109 patients with cancer

Interventions	MBSR vs wait-list control MBSR: 7 x 1,5 hours per week
Outcomes	Mood disturbance, physical, psychological and behavioural response to stress
Key conclusions	MBSR had significant effect on all outcome measures
Notes	Drop-outs had more baseline anxiety and depression. Best predictor of improvement was number of sessions attended (explained 13.2% of the variance)

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	A fixed randomisation scheme based on a table of random numbers
Allocation concealment (selection bias)	Low risk	A list of numbers where the investigator did not know which participant was behind the numbers were used to conceal allocation
Blinding (performance bias and detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Low risk	Intention to treat analyses with drop-outs imputed as last value carried over and with value entered as 0
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Surawy 2005

Methods	RCT
Participants	18 patients with chronic fatigue syndrome
Interventions	MBSR vs wait-list control MBSR: 8 x 2,5 hours per week
Outcomes	Anxiety and depression, fatigue, physical function
Key conclusions	Significant effect of MBSR on reducing anxiety and fatigue, but no effect on depression or physical function
Notes	Baseline differences not accounted for in the analysis

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Low risk	Only one loss to follow up
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	High risk	Study population had been seen a varying number of sessions by psychiatrist before study inclusion. Baseline differences not accounted for in the analysis

Tacon 2003

Methods	RCT
Participants	20 women with cardiovascular disease
Interventions	MBSR vs wait-list control MBSR: 8 x 2 hours per week
Outcomes	Anxiety, emotional control, coping, health locus of control, health related quality of life, cortisol, submaximal exercise response
Key conclusions	Significant effect on anxiety, emotional control and reactive coping. Significant effect on breathing pattern with increased ventilatory efficiency during exercise. No effect on resting levels in hormones.
Notes	Data from exercise tests and hormone measurements published in separate article by Robert-McComb in 2004

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Random selection with number 1 & 2, unclear how it was performed

Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Low risk	Only two dropouts one from each group
Selective reporting (reporting bias)	High risk	Relevant outcome data not provided for non-significant outcomes
Other bias	Low risk	No other bias detected

Vieten 2008

Methods	RCT
Participants	34 pregnant women with mood problems
Interventions	MBSR vs wait-list control MBSR: 8 x 2 hours per week, exercises adapted to suit pregnant women
Outcomes	Stress, anxiety, affect, affect regulation, mindfulness
Key conclusions	Mindfulness training during pregnancy may significantly reduce anxiety and negative affect
Notes	Intention to treat analysis not reported

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Unclear risk	Not specified
Incomplete outcome data (attrition bias)	Low risk	Small number of missing data
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	Large imbalance at baseline, but adjusted for by ANCOVA analysis

Vøllestad 2011

Methods	RCT
Participants	76 with different anxiety disorders diagnosed after structured interview, mean age 42, 67% female. Exclusion criteria: Suicidality, substance abuse/dependency, severe mental disorder, other axis 1 disorder as primary diagnoses. Use of anxiolytics, deficit in impulse control assessed by MINI, other concurrent treatment, change of SSRI/MAOI last 3 ms
Interventions	MBSR vs WL
	MBSR: 8 x 2 ½ + 6 hour session. Daily practice logs. 77% completed 8 sessions, mean 7.6, mean practice 34 min/dag
Outcomes	Self-report at baseline, post-intervention: BAI, PSWQ, STAI, BDI-II, SCL-90-R, FMMQ
Key conclusions	ITT moderate between-group effect on all outcome measures except sleep disturbance. Effect mediated by mindfulness.
Notes	6 ms follow-up data only for MBSR group and cannot therefore be used in MA.

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Method of randomization not described
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Unclear risk	Blinding not described
Incomplete outcome data (attrition bias)	Low risk	LOCF used to impute missing data, ITT analyses
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	

Weissbecker 2002

Methods	MBSR
Participants	91 women with fibromyalgia
Interventions	MBSR vs wait-list control
	MBSR: 8 x 2 hours per week

Outcomes	Sense of coherence (SOC), fibromyalgia symptom impact, perceived stress and depression
Key conclusions	Significant increase in SOC in MBSR group correlated to degree of attendance. A higher SOC was significantly related to less distress and depression but SOC did not buffer for the negative effects of fibromyalgia symptoms on psychological distress (as analysed by hierarchical regression).
Notes	Only given full data on SOC variable, same study as Sephton 07

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Low risk	Tested for differential attrition showed no significant differences across treatment & control
Selective reporting (reporting bias)	High risk	full data on perceived stress and depression not given
Other bias	Low risk	No other bias detected

Wells 2013

Methods	RCT
Participants	14 adults (age 55-90 years) with mild cognitive impairment (MCI)
Interventions	MBSR vs. Usual care MBSR: 8 weeks x 2h + one mindfulness retreat day
Outcomes	Seed based functional connectivity and brain morphometry analyses
Key conclusions	MBSR participants had increased functional connectivity between the posterior cingulate cortex and bilateral medial prefrontal cortex and left hippocampus compared to controls. In addition, MBSR participants had trends of less bilateral hippocampal volume atrophy.
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	block randomization with randomly varying block size to generate treatment assignment
Allocation concealment (selection bias)	Unclear risk	not described
Blinding (performance bias and detection bias)	Low risk	all analyses blinded
Incomplete outcome data (attrition bias)	Low risk	ITT
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Wells 2014

Methods	RCT
Participants	19 people with episodic migraine
Interventions	MBSR (8 x 2hs + 6 h day) vs WL
Outcomes	Primary outcome was change in migraine frequency from baseline to initial follow-up. Secondary outcomes included change in headache severity, duration, self-efficacy, perceived stress, migraine-related disability/impact, anxiety, depression, mindfulness, and quality of life from baseline to initial follow-up
Key conclusions	Although the small sample size of this pilot trial did not provide power to detect statistically significant changes in migraine frequency or severity, secondary outcomes demonstrated a beneficial effect on headache duration, disability, self-efficacy, and mindfulness.
Notes	Results given as median values and cannot be included in the meta-analyses

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Block randomization with a block size of four (ICIC design)

Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes
Blinding (performance bias and detection bias)	Low risk	Data kept from leader of intervention
Incomplete outcome data (attrition bias)	Low risk	ITT
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Unclear risk	Participants were informed of two randomization points, and that makes it unclear if they are a WL og TAU group

Whitebird 2013

Methods	RCT
Participants	78 family caregivers of people with dementia
Interventions	MBSR (8x2,5 h + 5 h) vs Caregiver Educ support (amount not specified but received weekly information input and also some group discussions)
Outcomes	PSS, CED-S, STAI, Caregiver burden and social support
Key conclusions	MBSR more effective at improving mental health, stress and depression. same effect on anxiety, social support and burden
Notes	

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	computer algorithm
Allocation concealment (selection bias)	Unclear risk	not described
Blinding (performance bias and detection bias)	Unclear risk	not described
Incomplete outcome data (attrition bias)	Low risk	ITT
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Williams 2001

Methods	RCT

Participants	103 community volunteers who were stressed
Interventions	MBSR (2,5x8 + all day) vs Educational group
Outcomes	Daily stress inventory, distress (SCL90) and medical symptoms
Key conclusions	MBSR group significant reduction in stress, distress and medical symptoms
Notes	Used stress map inventory and action plan workbook in the MBSR classes

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Low risk	ITT reported
Selective reporting (reporting bias)	Low risk	All outcome reported in figures
Other bias	Low risk	No other bias detected

