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Mindfulness Based Stress Reduction (MBSR) for Improving Health, Quality of Life, and Social Functioning in Adults

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Campbell Systematic Reviews

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Table of contents

Key messages

Mind-body interventions to manage stress-related health problems are of widespread interest. One of the best known methods is mindfulness-based stress reduction (MBSR), and MBSR courses are now offered by health services, as well as in social and welfare settings. In this systematic review, we report on the effects of MBSR interventions on health, quality of life, and social functioning. From the more than 3,000 potentially relevant references identified in two extensive searches, we included 31 relevant studies with an overall total of 1,942 participants, each of whom had been randomised to receive MBSR or other treatment strategies (most often a waiting list control). We utilised all outcome data published in the selected studies using a new statistical method for calculating the effect size. This method addressed the problems presented by the interdependence of many measurements of outcomes.

26 of the 31 studies were identified as having data suitable for meta-analysis. MBSR was found to have a moderate and consistent positive effect on mental health outcomes in both patients selected with somatic problems and with mild to moderate psychological problems, and among participants recruited from community settings. MBSR interventions improved outcomes measuring different aspects of personal development and quality of life. The effects on somatic health outcomes were somewhat smaller. No adverse effects were described. Few studies were found that evaluated the impact of MBSR on social functioning, such as the ability to work.

Executive summary/Abstract

BACKGROUND

Stress and distress are common experiences central to many of the problems occupying health and social services and efforts to improve both health and quality of life are receiving increasing attention. Evaluative research on mind-body interventions is also growing and one of the best studied efforts to reduce stress is mindfulness-based stress reduction (MBSR). Developed by Kabat-Zinn in 1979, MBSR is based on old spiritual traditions and includes regular meditation. Mindfulness is a way of intentionally attending to the present moment in a non-judgemental way. A number of reviews and meta-analyses on MBSR have been conducted, but few have adhered to the meta-analytic protocol stipulated by the Cochrane and Campbell collaborations. The last review of all relevant target groups was published in 2004.

OBJECTIVES

To evaluate the effect of mindfulness-based stress reduction (MBSR) on health, quality of life, and social functioning in adults.

SEARCH STRATEGY

We searched all relevant databases: MEDLINE, AMED, PsycINFO, EMBASE, Ovid Nursing Full Text Plus, the British Nursing Index and Archive, the Cochrane Central Register of Controlled Trials (CENTRAL), SIGLE, Web of Science®, SveMed+, Dissertation Abstracts International, ERIC, Social Services Abstracts, Sociological Abstracts, the International Bibliography of Social Sciences, and ProQuest. The searches were conducted in July 2008 and again in September 2010.

SELECTION CRITERIA

Randomised controlled trials on all target groups were included where the intervention followed the MBSR protocol developed by Kabat-Zinn, allowing for variations in the length of the MBSR courses. We accepted all types of control groups and no language restrictions were imposed.

DATA COLLECTION AND ANALYSIS

Two reviewers independently read the titles, retrieved the studies, and extracted data from all the included studies. We calculated standardised mean differences (expressed as Hedges' g-values) from all of the study outcomes using Comprehensive Meta Analysis. The meta-analyses were undertaken using the Metafor Package which is part of the statistical program 'R'; we used a newly developed technique (Robust Standard Errors) to address the statistical challenge presented by clusters of internally correlated effect estimates.

RESULTS

We identified 31 RCTs with an overall total of 1,942 participants. Seven studies included people with mild to moderate psychological problems, 13 studies targeted people with various somatic conditions, and 11 studies recruited people from the general population. 26 of the 31 RCTs were used for the meta-analyses (an overall total of 1,456 persons). All effect sizes are expressed using Hedges' g-values, and positive values indicate beneficial effects. Post-intervention effect sizes were as follows: for measures of anxiety 0.53 (95% CI 0.43, 0.63), for depression 0.54 (95% CI 0.35, 0.74), and for stress/distress 0.56 (95% CI 0.44, 0.67). The overall effect size post-intervention for the combined outcome 'mental health' was 0.53 (95% CI -0.43, 0.64). Heterogeneity was low and tau square-values (for between-study variance) ranged from 0 to 0.03. The results for measures of personal development were 0.50 (95% CI 0.35, 0.66), quality of life 0.57 (95% CI 0.17, 0.96), mindfulness 0.70 (95% CI 0.05, 1.34), and somatic health 0.31 (95% CI 0.10, 0.52). Results for quality of life and mindfulness showed moderate to large heterogeneity.

Effect sizes for the combined mental health outcomes were relatively similar across the range of target groups: 0.50 for clinical and 0.62 for non-clinical populations and this difference is not significant. Likewise the effect size was 0.51 both for people recruited because of a somatic condition and for those with a mental health problem. Effect sizes for mental health were not particularly influenced by the length of intervention, self-reported practice, risk of bias, or whether analyses were done as intention to treat or per protocol, but they were positively correlated with course attendance. Only nine studies included follow-up data; the effects diminished over time except in one study in which refresher classes were held. Very little data were found on social functioning, and no information at all on side effects and costs.

AUTHORS' CONCLUSIONS

MBSR has a moderate and consistent effect on a number of measures of mental health for a wide range of target groups. It also appears to improve measures of personal development such as empathy and coping, and enhance both mindfulness, quality of life and improve some aspects of somatic health. Hardly any included

studies measured either social function or work ability. There is a paucity of data on long-term effects.