Wong 2011

Methods	RCT
Participants	100 Chronic pain patients >3 ms, 18-65ys, mean 48. Exclusion criteria: Other therapies except for pain, Axis I disorders, previous MBSR course, or regular meditation practice or illiterate
Interventions	MBSR vs MPI (multidisciplinary pain I). MBSR: 8 x 2 ½ + 7 hour session. MBI: 8 x 2 ½ + 7 h retreat. Attendance MBSR 7.2 og MPI 8.5.
Outcomes	Self-report at baseline, post-intervention and 3 and 6 ms follow-up. Pain intensity, Pain distress, POMS, CES-D, STAI, SF-12, sick leave
Key conclusions	No difference between the interventions. Both showed reductions in Pain intensity, Pain distress.
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random table in Excel
Allocation concealment (selection bias)	Low risk	Allocation concealed until intervention time
Blinding (performance bias and detection bias)	Low risk	Blinding of outcome assessors and those who analysed the data
Incomplete outcome data (attrition bias)	Unclear risk	Not fully ITT as read from table 3. Unclear handling of missing protocols. Twice as many in MBSR group dropped out.
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	

Würtzen 2013

Methods	RCT
Participants	336 women with breast cancer 18-75ys, operated within 3-18 ms for stage I-III. Mean age 54 ys. Exclusion criteria: Current active treatment for major psychiatric disorder or other medical condition that would limit participation, diagnosis of another cancer within 10 ys
Interventions	MBSR+ usual care vs usual care MBSR: 8 x 2 + 5 hour session. Training log provided but not reported, attendance not reported
Outcomes	Self-report SCL-90-R depression and anxiety subscales and CES-D, post intervention, and 4 and 10 ms follow-up after the intervention
Key conclusions	Medium to large effect on anxiety and depression at 10 ms. No difference between the interventions.
Notes	Different results on SCL depression and CES-D, possibly because of difference in item content

Risk of bias table

Bias	Authors' judgement	Support for judgement

Random sequence generation (selection bias)	Low risk	Computer generated sequences of 10
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding (performance bias and detection bias)	Unclear risk	Not described
Incomplete outcome data (attrition bias)	Low risk	27 dropped out from the MBSR program (+2 before randomization). No significant differences in distress (mean GSI, scl-90-r) or time since diagnosis between completers and those who dropped out. There were twice as many participants with missing data in the MBSR group at 12 month follow-up as compared to the control group. Comparison between those who provided 12-month follow-up data and those who did not showed no differences in baseline characteristics. Intention to treat analysis was carried out with last observation carried forward for 12-month follow-up data.
Selective reporting (reporting bias)	Low risk	All data reported as specified in trial protocol
Other bias	High risk	Many outcomes reported in different articles but without adjustment for possible type I error

Zernicke 2013

Methods	RCT
Participants	90 IBS, mean age 45, 90% women. Inclusion: >18 ys, English speaking, diagnosed by GI spes. using Rome III criteria. Exclusion: DSM-IV axis I mood, anxiety og psychotic disorder, current use of antipsychotics, past participation in MBSR
Interventions	MBSR+TAU vs TAU. MBSR: 8 x 1 ½ + 3 hour session. mean Attendance 6 of 9 sessions, reported practice from weekly logs 137min/wk
Outcomes	IBS-SSS, secondary: IBS-QOL, POMS, C-SOCI, Facit-sp
Key conclusions	Both groups improved over time. At 6 ms follow-up MBSR group maintained meaningful reductions in IBS symptoms compared to TAU, although no sign between group difference at follow-up.

	Improvement in mood, QOL and spirituality in both groups over time
Notes	Pre to post intervention drop out 44 and 23% in MBSR and TAU groups

Risk of bias table

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-based 2-digit random number generator
Allocation concealment (selection bias)	Low risk	Se above
Blinding (performance bias and detection bias)	Unclear risk	Not described
Incomplete outcome data (attrition bias)	Low risk	ITT used, when using linear mixed for repeated measures, and analyses of dropouts performed
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	

9.1.2 Characteristics of excluded studies

Abbey 2003

Reason for exclusion	Not RCT

Abbott 2006

Reason for exclusion	Unobtainable

Alexzander 1989

Reason for exclusion	Not MBSR

Allen 2006

Reason for exclusion	Not primary study

Alterman 2004

Reason for exclusion	Not RCT

American 2007

Reason for exclusion	Not primary study

Arch 2013a

Reason for exclusion	moderator analysis related to Arch 2013 study

Arias 2006

Reason for exclusion	Not primary study

Arnold 2001

Reason for exclusion	Not primary study

Arthur 2006

Reason for exclusion	Not primary study

Astin 2003a

Reason for exclusion	Measures effect of MBSR in combination with Qi-Gong

Astin 2003b

Reason for exclusion	Not primary study

Astin 2004

Reason for exclusion	Not primary study

Azargoon 2010

Reason for exclusion	Not described as MBSR in abstract (article in Farsi language)

Bahrke 1978

Reason for exclusion	Not MBSR

Barrows 2002

Reason for exclusion	Not primary study

Bauer-Wu 2011	
Reason for exclusion	Unobtainable

Berghmans 2012	
Reason for exclusion	Not RCT

Berking 2007	
Reason for exclusion	Not primary study

Bevan 2010	
Reason for exclusion	Not MBSR

Biegel 2009	
Reason for exclusion	Not RCT

Bishop 2002	
Reason for exclusion	Not primary study

Boerstler 1987	
Reason for exclusion	Not primary study

Brach 1992	
Reason for exclusion	Not MBSR

Brandon, 1985	
Reason for exclusion	Not MBSR

Brazier 2006	
Reason for exclusion	Not MBSR

Bremner 2011	
Reason for exclusion	not obtainable

Britton 2007

Reason for exclusion	Unobtainable, author contacted

Bruckstein 1999

Reason for exclusion	Not an RCT. Participants could themselves choose which group they would participate in.

Bruning 1987

Reason for exclusion	Not MBSR

Butler 2006

Reason for exclusion	Not MBSR

Bögels 2008

Reason for exclusion	Not RCT

Campbell 2012

Reason for exclusion	Not MBSR

Carlson 2013

Reason for exclusion	Not MBSR

Carmody 2006

Reason for exclusion	not RCT

Carson 2006

Reason for exclusion	Not primary study

Cathcart 2014

Reason for exclusion	Not RCT

Chan 2015

Reason for exclusion	Not MBSR

Chang 2003

Reason for exclusion	Not MBSR

Cohen-Katz 2004	
Reason for exclusion	Not primary study

Cole 2012	
Reason for exclusion	Not MBSR

Coulter 2002	
Reason for exclusion	Not primary study

Cour 2011	
Reason for exclusion	Unobtainable

Daubenmier 2012	
Reason for exclusion	Not MBSR

Davies 2008	
Reason for exclusion	Not primary study

Davis 2012	
Reason for exclusion	Unobtainable

de la Fuente 2010	
Reason for exclusion	Not MBSR

de la Fuente 2010a	
Reason for exclusion	Not MBSR

Deepak, 1994	
Reason for exclusion	Not MBSR

Delmonte 1985	
Reason for exclusion	Not primary study

Delmonte 1990

Reason for exclusion	Not primary study

Diamond 1987

Reason for exclusion	Not primary study

Dosh 2002

Reason for exclusion	Not primary study

Dreeben 2011

Reason for exclusion	Unobtainable

Ebell 2001

Reason for exclusion	Not primary study

Edwards 2003

Reason for exclusion	Not primary study

Ernst 2008

Reason for exclusion	Not RCT

Ferren 2004

Reason for exclusion	Not RCT

Fjorback 2008

Reason for exclusion	Not primary study

Flanzbaum 2003

Reason for exclusion	Not MBSR

Foley 2006

Reason for exclusion	Unobtainable

Frank 2015

Reason for exclusion	Not RCT

Galantino 2005	
Reason for exclusion	Not RCT

Garland 2007	
Reason for exclusion	Not RCT

Garland 2010	
Reason for exclusion	Not RCT

Garland 2011	
Reason for exclusion	Study protocol

Gaston 1991	
Reason for exclusion	Not MBSR

Gazella 2005	
Reason for exclusion	Not primary study

Goodman 2004	
Reason for exclusion	Primary study reported in Plews-Ogan 2005

Green 2013	
Reason for exclusion	Unobtainable

Greene 1988	
Reason for exclusion	Not MBSR

Grossman 2004	
Reason for exclusion	Not primary study

Grossman 2007	
Reason for exclusion	Not RCT

Haines 2015

Reason for exclusion	Not MBSR

Hall 1999

Reason for exclusion	Not MBSR

Hart 2007

Reason for exclusion	Not primary study

Hassed 2004

Reason for exclusion	Not MBSR

Haynes 2007

Reason for exclusion	Unobtainable

Health & Medicine 2008

Reason for exclusion	Not RCT

Hebert 2001

Reason for exclusion	Not MBSR, Several sessions lead by psychiatrist addressing issues of coping with breast cancer

Hellman 1990

Reason for exclusion	Not MBSR

Hick 2010

Reason for exclusion	Not RCT

Hildenbrand 1986

Reason for exclusion	Not primary study

Hill 2011

Reason for exclusion	Not MBSR

Hodges 2000

Reason for exclusion	Not primary study

Hoffman 2012a	
Reason for exclusion	Conference abstract of included study Hoffman 2012

Hoge 2013a	
Reason for exclusion	Abstract of included study Hoge 2013

Holzel 2011	
Reason for exclusion	Not RCT

Horrigan 2006	
Reason for exclusion	Not primary study

Horrigan 2007	
Reason for exclusion	Not primary study

Horton-Deutsch 2003	
Reason for exclusion	Not primary study

Horton-Deutsch 2007	
Reason for exclusion	Not RCT

Humphrey 1999	
Reason for exclusion	Not MBSR

Issel 2007a	
Reason for exclusion	Not primary study

Issel 2007b	
Reason for exclusion	Not RCT

Ivanovski 2007	
Reason for exclusion	Not primary study

Jackson 2004

Reason for exclusion	Unpublished, unobtainable

Jacobs 2003

Reason for exclusion	Not RCT

Jaltuch 1997

Reason for exclusion	Unobtainable

Jha 2007

Reason for exclusion	Not RCT

Johnson 2004

Reason for exclusion	Not MBSR

Jung 2015

Reason for exclusion	Not MBSR

Kabat-Zinn 1985

Reason for exclusion	Not RCT

Kabat-Zinn 1986

Reason for exclusion	Unobtainable

Kabat-Zinn 1992

Reason for exclusion	Not RCT

Kabat-Zinn 1998

Reason for exclusion	Not MBSR (audiotapes only)

Kao 2014

Reason for exclusion	Not MBSR

Keng 2013

Reason for exclusion	Not MBSR

Kindlon 1983	
Reason for exclusion	Not MBSR

Kirk 2013	
Reason for exclusion	No health outcome data reported

Koerbel 2007	
Reason for exclusion	Not primary study

Krisanaprakornkit 2006	
Reason for exclusion	Not primary study

Krisanaprakornkit 2007	
Reason for exclusion	Not primary study

Kroese 2005	
Reason for exclusion	Not primary study

Kron 2004	
Reason for exclusion	Not primary study

Kron 2007	
Reason for exclusion	Not primary study

Kulshreshtha 2011	
Reason for exclusion	Unobtainable

Labelle 2015	
Reason for exclusion	Not RCT

Lazar 2011	
Reason for exclusion	Not RCT

Lee 2007

Reason for exclusion	Not MBSR

Lehto 2014

Reason for exclusion	Not MBSR

Lerman 2012

Reason for exclusion	not MBSR (psychoeducation in addition)

Linden 2001

Reason for exclusion	Not RCT

Liu 2015

Reason for exclusion	Not MBSR

Loganathan 2007

Reason for exclusion	Not MBSR

Lombart 1998

Reason for exclusion	Not RCT

Lopez-Navarro 2015

Reason for exclusion	Not MBSR

Lundh 2005

Reason for exclusion	Not primary study

Luskin 2000

Reason for exclusion	Not primary study

Lynch 2004

Reason for exclusion	Not RCT

Mackenzie 2006

Reason for exclusion	Not RCT

Manzoni 2008	
Reason for exclusion	Not primary study

Maras 1984	
Reason for exclusion	Not RCT

Marcus 2001	
Reason for exclusion	Not RCT

Marcus 2007	
Reason for exclusion	Not RCT

Massion 1997	
Reason for exclusion	Unobtainable

Matchim 2007	
Reason for exclusion	Not primary study

Mawani 2014	
Reason for exclusion	Not MBSR

McCarberg 1999	
Reason for exclusion	Not MBSR

McMillan 2002	
Reason for exclusion	Not MBSR

Medical Devices 2008	
Reason for exclusion	Not RCT

Melnyk 2005	
Reason for exclusion	Not primary study

Michalak 2006

Reason for exclusion	Not primary study

Michalsen 2002

Reason for exclusion	Not RCT

Moghaddam 2007

Reason for exclusion	Not MBSR

Monk-Turner 2003

Reason for exclusion	Not RCT

Monti 2005

Reason for exclusion	Not MBSR, the art therapy element considered more than an adaption of MBSR

Morone 2005

Reason for exclusion	Primary study reported in Morone 2008

Morone 2006

Reason for exclusion	Primary study reported in Morone 2008

Morone 2007

Reason for exclusion	Not primary study

Mularski 2009

Reason for exclusion	Not MBSR (addition of CAM)