1 Background

1.1 DESCRIPTION OF THE CONDITION

Stress is ubiquitous in modern life. While some people are prompted to respond positively to it, more often than not it exerts a negative influence. At its worst, stress destroys lives. The demands of life are external but stress is generated from within and stressors may be real or imagined. How we handle situations, persons and emotions – in other words, how we become stressed or manage to keep calm – is central to staying healthy, coping with illness and enjoying life. These are skills that can be practised and exercised.

Prevalence rates for distress and mild to moderate psychological problems are high among children, adolescents and adults, and associated chronic musculoskeletal pain is common. While our understanding of such widespread problems is limited, we do know that stress is probably both a cause and a consequence of them.

Stress is also part of our everyday working life. In a series of surveys undertaken at five year intervals in the European Union, stress was identified as the second most common threat posed by working environments and an issue affecting a fifth of the workforce at any time (European Risk Observatory, 2009). Stress can lead to an increased risk of disease, including cardiovascular disease (Cohen, 2007; Chandola, 2008). Likewise there is mounting evidence that stress caused by traumatic life events increases the risk of chronic somatic and psychological problems affecting health and quality of life (McEwen, 2008); adverse childhood experiences are especially harmful (Brown, 2009).

1.2 DESCRIPTION OF THE INTERVENTION

Mindfulness-Based Stress Reduction, or MBSR, is a well described group-based mind-body intervention programme that has received considerable research attention (Kabat-Zinn 1990). 'Mindfulness' may be defined as the ability to non-judgementally observe sensations, thoughts, emotions, and the environment while, at the same time, encouraging openness, curiosity and acceptance. An MBSR programme to develop and strengthen this skill was developed by the University of Massachusetts Medical Center in 1979 as an intervention designed to relieve stress

and help people cope with illness. This programme is now offered at several hundred healthcare institutions in the USA and Europe (Santorelli, 1999). Target groups include people with chronic physical pain, illnesses such as cancer, or mental illnesses, including anxiety, depression or burnout. In addition, the programme has been applied to non-clinical populations, including students, therapists and prison inmates.

The standard MBSR mindfulness training is an eight week group programme with weekly sessions of between 2-2 ½ hours and an all-day session in the last two weeks. Shorter weekly sessions (30-90 minutes) may be offered as an alternative, and some programmes omit the all day session entirely. Weekly sessions include mental and physical mindfulness exercises as standardised core elements. These include: body scan exercises in which 'neutral attention' is directed towards sensations from the different parts of the body when sitting or lying still (in other words, participants observe these sensations without trying to achieve any particular objective); mental exercises focusing attention on breathing; physical exercises focussing on an awareness of bodily sensations; and practising being fully aware during everyday activities by using breathing as an anchor for attention. Essential to all parts of the programme is the development of an accepting and non-reactive attitude to what one experiences in each moment. The intervention is rooted in ancient Buddhist Vipassana ('insight') and Shamatha ('focussed') meditation and yoga exercises. However, it is free from religious purpose or affiliation and is described using only Western terminology.

In addition to the exercises, information (and a discussion) is provided and discussion is facilitated on the topics of stress, stress management, and how to apply mindfulness to interpersonal communication and everyday situations. Each group session includes time for participants to reflect together on what they experience while practising mindfulness. Outside the sessions, participants are encouraged to practice each day for 30-45 minutes while listening to audiotapes and using the guided exercises (these include body-scanning, the mindfulness sitting exercise which focuses on breathing, as well as yoga stretching exercises). The group usually includes 10-30 members and is led by one or two trained instructors.

1.3 HOW THE INTERVENTION MIGHT WORK

The MBSR programme provides systematic training in mindfulness as a self-regulation strategy to reduce stress and manage emotion. The programme is intended to foster greater awareness of what happens in each moment through the application of an attitude of acceptance. MBSR is designed to help people avoid habitual negative thoughts, emotions and behavioural patterns. Instead, increased awareness and acceptance is seen as allowing for new ways to respond and cope both in relation to oneself and the wider world. Mindfulness training has been linked to changes in areas of the brain responsible for affect regulation, and to stress impulses reactions; in turn, these changes influence body functions such as

breathing, heart rate and immune function (Davidson, 2003; Lazar, 2005; Hölzel, 2010).

1.4 WHY IT IS IMPORTANT TO DO THIS REVIEW

MBSR is increasingly widespread and it is important therefore to find out whether it is effective, for whom, and under what circumstances. Knowing such details can help to guide future research. A number of recent published reviews have suggested overall that MBSR may be effective in reducing the symptoms of anxiety, depression and stress. However, most such reviews have been narrative reviews rather than meta-analyses. This has led Hofmann et al. (Hofmann, 2010) to argue that "the field has become saturated with qualitative reviews" (p.170).

Quantified effect sizes in other meta-analyses we have identified were based on randomised controlled trials combined with quasi-experimental design studies (Baer, 2003; Carmody, 2009; Grossman, 2004; Ledesma, 2009; Hofmann, 2010). Baer found an overall Hedges' g-value of effect size of 0.59 for all outcomes, but this included both MBSR and Mindfulness Based Cognitive Therapy (MBCT) studies. Similarly, Carmody calculated an overall Hedges' g-value for effect size of 0.63 for psychological outcomes, but included control groups with both treatment-as-usual, waiting-list, and alternative treatments. Grossman reported an overall Cohen's d-value of effect size of 0.5 for studies of MBSR with combined outcomes of physical and mental well-being. Hofmann also included MBSR and other interventions like mindfulness based cognitive therapy in the same meta-analysis, reporting an overall Hedges' g-value of effect size for anxiety of 0.63 and 0.59 for mood symptoms. Bohlmeijer et al. (2010) included only controlled MBSR studies, and calculated an overall Hedges' g-value of effect size of 0.47 for anxiety outcomes and 0.32 for psychological distress outcomes. However the authors grouped together studies using waiting-list controls and studies where the control group was offered alternative active treatment.

A health technology assessment report from 2007 (searches conducted up to 2005) identified five broad categories of meditation practices of which mindfulness meditation was one (Ospina, 2007). In this instance, the meta-analysis was focussed on effects on hypertension, cardiovascular disease and substance abuse, and it did not specifically evaluate MBSR.

2 Objectives

To assess the effectiveness of MBSR in improving health, quality of life, and social functioning in adults.

3 Methods

3.1 CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

3.1.1 Types of studies

Studies of mind-body interventions such as MBSR are especially prone to bias introduced by the self-selection of study participants to intervention or control groups. For this reason, we have only included RCTs in this systematic review. We expected to find a sufficient number of such studies.

3.1.2 Types of participants

MBSR is a general method for self-regulation that has been applied to a variety of target groups: we therefore included all populations. There were two exceptions to this approach: both children (under the age of 18) and persons with cognitive impairment or severe mental illness were not included. This was because children are less able to be self-aware; MBSR is dependent on the ability of individuals to pay attention and to be able to remember from one moment to the next.

3.1.3 Types of interventions

We included studies of MBSR training programmes which had been based on the protocol elements specified by John Kabat-Zinn (Kabat-Zinn, 1990). This meant that to be considered, the intervention had to be explicitly termed 'MBSR' and contain all four of the requisite core elements, namely: body-scan exercises, mental exercises focusing attention on breathing, physical exercises focussing on the awareness of bodily sensations, and the practice of being fully aware during everyday activities. Studies of varying MBSR course duration and intensity were included. Studies that combined MBSR with other therapeutic approaches, such as cognitive therapy or art therapy, were excluded.

Waiting lists and treatment-as-usual were acceptable control groups. RCTs in which the control group had been offered alternative active treatment were also included, but these were analysed separately.

3.1.4 Types of outcomes

Primary outcomes were measures of mental health (anxiety, depression and stress/distress), somatic health (self-reported physical health inventories and somatic measures related to antibodies, heart rate or respiratory functions) and quality of life (only including measures designed specifically to measure quality of life, such as the WHO Quality Of Life Inventory). Secondary outcomes were social functioning (such as the ability to work, sickness rates, and self-reported measures of social functioning e.g., The Social Functioning Questionnaire SFQ) and measures of personal development (e.g., self-acceptance, empathy, coping and forgiveness). The different measurement scales and outcome groups are listed in additional Tables 4 and 5.

3.2 SEARCH METHODS FOR IDENTIFICATION OF STUDIES

3.2.1 Electronic searches

Electronic searches of bibliographic databases and open websites were conducted. We examined reference lists from the articles under consideration and asked key researchers within the field for information. In addition, we searched for 'grey literature' trials and for ongoing studies registered at www.clinicaltrials.gov. No publication, geographic, or language restrictions were applied.

3.2.2 Search terms

The following sources were searched at the outset of the project in July 2008 and again in September 2010:

MEDLINE
AMED (Allied and Complementary Medicine)
PsycINFO
EMBASE
Ovid Nursing Full Text Plus
British Nursing Index and Archive
Cochrane Central Register of Controlled Trials (CENTRAL)
SIGLE
Web of Science®
SveMed+
Dissertation Abstracts International
ERIC
Social Services Abstracts
Sociological Abstracts
International Bibliography of Social Sciences
ProQuest

The Cochrane Collaboration' search strategy includes a RCT search filter for identifying randomised trials in MEDLINE and this was used when searching this database. This filter was subsequently modified for other database searches. Appendix 15.1 contains full documentation of all the search terms used.

3.3 DATA COLLECTION AND ANALYSIS

3.3.1 Selection of studies

Two reviewers independently read the titles and available abstracts of the studies in order to exclude those that were obviously irrelevant. Any citation deemed potentially relevant by at least one reviewer was retrieved in full text form. Multiple papers reporting on the same study were linked together. Two reviewers (one with content expertise and the other with methodological expertise) independently read all the retrieved studies in order to determine whether they met the selection criteria (Appendix 12.1). The reviewers were not blinded to journal names, author names, author affiliations or the study results. Disagreements about the relevance of particular studies were resolved during discussions with a third reviewer with methodological expertise. Correspondence with investigators, where necessary, helped to clarify study eligibility. Those studies that met the screening criteria but did not meet all the inclusion criteria are listed in Section 11.2 (Characteristics of Excluded Studies), together with the reasons for their exclusion.

3.3.2 Data extraction and management

Information on study design and implementation, sample characteristics, intervention characteristics, and outcomes was extracted from studies. This information was entered on a paper form (see Appendix 15.3). The data extraction form included a coding list which was piloted on two of the selected studies at the outset of the data extraction phase. Two reviewers independently extracted data from all the studies. Disagreements were resolved through discussions with a third reviewer with relevant methodological expertise.