Mulligan 2004

Reason for exclusion	Not primary study

Murphy 1986

Reason for exclusion	Not MBSR

Murphy 1996

Reason for exclusion	Not primary study

Napoli 2005	
Reason for exclusion	Not MBSR

Nash-McFeron 2006	
Reason for exclusion	not obtainable

Neale 2007	
Reason for exclusion	Not primary study

Nielsen 2006	
Reason for exclusion	Not RCT

Nyklicek 2014	
Reason for exclusion	Not MBSR

Ormrod 1991	
Reason for exclusion	Not MBSR

Ortner 2007	
Reason for exclusion	Not MBSR

Ott 2006	
Reason for exclusion	Not primary study

Ozcelik 2007	
Reason for exclusion	Unobtainable

Palmkron 2008	
Reason for exclusion	Not primary study

Papp 2001	
Reason for exclusion	Not primary study

Paradies 2006

Reason for exclusion	Not primary study

Patel 1985

Reason for exclusion	Not MBSR

Paterniti 2008

Reason for exclusion	Not RCT

Pauzano-Slamm 2005

Reason for exclusion	Not RCT

Pearl 1994

Reason for exclusion	Not RCT

Perkins 1998

Reason for exclusion	MBSR and progressive relaxation

Phelps 2005

Reason for exclusion	Unobtainable

Pinniger 2012

Reason for exclusion	Not MBSR

Poulin 2005

Reason for exclusion	Not RCT

Poulin 2008

Reason for exclusion	Not RCT

Praissman 2008

Reason for exclusion	Not primary study

Proulx 2003

Reason for exclusion	Not primary study

Rainforth 2007	
Reason for exclusion	Not primary study

Ramel 2004	
Reason for exclusion	Not RCT

Randolph 1999	
Reason for exclusion	Not RCT

Ratanasiripong 2012	
Reason for exclusion	Not MBSR

Rhead 1983	
Reason for exclusion	Not RCT

Robinson 2003	
Reason for exclusion	Not RCT

Roeser 2013	
Reason for exclusion	Not MBSR

Rosdahl 2003	
Reason for exclusion	Not RCT

Rosenzweig 2003	
Reason for exclusion	Not RCT

Roth 2004	
Reason for exclusion	Not RCT

Sagula 2004	
Reason for exclusion	Not RCT

Salmon 2004

Reason for exclusion	Not primary study

Saxe 2001

Reason for exclusion	Not RCT

Schmidt 2008

Reason for exclusion	Not RCT

Schure 2008

Reason for exclusion	Not RCT

Sephton 2011

Reason for exclusion	Unobtainable

Severtsen 1986

Reason for exclusion	Not MBSR

Shapiro 1998a

Reason for exclusion	Primary study reported in Shapiro 1998b

Shapiro 2002

Reason for exclusion	Unobtainable

Shapiro 2003

Reason for exclusion	Quasi-experimental due to pre-intervention measures given after randomizaton and the two treatment options not equivalent and affected answers to pre-intervention protocol

Shapiro 2007

Reason for exclusion	Not RCT

Sherr 2011

Reason for exclusion	Moderation study based on Gross 2010 in included studies

Shigaki 2006

Reason for exclusion	Not primary study

Simpson 2011

Reason for exclusion	Not RCT, both groups received MBSR and data given for both groups together

Singh 2002

Reason for exclusion	Not RCT

Singh 2004

Reason for exclusion	Not RCT

Singh 2006a

Reason for exclusion	Not RCT

Singh 2006b

Reason for exclusion	Not RCT

Smith 2004

Reason for exclusion	Not primary study

Smith 2005a

Reason for exclusion	Not primary study

Smith 2005b

Reason for exclusion	Unobtainable

Smith 2007

Reason for exclusion	Unobtainable

Smith 2008

Reason for exclusion	Not RCT

Snaith 1998

Reason for exclusion	Not primary study

Solloway 2007	
Reason for exclusion	Not RCT

Soskis 1989	
Reason for exclusion	Not RCT

Spanos 1980	
Reason for exclusion	Not RCT

Spence 2006	
Reason for exclusion	Not MBSR

Starks 2007	
Reason for exclusion	Unobtainable

Stauffer 2008	
Reason for exclusion	Not RCT

Stefanaki 2015	
Reason for exclusion	Not MBSR

Tacon 2003a	
Reason for exclusion	Not primary study

Tacon 2004	
Reason for exclusion	Not RCT

Tate 1994	
Reason for exclusion	Not RCT

Toneatto 2007	
Reason for exclusion	Not primary study

Tremblay 2008

Reason for exclusion	Not primary study

Van Dam 2014

Reason for exclusion	Not MBSR

Victorson 2012

Reason for exclusion	Not obtainable

von Weiss 2002

Reason for exclusion	Not primary study

Walach 2007

Reason for exclusion	Not RCT

Wei 2015

Reason for exclusion	Not MBSR

Weiss 2005

Reason for exclusion	Not RCT

Weston 2012

Reason for exclusion	conference abstract, no data for plotting

Wilson 2000

Reason for exclusion	Unobtainable

Winbush 2007

Reason for exclusion	Not primary study

Wong 2009

Reason for exclusion	Duplicate of Wong 2011

Woods 2014

Reason for exclusion	Review

Xing-Hua 2013	
Reason for exclusion	Not MBSR

Zernicke 2014	
Reason for exclusion	Not MBSR, online program

Åsberg 2006	
Reason for exclusion	Not primary study

9.1.3 Characteristics of studies awaiting classification

Chavooshi 2016	
Methods	
Participants	
Interventions	
Outcomes	
Notes	

Cherkin 2016	
Methods	
Participants	
Interventions	
Outcomes	
Notes	

Faucher 2016	
Methods	
Participants	
Interventions	
Outcomes	
Notes	

George 2015	
Methods	
Participants	

Interventions	
Outcomes	
Notes	

Goldin 2016

Methods	
Participants	
Interventions	
Outcomes	
Notes	

Johns 2016

Methods	
Participants	
Interventions	
Outcomes	
Notes	

Kearney 2016

Methods	
Participants	
Interventions	
Outcomes	
Notes	

Nellson 2016

Methods	
Participants	
Interventions	
Outcomes	
Notes	

Omidi 2014

Methods	
Participants	

Interventions	
Outcomes	
Notes	

Pargaonkar 2015

Methods	
Participants	
Interventions	
Outcomes	
Notes	

Zhang 2016

Methods	
Participants	
Interventions	
Outcomes	
Notes	

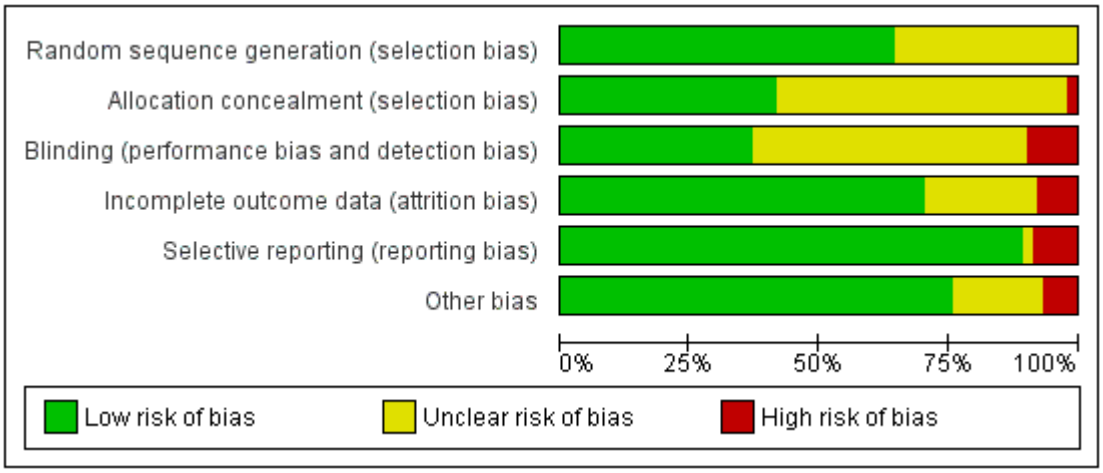
9.2 Summary of findings tables

9.2.1 Table 1: Study characteristics with measurement scales

Table 1 is presented in section 4.1.1

10. Data and analyses

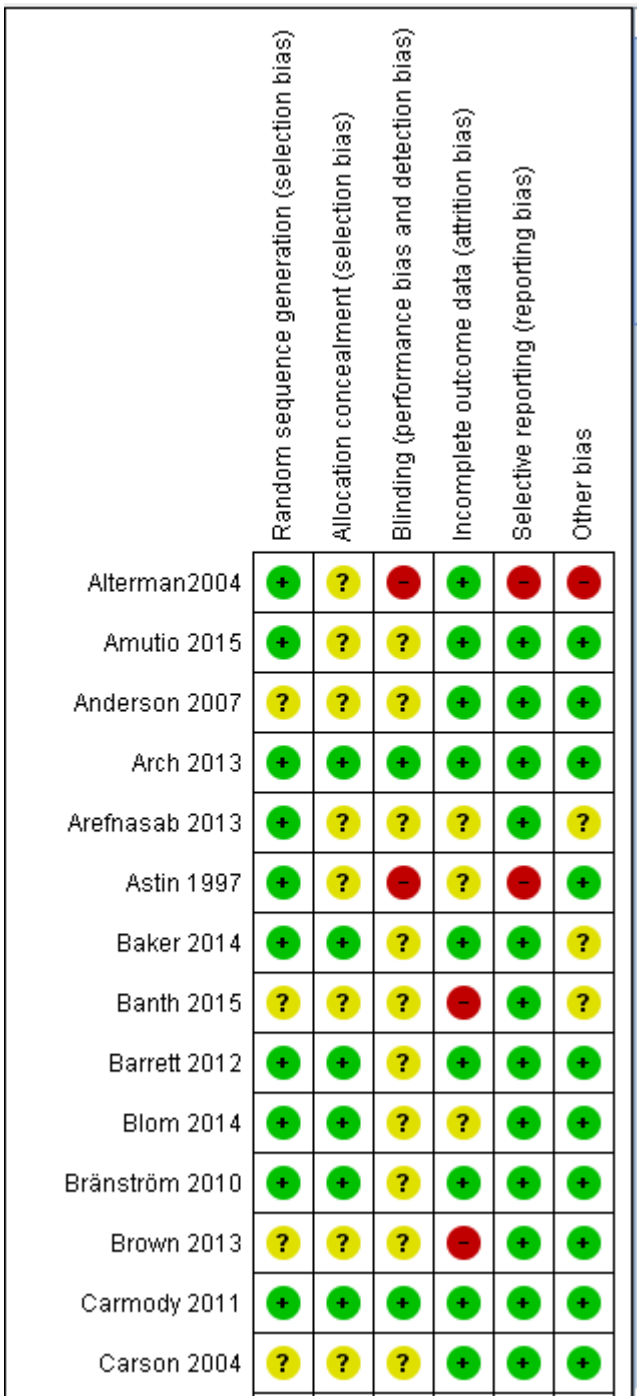
10.1 Methodological quality graph

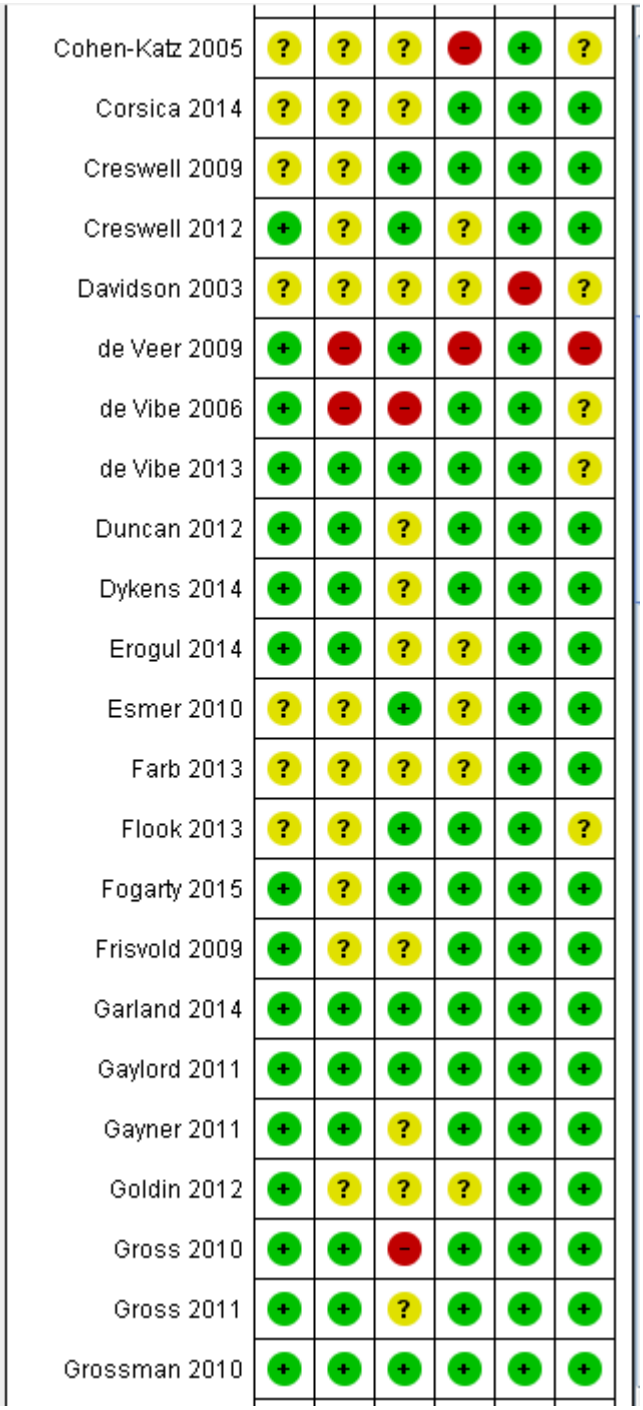


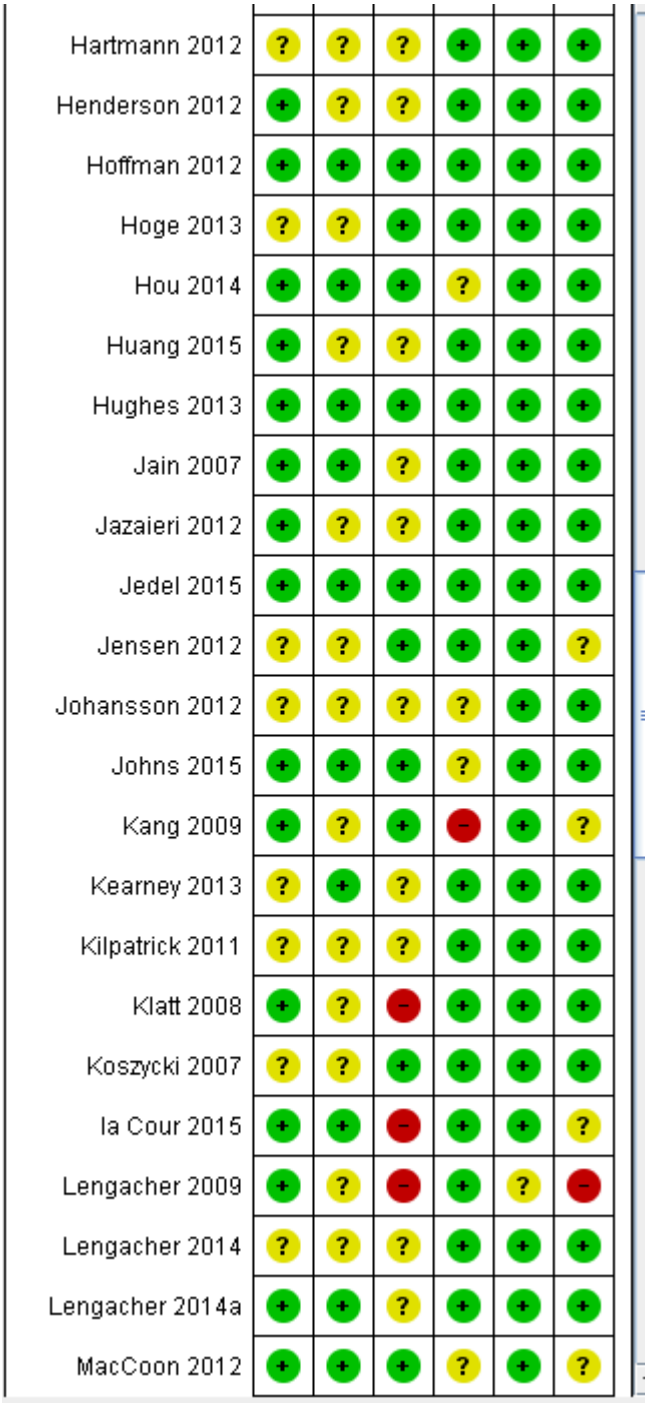
Review authors' judgments about each methodological quality item presented as percentages across all included studies.