3.3.3 Assessment of risk of bias in included studies

Risk of bias was evaluated according to the criteria stated in the Cochrane Handbook (Higgins, 2008). Two independent reviewers assessed the issues of sequence generation, allocation concealment, the blinding of outcome assessors, the completeness of outcome data, outcome reporting, and any other potential sources of bias. Using the GRADE approach, further analysis of the quality of evidence was undertaken related to each of the key outcomes (Guyatt, 2008; Higgins, 2009). The quality of the body of evidence for each key outcome was rated 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, 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 four studies the effect sizes were calculated from other data; in Astin (1997) from the F-values for the difference in change in the MBSR and control group; in Cohen-Katz (2005) and Creswell (2008) from the difference in mean change between the MBSR and control group and the corresponding p-values; and in Grossman (2010) from the difference in mean change between the intervention and control group and the corresponding F- values.

3.3.5 Unit of analysis issues

We assessed the unit of analysis of all the trials: one study was found to have randomised couples rather than individuals. The robust standard error analysis we used (see below) was able to process the data while accommodating for such dependencies.

3.3.6 Dealing with missing data and incomplete data

Study authors were contacted if missing information was needed (related, for example, to standard deviations). Most authors did not respond or were unable to retrieve the data. Some studies presented data visually and this made it possible to read data from the graphs (Anderson, 2007; Davidson, 2003; Plews-Ogan, 2005; Shapiro, 1998; Williams, 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, 2007; Davidson, 2003; Lengacher, 2009; Moritz, 2006; Plews-Ogan, 2005; Williams, 2001). In only one instance was a study excluded from the analysis due to a lack of information (no SD or SE) (Alterman, 2004).

Means and standard deviations values were based on those stated in the original study publications, irrespective of how such missing data may have been processed in the primary analysis.

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 tau2 values (where <0.05 indicates low heterogeneity). The percentage of the total variability due to heterogeneity was estimated using I2 values; 0% representing

no heterogeneity, 50% indicating moderate heterogeneity and 75% indicating high heterogeneity (Higgins, 2003).

3.3.8 Assessment of publication bias

We investigated possible reporting biases using funnel plots and tested for funnel plot asymmetry using Egger's regression test (Egger, 1997).

3.4 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 (see Table 13.4). The majority of the studies identified included multiple measures of the same construct, and the sizes of effect were typically calculated 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, 2010).

This technique calculates standard errors using an empirical estimate of the variance: it does not require any assumptions regarding the distribution of the 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. 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 et al (Hedges, 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 the results we calculated, weights were used based on estimates of τ^2 and I2, where $\rho = 0.80$. 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 I2) 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 were often fairly similar) and the measurement of correlation (which were consistently high) cast doubt on whether the standard methods of measuring anxiety and depression do, in fact, always tap into different constructs in practice. The described analyses are therefore an explicit attempt to look at this difficult issue using both such approaches.

This 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.

3.4.1 Subgroup analysis, moderator analysis and investigation of heterogeneity

Theoretical and empirical reasons suggest that, by and large, one may expect similar effects across chosen target groups, varieties of an intervention, and relevant outcomes. Nevertheless the following subgroup analysis was undertaken in order to explore potential differences in effects on mental health:

- Clinical and non-clinical samples (expecting a somewhat larger effect in studies of patients with established health problems compared to studies where participants were recruited from the general population)
- Psychological and somatic conditions (expecting a somewhat larger effect in studies of participants with psychological distress compared to studies of people with somatic problems)
- Effect of length of the MBSR intervention (expecting a somewhat smaller effect in studies that used a shorter MBSR programme compared to a standard approach)
- Effect of compliance (expecting a somewhat larger effect in studies where participants generally attended most of the programme versus studies where attendance was lower, and in studies where people spent more rather than less time practising at home)
- Effect of follow-up time (expecting effect sizes to diminish over time in studies with a longer follow-up period)
- Risk of bias (expecting a larger effect in studies with higher risk of bias). In this particular analysis we used the risk of bias scores as a scale
- Whether or not the authors claimed to have done an intention to treat (ITT) analysis (expecting somewhat lower effect estimates in studies that reported ITT analyses).

Each of these questions was investigated using a separate bivariate regression model. Each model was estimated using the robust standard error method outlined above (Hedges, 2010). Since this robust standard error method uses degrees of freedom based on the number of studies (rather than the total number of effect sizes), we elected to apply individual regression models instead of combined models. In Appendix 12.4 we provide a correlation matrix for the following variables: clinical (vs. non-clinical) samples, clinical somatic (vs. clinical psychological) samples,

length of MBSR invention, attendance, follow-up time, risk of bias, and if the analysis was based on an intention-to-treat effect.

4 Results

4.1 RESULTS OF THE SEARCH

The original search in July 2008 identified 2,162 potentially relevant articles; a second search in September 2010 found 972 additional references. Based on our screening and inclusion criteria 31 studies were included in the review.

4.2 DESCRIPTION OF THE STUDIES

4.2.1 Included studies

The characteristics of the included studies are listed in Table 10.1 and 11.1. 20 studies recruited people with health problems: 13 of these included patients with somatic conditions (musculoskeletal disease, cancer, other chronic illness, HIV, cardiovascular disease and substance abuse (Bränström, 2010; Creswell, 2007; de Vibe, 2006; Grossman, 2010; Lengacher, 2009; Monrone, 2008; Plews-Ogan, 2008; Pradhan, 2007; Sephton, 2007; Speca, 2000; Speca, 2000; Surawy, 2005; Tacon, 2003). Seven studies included persons with psychological conditions (stress/distress, anxiety, mood disorder, aggression and stuttering) (Alterman, 2004; de Veer, 2009: Koszycki, 2007; Moritz, 2006; Nyclicek, 2008; Vieten, 2008; Willliams, 2001). 11 studies included people from the general population (Anderson, 2007; Carson, 2004; Cohen-Katz, 2005; Davidson, 2003; Klatt, 2009; Shapiro, 2005); five such studies used student samples (Astin,1997; Jain, 2007; Murrey, 2004; Oman, 2008; Shapiro, 2005). One study included prisoners (Murphy, 1995). Altogether 1,942 persons were randomised; 26 studies compared MBSR with waiting-list or treatment-as-usual controls.

Three of the studies included another intervention group in addition to the waitlist control group (Jain, 2007; Moritz, 2006; Plews-Ogan, 2005) and in these cases we used only the data from the comparison of MBSR with the waitlist controls. The results of four additional included studies were reported separately because they compared MBSR with other active interventions. Creswell (Creswell, 2008), for example, compared a standard eight-week MBSR course with a one-day MBSR course. Koszycki (Koszycki, 2007) compared MBSR with MBCT. Murphy (1994) compared MBSR with progressive relaxation training. And Oman (2008) compared MBSR with a generally similar mindfulness training called Easwaran's Eight-Point

Program (EPP), and with treatment-as-usual. In this paper, only combined data from the groups receiving MBSR or EPP were reported.

In addition, we included – but could not use – data from one study (Alterman, 2004; see 'Studies where data could not be used in the meta-analysis'). Two studies were reported in two publications: Sephton (Sephton, 2007) also presented results in Weissbecker (Weissbecker, 2002), and one study was presented both by Tacon (2002) and Robert-McComb (2004).

4.2.2 Excluded studies

188 studies were excluded either because they were neither primary studies nor RCTs, or because the intervention did not conform to the MBSR protocol. Reasons for exclusion are listed in Table 11.2.

4.2.3 Studies awaiting classification

Four studies are awaiting classification (Esmer, 2010; Schmidt, 2011; Vøllestad, 2011; Wong, 2011).

4.3 RISK OF BIAS IN INCLUDED STUDIES

4.3.1 Allocation concealment

The quality item with the lowest score was allocation concealment. Only nine studies reported adequate concealment of allocation. Most studies failed to state clearly how randomisation had been achieved.

4.3.2 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 ten studies.

4.3.3 Incomplete outcome data

Attrition was 15% overall and 25 studies reported all data, while only four studies had a definite incomplete reporting of all results. Nine studies reported intention to treat analyses data, and they used the last observation carried forward as the method for imputing missing data.

4.3.4 Selective reporting

Assessing publication bias, we detected no important funnel plot asymmetry (see Figure 13.13) and the Egger's r-test for funnel plot symmetry indicated an intercept value of 0.95 (95% CI -0.24, 2.15). When applied, a Fail-Safe N (Rosenthal,1979) analysis showed that the number of missing trials needed to raise the p-value to >0.05 was 689; a Fail- safe N (Orwin, 1983) analysis showed that the number of

missing studies with zero effect – that would reduce the Hedges's g-value to <0.2 (indicating a small effect) – was 44.

4.3.5 Other sources of bias

Many studies are carried out by researchers believing in the intervention and who also provide the intervention and are responsible for the assessment. 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 changed group after randomization (Oman, 2008), and some participants were given additional sessions with a therapist (Surawy, 2005).

4.4 EFFECTS OF THE INTERVENTIONS

4.4.1 MBSR vs. waiting-list/treatment-as-usual

All effect sizes are expressed using Hedges' g-values (Hedges 1985), and conventionally a value of 0.2-0.5 signifies a small effect, 0.5-0.8 a moderate effect and values >0.8 signifies a large effect of the intervention (Cohen, 1988). Positive values indicate beneficial effects.

Converting effect sizes to percentile values is a useful way to illustrate possible clinical importance: an effect size of 0.53, for example, indicates that the average person in the intervention group will be placed at the 30th score percentile for the control group.

Table 11.5 and Figures 13.4-13.7 show that the average effects were fairly similar for anxiety (0.53, 95% CI 0.43, 0.63), depression (0.54, 95% CI 0.35, 0.74), stress/distress (0.56, 95% CI 0.44, 0.67) and other measures of mental health (0.48, 95% CI 0.34, 0.61). Values for heterogeneity, from tau square analysis, were very small and ranged from 0 to 0.003. 26 studies with 79 different outcome variables (of anxiety, depression, stress/distress and various other measures of psychological functions) contributed to the meta-analysis of mental health in which the robust standard error approach was used (Figure 13.8). The overall effect size for the composite measure of 'mental health' was 0.53 (95% CI 0.46, 0.61). Again, heterogeneity across the studies was low: the values were tau2 = 0 and I2 = 0.

The effects on measures of personal development (0.50, 95% CI 0.35, 0.66), quality of life (0.57, 95% CI 0.17, 0.96), and mindfulness (0.70, 95% CI 0.05, 1.34) were also of moderate size (Figures 13.9-13.11). However, as shown in Figure 13.12, the effect size was somewhat smaller for measures of somatic health (0.31, 95% CI 0.10, 0.52). Results for quality of life and mindfulness were somewhat heterogeneous across trials with tau2 values of 0.07 and 0.40.