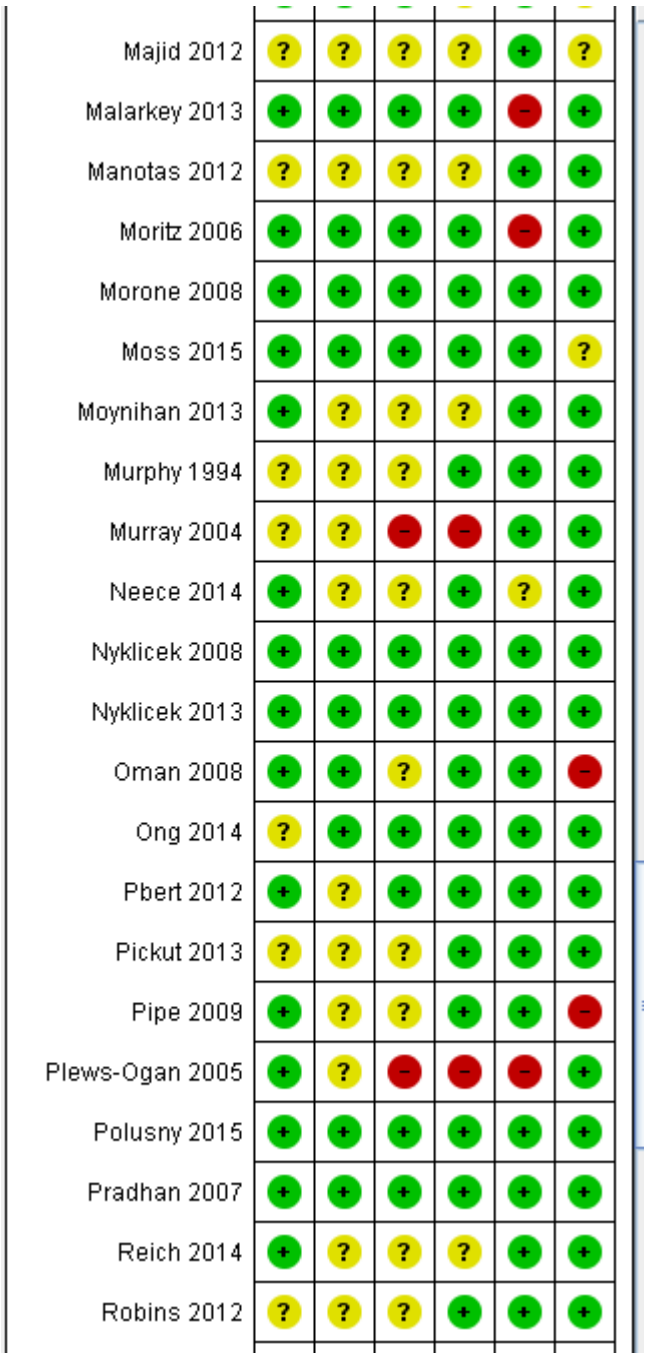
Figure 2: Methodological quality graph

10.2 Methodological quality summary


Random sequence generation (selection bias)
Allocation concealment (selection bias)
Blinding (performance bias and detection bias)
Incomplete outcome data (attrition bias)
Selective reporting (reporting bias)
Other bias
Alterman2004
Amutio 2015
Anderson 2007
Arch 2013
Arefnasab 2013
Astin 1997
Baker 2014
Banth 2015
Barrett 2012
Blom 2014
Bränström 2010
Brown 2013
Carmody 2011
Carson 2004


Cohen-Katz 2005
Corsica 2014
Creswell 2009
Creswell 2012
Davidson 2003
de Veer 2009
de Vibe 2006
de Vibe 2013
Duncan 2012
Dykens 2014
Erogul 2014
Esmer 2010
Farb 2013
Flook 2013
Fogarty 2015
Frisvold 2009
Garland 2014
Gaylord 2011
Gayner 2011
Goldin 2012
Gross 2010
Gross 2011
Grossman 2010


Hartmann 2012
Henderson 2012
Hoffman 2012
Hoge 2013
Hou 2014
Huang 2015
Hughes 2013
Jain 2007
Jazaieri 2012
Jedel 2015
Jensen 2012
Johansson 2012
Johns 2015
Kang 2009
Kearney 2013
Kilpatrick 2011
Klatt 2008
Koszycki 2007
la Cour 2015
Lengacher 2009
Lengacher 2014
Lengacher 2014a
MacCoon 2012


Majid 2012
Malarkey 2013
Manotas 2012
Moritz 2006
Morone 2008
Moss 2015
Moynihan 2013
Murphy 1994
Murray 2004
Neece 2014
Nyklicek 2008
Nyklicek 2013
Oman 2008
Ong 2014
Pbert 2012
Pickut 2013
Pipe 2009
Plews-Ogan 2005
Polusny 2015
Pradhan 2007
Reich 2014
Robins 2012

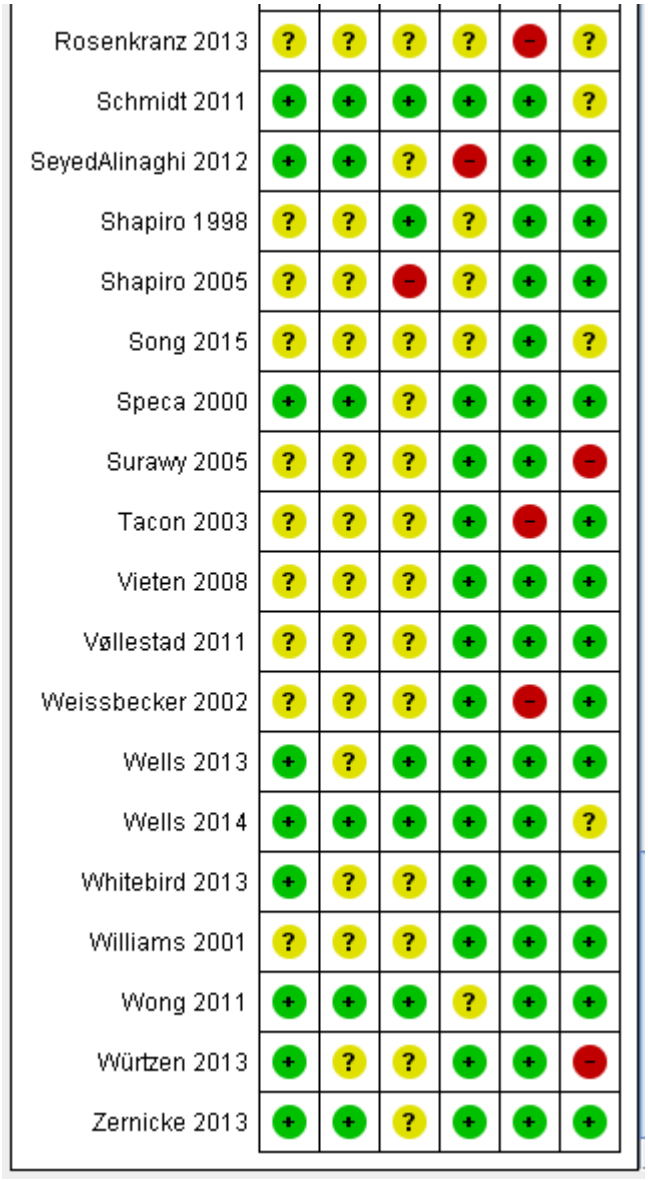


Figure 3.Methodological quality summary: review authors' judgments about each methodological quality item for each included study.

11. Appendices

11.1 Appendix 1: Study inclusion and exclusion form

STUDY INCLUSION AND EXCLUSION FORM MBSR REVIEW					
Reference ID:			**Reviewer ID**: **Date**:		
Author:			**Year of publication:**		
1.	**Reported data from a primary study**	**Yes**	**No**	**Uncertain**	**Notes**
2.	**Two or more groups randomised to intervention or control**				
3.	**The intervention is described as MBSR**				
4.	**The duration of the MBSR intervention is 8 weeks**				
5.	**The study population includes adults**				
6.	**The study aims to estimate/measure the effect of MBSR only** (E.g. exclusion criteria is MBSR plus something else vs. no intervention)				
7.	**Study reports numeric data on at least one indicator of health, quality of life or social function**				
8.	**The study is included**				
	Additional comments:				

11.2 Appendix 2: Coding and data extraction form

CODING AND DATA EXTRACTION FORM MBSR REVIEW	
Reference ID:	**Reviewer ID**:
Study ID:	**Date**:
Year of Publication:	

Author:
Notes:
STUDY DESIGN
1. Intervention group(s) were formed by:
Random assignment:
Other (specify):
Not reported:
Description unclear
2. Control group(s) were formed by:
Random assignment:
Other (specify):
Not reported:
Description unclear:
3. If random assignment specify:
Individual randomisation:
Cluster (group) randomisation:
Other (specify):
Not reported:
Description unclear:
4. How was random assignment performed?
Computer generated:
Random numbers table:
Coins/dice/shuffling:
Other (Specify):
Not reported:
Unclear description:
5. What method was used to conceal the allocation sequence?
(Was allocation adequately concealed, could assignments have been predicted?)
Sealed numbered/ coded envelope:
Telephone:
No concealment:
Other (specify):
Not stated:
Unclear description:
Blinding of intervention – not applicable due to the nature of the intervention

6. Were the outcome assessors' blinded? (Assessors unaware of assignment when collecting outcome measures)
Yes:
No:
Not reported:
Unclear from description:

7. Other concerns about bias?
If yes describe here:

PARTICIPANTS

8. Target population: Type of primary health problem/condition:
Clinical:
Non-Clinical:
(Such as students, inmates, impoverished inner city dwellers and corporate employees.)

9. Are inclusion criteria for study participation mentioned?
NO:
YES:
If yes, describe see below:
If clinical, specify main problem:
- Cardiovascular:
- Musculoskeletal:
- Psychological:
- Oncology:
- Respiratory:
- Rheumatological:
- Other (specify):
If non-clinical, specify:
Both clinical and non-clinical, specify:

10. Are exclusion criteria for study participation mentioned?
NO:
YES:
If yes, describe (cite pg. no.):

STUDY SAMPLE

11. Number of cases in sample	MBSR n= (Add columns as required)	Control n=	Total n=	Notes & pp. no.

		(Add columns as required)		
a. Eligible sample size				
b. Number randomised				
c. In final sample at start of treatment				
d. Completed treatment				
e. End point measurement				
f. % Attrition and reasons				

BASELINE CHARACTERISTICS OF PARTICPIANTS

12. Were there any differences between program and control groups at baseline?

Yes (describe differences):

No:

Not reported:

13. Was there any analysis of differences between completers and dropouts in the MBSR group?

Yes (describe differences):

No:

Not reported:

14. Was there any analysis of differences between completers and dropouts in the control group?

Yes (describe differences):

No:

Not reported:

15. Was intention to treat analysis used by investigators?

Yes:

No:

Not reported :

If yes, describe:

(E.g. last measure used, or analysis explores best and worst measure scenarios etc.)

20. OUTCOME CHARACTERISTICS

Instrument/unit	Outcome definition	Timing of measurement			
	What does the scale measure, e.g. stress, depression, or a combination? Direction of scale. Is the described as validated? Cite how the study has described this outcome.	State exact times within the categories below			
		<3months	3-6 months	> 6-12 months	>12 months
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					

21. RESULTS: Data will be extracted as reported and entered in excel and exported into revman5

Outcome	Intervention group 1		Control 1		Between group analysis
	Baseline	Final	Baseline	Final	Values for
	Median	Median	Median	Median	p
	Mean	Mean	Mean	Mean	df
	(SD)	(SD)	(SD)	(SD)	t
	(SMD)	(SMD)	(SMD)	(SMD)	f
	(SE)	(SE)	(SE)	(SE)	other
1.					
2.					
3.					
4.					

5.					
6.					
7.					
8.					
9.					
10.					

22. Outcome bias

Are there outcomes that were measured but not report?

If yes, are reasons reported?

23. Miscellaneous:

Specific source of funding

- Pharmaceutical industry:
- Internal funds:
- Professional org.:
- Other industry:
- Government:
- Other (specify):

Key conclusions of study authors:

Special comments by study authors:

Comments by reviewers:

Reference to other studies:

Contact details of the authors:

Need to contact authors:

If yes list issue(s), content and date contacted:

Additional comments:

11.3 Appendix 3: Search terms

PsycINFO 1806 to October Week 2 2015
21.10.2015

1	meditation/
2	meditat*.ti,ab.
3	mindfulness/
4	mindfulnes*.ti,ab.
5	mbsr*.ti,ab.
6	or/1-5
7	empirical methods/
8	experimental methods/
9	quasi experimental methods/
10	experimental design/
11	between groups design/
12	followup studies/
13	repeated measures/
14	experiment controls/
15	experimental replication/
16	exp "sampling (experimental)"/
17	placebo/
18	clinical trials/
19	treatment effectiveness evaluation/
20	experimental replication.md.
21	followup study.md.
22	prospective study.md.
23	treatment outcome clinical trial.md.
24	placebo*.tw.
25	randomi?ed controlled trial*.tw.
26	rct.tw.
27	random allocation.tw.
28	(randomly adj1 allocated).tw.
29	(allocated adj2 random).tw.
30	((singl* or doubl* or treb* or tripl*) adj (blind* or mask*)).tw.
31	(clinic* adj (trial? or stud*)).tw.