For mental health as a composite outcome, there was an insignificant difference in effect size between studies in which persons were recruited because of stress or diagnosed problems (in other words, from clinical populations) and target groups which had been recruited from the general population (p=0.19). Likewise, studies of people with somatic problems as entry criteria achieved a very similar effect on average to those studies in which people with psychological difficulties were recruited (p=0.96) (Table 11.6).

The effect size for 'mental health' rose slightly with increasing intervention length (between 6 and 28 hours), but again this increase was not statistically significant (p=0.16).

18 studies reported on course attendance which ranged from 65% to 92%. There was a significant increase in effect on mental health for each hourly increase in attendance (reported as averages per study) (p <0.01). Only 13 studies described self-reported time spent practising MBSR techniques at home (with an average range per study of between 7 and 45 minutes). In this analysis, length of self-reported time spent practicing MBSR techniques at home did not appear to increase mental health outcome scores (p=0.44).

For follow-up time, we first compared the effect at post-intervention in studies with data (9 studies) and without follow-up data (17 studies) and found no difference. We then assessed the effect of the number of months of follow-up on the reported effect size. There was a slight, but statistically significant, decrease in effect size on 'mental health' for each additional month of follow-up (p<0.05).

A slight decrease in effect size was seen as risk of bias increased, but this finding was not statistically significant (p=0.29). Neither were there significant differences in effect sizes between those studies reporting results as intention to treat (ITT) analyses and studies reporting per protocol data (p=0.13).

Mindfulness was measured in seven studies (measures used are listed in additional Tables 2 and 3): six reported increases at the post-intervention stage, while one study showed an increase only at four months follow-up (Pradhan, 2007). Two studies performed mediation analysis, suggesting that the effect on the outcomes were mediated by the increase in mindfulness scores (Bränström, 2010, Nycklicek, 2008). Because few studies measured mindfulness and because we do not have access to data on individuals in the studies, further mindfulness mediator/moderator analyses could not be performed.

Unfortunately, very few studies measured social functioning. One study reported on ability to work, but the numbers of people involved were too small to allow conclusions to be drawn. There were no reports on adverse events or costs in any of the studies.

4.4.2 MBSR vs. Alternative active interventions

The data from these studies are treated separately and the effect sizes are not pooled.

Koszycki et al. (2007) compared an eight-week (27.5 hour) MBSR course with a 12-week (30 hours) cognitive behavioural therapy course for 53 patients with moderately severe social anxiety disorder. All sessions were videotaped and reviewed to assess protocol fidelity. Homework forms were reviewed each week. Both interventions produced meaningful clinical changes. The MBSR group showed high to moderate beneficial effect judged by within group Hedges' g-value effect sizes on measures of social anxiety (1.42, CIs not given), mood (0.66), disability (0.63), and quality of life (0.53). Patients in the cognitive therapy group improved significantly more than those in the MBSR group in terms of social anxiety. There were no between-group differences in the other outcomes. The MBSR programme had a dropout rate of only 15%.

Oman et al. (2008) compared an eight-week (12 hour) MBSR course with an alternative eight week (12 hour) programme (on Easwaran 8-point mindfulness), while the third group was a wait-list control group of 44 college students. Because the unreported data results were similar for both the MBSR and EPP participants, both groups were analysed together and compared to the wait-list control group. The between-group Hedges' g-values for effect sizes for the main outcomes at post-intervention (and at the eight weeks follow-up) were 0.44 (0.50) for perceived stress, 0.33 (0.44) for rumination, and 0.33 (0.30) for forgiveness (confidence intervals not given). There were no significant changes in measures of hope.

Murphy (1994) compared the effect of a six-session (12 hour) MBSR course with six two-hour sessions of progressive muscle relaxation (PMR) for 31 inmates who had alcohol abuse and aggression problems. No substantial differences were found on measures of anger (using the State Trait Anger Expression Inventory), egocentricity (using Self Focus Sentence Completion), and stress reactivity measured by the post-stress testing of salivary cortisol at the post-intervention stage.

Creswell et al. (2008) compared an eight week (24 hour) MBSR course with a one day (6 hour) MBSR course among 48 HIV+ people experiencing distress and scores of >4 on the Patient Health Questionnaire-9 scale). CD4+ T lymphocyte counts were shown to decrease in the one-day control group, but not among participants in the full MBSR course. The between-group Hedges' g-value of effect size was 0.74 (CI not given).

4.4.3 Studies where data could not be used in the meta-analysis

Alterman et al. (2004) compared the effect of an eight-week (23 hour) MBSR course with treatment-as-usual for 31 substance-abuse recovery inpatients at post-intervention and at five months follow-up (Alterman, 2004). The data were analysed using repeated measures analysis of variance at three time points. The intervention

group improved more than the control group in terms of self-reported medical problems when analysed as a group over three follow-up times (p=0.007). However, because only mean values were reported, a Hedges' g-value of effect size could not be calculated. No significant group differences were found for measures of psychological health.

5 Discussion

5.1 SUMMARY OF THE MAIN RESULTS

It is encouraging to see that the MBSR mind-body intervention has been analysed in substantial numbers of randomised controlled trials. This review has reported on more trials than ever before: 31 RCTs were selected, with a combined total of 1,942 participants. The overall effect size for the combined outcome of mental health was moderately large (Hedges' g-values = 0.53, 95% CI 0.46, 0.61). The effect sizes were remarkably similar across a range of target groups (with mild to moderate distress), intervention forms, outcome measures and settings. Heterogeneity was therefore low.