32	or/7-31
33	comment reply.dt.
34	editorial.dt.
35	letter.dt.
36	clinical case study.md.
37	nonclinical case study.md.
38	animal.po.
39	human.po.
40	38 not (38 and 39)
41	or/33-37,40
42	32 not 41
43	6 and 42
44	("2013" or "2014" or "2015").dp,up,yr.
45	43 and 44

Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present
21.10.2015

1	Meditation/
2	Mindfulness/
3	meditat*.ti,ab.
4	mindfulnes*.ti,ab.
5	mbsr*.ti,ab.
6	or/1-5
7	randomized controlled trial.pt.
8	controlled clinical trial.pt.
9	randomized.ab.
10	placebo.ab.
11	drug therapy.fs.
12	randomly.ab.
13	trial.ab.
14	groups.ab.
15	or/7-14
16	exp animals/ not humans.sh.
17	15 not 16
18	6 and 17
19	("2013" or "2014" or "2015").dc,dp,ed,rd,up,yr.
20	18 and 19

Embase 1974 to 2015 October 20
21.10.2015

1	meditation/
2	meditat*.ti,ab.
3	mindfulness/
4	mindfulnes*.ti,ab.
5	mbsr*.ti,ab.
6	or/1-4
7	clinical trial/
8	randomized controlled trial/
9	randomization/
10	double blind procedure/
11	single blind procedure/
12	crossover procedure/
13	placebo/
14	placebo effect/
15	placebo*.tw.
16	randomi?ed controlled trial*.tw.
17	rct.tw.
18	random allocation.tw.
19	randomly allocated.tw.
20	allocated randomly.tw.
21	(allocated adj2 random).tw.
22	single blind*.tw.
23	double blind*.tw.
24	((treble or triple) adj blind*).tw.
25	prospective study/
26	or/7-25
27	case study/
28	case report.tw.
29	abstract report/
30	letter/
31	human/
32	nonhuman/
33	animal/
34	animal experiment/

35	or/32-34
36	35 not (31 and 35)
37	or/27-30,36
38	26 not 37
39	6 and 38
40	("2013" or "2014" or "2015").dd,dp,rd,yr.
41	39 and 40

AMED (Allied and Complementary Medicine) 1985 to October 2015 **21.10.2015**

1	meditation/
2	meditat*.ti,ab.
3	mindfulnes*.ti,ab.
4	mbsr*.ti,ab.
5	or/1-4
6	("2013" or "2014" or "2015").up,yr.
7	5 and 6

Cochrane Central Register of Controlled Trials (CENTRAL) (Wiley) **22.10.2015**
#1 MeSH descriptor: [Meditation] explode all trees
#2 MeSH descriptor: [Mindfulness] explode all trees
#3 (meditat* or mindfulnes* or mbsr*):ti,ab,kw
#4 #1 or #2 or #3 Publication Year from 2013 to 2015, in Trials
CINAHL (Ebsco) **27.10.2015**
S12 S5 AND S11
S11 S6 OR S7 OR S8 OR S9 OR S10
S10 AB compar* N2 (study or studies)
S9 TI compar* N2 (study or studies)
S8 AB random* or control* or trial* or group* or placebo* or experiment* or evaluat* or prospectiv*
S7 TI random* or control* or trial* or group* or placebo* or experiment* or evaluat* or prospectiv*
S6 SU randomized controlled trials
S5 S1 OR S2 OR S3 OR S4
S4 AB meditat* or mindfulnes* or mbsr*
S3 TI meditat* or mindfulnes* or mbsr*
S2 SU mindfulness
S1 SU meditation
Ovid Nursing Full Text Plus 1950 to October 2015 **21.10.2015**

1	meditation/
2	mindfulness-based stress reduction/
3	meditat*.ti,ab.

4	mindfulnes*.ti,ab.
5	mbsr*.ti,ab.
6	or/1-4
7	("2013" or "2014" or "2015").cd,dp,ed,rd,up,yr.
8	6 and 7

ProQuest- **-British Nursing Index**
-ERIC **-ProQuest Medical Library** **-ProQuest Nursing & Allied Health Source** **-ProQuest Psychology Journals** **27.10.2015**
ti((meditat* OR mindfulnes* OR mbsr*) AND (random* OR control* OR trial* OR group* OR placebo* OR experiment* OR evaluat*)) OR ab((meditat* OR mindfulnes* OR mbsr*) AND (random* OR control* OR trial* OR group* OR placebo* OR experiment* OR evaluat*))Limits applied Narrowed by: Entered date: 2013 - 2015
Web of Science®
21.10.2015
3 #2 AND #1 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=2013-2015
2 TOPIC: (randomized) OR TOPIC: (placebo) OR TOPIC: (randomly) OR TOPIC: (trial) OR TOPIC: (groups) OR TOPIC: (controlled) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=All years
1 TOPIC: (meditat*) OR TOPIC: (mindfulnes*) OR TOPIC: (mbsr*) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=All years
SveMed+
22.10.2015
1 exp:"meditation" 2 exp:"mindfulness" 3 medit* 4 mindfulnes* 5 mbsr* 6 #1 OR #2 OR #3 OR #4 OR #5
Social Services Abstracts (ProQuest) **22.10.2015**
(su(meditation) OR su(mindfulness) OR ti(meditat* OR mindfulnes* OR mbsr*) OR ab(meditat* OR mindfulnes* OR mbsr*)) AND pd(20130101-20151231)
Sociological Abstracts (ProQuest) **21.10.2015**
((su(meditation) OR su(mindfulness) OR ti(meditat* OR mindfulnes* OR mbsr*) OR ab(meditat* OR mindfulnes* OR mbsr*)) AND (su("randomized controlled trials") OR su(placebo) OR ti((random* OR control* OR trial* OR group* OR placebo* OR experiment* OR evaluat*)) OR ab((random* OR control* OR trial* OR group* OR placebo* OR experiment* OR evaluat*)) OR ti(prospectiv* OR (compar* within 2 (trial* OR study OR studies))) OR ab(prospectiv* OR (compar* within 2 (trial* OR study OR studies))))) AND pd(20130101-20151231)
International Bibliography of the Social Sciences (Ovid) **27.10.2015** (su(meditation) OR su(mindfulness) OR ti((meditat* OR mindfulnes*)) OR ab((meditat* OR mindfulnes*)) OR ti(mbsr*) OR ab(mbsr*)) AND (ti((random* OR control*)) OR

ab((random* OR control*)) OR ti((trial* OR group*)) OR ab((trial* OR group*)) OR ti((placebo* OR experiment*)) OR ab((placebo* OR experiment*)) OR ti((evaluat* OR prospectiv*)) OR ab((evaluat* OR prospectiv*)) OR ti(compar*NEAR/2 study OR studies)) AND pd(20130101-20151231)

CampbellCollaboration

About this review

Stress and stress-related mental health problems are major causes of illness and disability. Mindfulness-based stress reduction (MBSR) is a group-based health promotion intervention to improve health and the way people deal with stress and life's challenges. The core ingredient is mindfulness training through physical and mental exercises practiced daily for eight weeks. The mindful non-judgmental attitude of being present with what arises is practiced in the formal exercises and in everyday situations.

This review assesses the effect of MBSR programs on outcome measures of mental and physical health, quality of life and social functioning in adults.

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