Many of the studies we included provided several different measures of the same construct and outcome measurements that were obviously interdependent. Failure to account for such dependencies – in other words, calculating an average 'anxiety effect' based on measurements with different anxiety scales – necessarily results in erroneous standard errors and will compromise any inferential statistics generated. Deciding on a criterion for electing only one outcome measure to include in the meta-analysis can be equally problematic. Statistical dependencies were also evident in follow-up measures post-test. As far as we know, this study is amongst the first to utilise a new method for estimating robust standard errors under such circumstances. This method makes it possible to use more information in the data-set than has traditionally been the case (Hedges, 2010).

5.2 OVERALL COMPLETENESS AND APPLICABILITY OF EVIDENCE

A number of MBSR evaluations have been published in this specialist knowledge field in the last decade. Baer identified four randomised trials in 2003 (Baer, 2003) and all of these are included in our study. Grossman (Grossman, 2004) reported on seven RCTs in 2004: one of these we classified as not being a randomised trial (Perkins, 1998). Carmody (2009) found 11 controlled studies: nine were classified by us as RCTs.

Later reviews have focussed on specific target groups. Ledesma & Kumano, for example, identified four trials on cancer patients (Ledesma, 2009). We have excluded three of these from our analyses – two because they included elements

other than those stipulated in the traditional MBSR protocol (Herbert, 2001; Monti, 2005), and one because it took the form of a quasi-experimental study (Shapiro 2003). Hofmann identified seven randomised trials measuring anxiety or depression (Hofmann, 2010) and all of these are included in our study. Bohlmeijer identified eight RCTs studying patients with a chronic medical condition (Bohlmeijer, 2010). Seven of these are included in this work, while one was excluded because it deviated from the standard MBSR protocol (Monti, 2005). Chiesa (Chiesa, 2009) included seven trial studies of healthy people, and all of these are included in our study.

Of the 26 studies used in our meta-analysis, five included persons with various psychological problems; 11 of the studies targeted people with various somatic conditions; and ten recruited people from the general population. The intervention effect has thus been evaluated across a broad spectrum of target groups. Study settings in a number of different countries (Norway, Sweden, Germany, Switzerland, Holland and the USA) contributed to the analysis, further serving to increase the applicability of the evidence.

Studies that implemented major modifications to the standard MBSR protocol were not included. However, studies of varying intervention length were accepted if the researchers had adhered to the MBSR principles as stated by Kabat-Zinn (Kabat-Zinn, 1990). Relatively few studies included follow-up data, and none included long-term follow-up data: the evidence therefore for the long-term effects of the intervention is clearly limited. All control groups received no treatment or treatment-as-usual. Control conditions therefore varied and it was often difficult to determine what the alternative conditions had been.

Unfortunately, only two trials provided data on social functioning (Nyklicek, 2008; de Vibe, 2006) and the ability to work (de Vibe, 2006) and there was a paucity of data related to functional outcomes. No explicit reporting on possible adverse effects or costs was provided. Such information should be addressed in future trials.

5.3 QUALITY OF THE EVIDENCE

The quality of the studies varied and the overall risk of bias was high for several studies (Davidson, 2003; Cohen-Katz 2005; Alterman, 2004; Astin, 1997; Lengacher, 2009; Murray 2004; Plews-Ogan, 2005; Shapiro, 2005; Weissbecker, 2002). However, it was encouraging that high-quality trials were also found (Bränstöm, 2010; Grossman, 2010; Jain, 2007; Moritz, 2006; Morone, 2008; Nyklicek, 2008; Pradhan, 2007; Speca, 2000). Effect sizes did not, however, differ significantly between studies carrying different risk of bias ($p = 0.32$, see additional tables 4). Judgements about evidence and recommendations in healthcare are complex. The GRADE system has been developed to improve judgements about the quality of evidence (GRADE, 2008). Grading of the evidence showed that the quality is high for evidence of effect on the composite score of mental health as well as for

measurements of stress/distress, but low for measurements of effect on quality of life, and moderate for effects on other outcomes (Figure 13.14).

5.4 POTENTIAL BIASES IN THE REVIEW PROCESS

All steps in the analyses were undertaken by researchers with content and methodological expertise.

Estimation of effects using the more robust method of variance estimation we applied showed typically similar effect size estimates compared to estimates made using the conventional method. The confidence intervals, however, were narrower. It was notable that we were able to make use of most of the data provided in the studies. We also avoided the often haphazard choice of which outcome to include in a meta-analysis in those instances where several measures of the same construct were presented in the primary studies. We anticipate that this new statistical method will become a standard technique in future meta-analysis.

5.5 AGREEMENTS AND DISAGREEMENTS WITH OTHER STUDIES OR REVIEWS

Overall, the effect sizes we estimated are relatively similar to the findings presented in other review evaluations of MBSR. This holds true for measures of anxiety, depression, stress, somatic health, and quality of life. This was not the case, however, with regard to Toneatto's study in which MBSR was shown to have no effect on depression and anxiety (Toneatto, 2007). Toneatto's finding though, we would contend, was due to comparisons of MBSR being made with alternative interventions in studies with varying designs. We suggest that the effect size compares favourably with a recent meta-analysis of psychological treatments of depressive symptoms in patients with medical disorders (van Straten, 2010). After removing two outliers, the data showed an overall effect size of d=0.42 (95% CI 0.27, 0.58) for the 15 controlled studies comparing psychological treatments with a wait-list or care-as-usual control group. Likewise, the effect size is in the same range as those recently reported for interpersonal psychotherapy for depression (Cuijpers, 2011). The potential for MBSR as a useful intervention for improving mental health, we argue, is therefore promising.

Based on the assumption that many self-reported mental health outcomes are actually rooted in similar aspects of mental functions, we developed a single composite measure of mental health based on the outcomes for anxiety, depression, stress/distress and other mental health outcomes. These latter outcomes included measures of emotional disturbance and regulation, anger, worry, rumination, relaxation, and life orientation. This mental health measure captured data from all 26 studies; the measure included 79 of the 132 outcomes. Three other reviews (that also included non-randomised studies) measured 'mental health' as a single

construct and the results were in the same range as our own (Baer, 2003; Grossman, 2004; Carmody, 2009).

5.5.1 Subgroup analyses

All subgroup analyses were conducted using the single composite mental health outcome measure as the dependent variable. The correlation matrix of the variables is shown in additional Table 11.6. A somewhat larger effect size among patient populations (16 studies) than non-clinical populations (ten studies) was expected. We hypothesised that effects would be larger in clinical populations with psychological problems (five studies) than in somatic clinical populations (11 studies). However, neither of the comparisons showed any significant difference, and both Grossman (2004) and Carmody (Carmody, 2009) reported similar findings. A possible explanation for this is that all the studies included participants who were self-selected. Given that the MBSR intervention is a well-known intervention for stress-related problems, those included in the studies might therefore be expected to be more similar in terms of their level of mental health problems than the different group categories might suggest. Another explanation for the similarity of effects across the different groups in terms of distress is because the studies on somatic health problems mainly included patients with chronic musculoskeletal problems, and the studies on psychological problems included only patients with minor mental problems.

However, there is evidence to suggest that the effect is larger for people who have substantially higher levels of mental health problems. One study which included patients with clinical psychiatric diagnoses (Koszycki, 2007) found a larger effect size, as did Grossman (2010) and de Vibe (2006), for subgroups of patients with higher levels of psychological symptoms. More studies should therefore attempt to elucidate which groups would benefit most from MBSR interventions and whether or not there is a floor effect (i.e., a particular level of symptoms that would be needed to demonstrate an effect).

Among the nine studies with follow-up data at 1-6 months, the effect size was shown to decrease slightly over time. More studies with longer follow-up periods are thus needed. Most trials offered the intervention to the control group immediately after the end of the intervention period. While this may be understandable from a practical or perhaps an ethical point of view, doing this destroys the possibility of examining evidence on long-term effects. One study (Pradhan, 2007), for example, gave three refresher classes in the four months follow-up period. A significant increase in the effects on psychological distress, well-being and mindfulness at follow-up was found when compared to post-intervention. We recommend further investigation to identify what will be required to maintain such treatment effects over time.

We expected the lengths of the intervention, attendance and home practice to influence the effect size to some degree, but only found this to be true for

attendance. The length required for MBSR course interventions to have an effect is thus still unknown. It should also be noted that the effect may occur due to moments of insight which lead to a change in the way people view themselves and the world. This may be due as much to a person's readiness to change as from the length of an MBSR course. In a more detailed analysis of dose-response, Carmody (2009) did not find any significant effect from the length of an MBSR course or assigned home practice. But we do not know, however, anything about the quality of the actual practice undertaken. One could argue therefore that a 30-minute daily practice routine which lacks attention or focus may actually be less effective than learning instead to be mindful in everyday life – this would be very difficult to measure and evaluate.

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, 2008). When analysed on the basis of more careful recording, Rosenzweig (2010) showed that the effect varied both as a function of clinical condition and compliance. A recent uncontrolled study showed 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).

Attendance was found to be associated positively with the effect of the MBSR intervention in seven of the 11 studies examining this possible predictor. Attendance may be a measure of motivation or an indicator that participants found the intervention useful. It may simply be that seeing a course through to the end is necessary for a course to have effect. We suggest that this issue should be investigated further. This could be achieved by, for instance, trying to measure motivation, interviewing those who complete the courses as well as any dropouts, and measuring the effect of MBSR several times during the course period in order to explore whether attendance mediates the effects.

Eight studies reported intention to treat (ITT) data, and showed a slightly smaller mental health effect size (0.47) relative to the 18 studies with non-ITT data (0.59). The difference, however, was not significant. On the whole, attrition was low (ca. 15%). The data suggested no significant differences in average mental health effect size due to variations in risk of bias. However, it was somewhat difficult to distinguish between inadequate reporting and a de facto high risk of bias.

6 Authors' conclusions

6.1 IMPLICATIONS FOR PRACTICE

There is moderate- to high-quality evidence of a consistent and moderately large effect of Mindfulness Based Stress Reduction (MBSR) on health and quality of life. The intervention appears to improve measures of personal development, including empathy, coping, and a sense of coherence, as well as enhancing mindfulness.

Consistent effects across different populations, intervention forms and comparisons further enhance the relevance of the intervention. While MBSR clearly alleviated symptoms of stress and distress (and mental health more broadly defined), it also had effects on measures of personal development and quality of life. MBSR might be an attractive option for those interested in improving the way they cope with stress.

MBSR is group-based and can be delivered by non-medical personnel who have been given sufficient training and have experience in teaching and practising mindfulness.

6.2 IMPLICATIONS FOR RESEARCH

Further studies should explore ways to enhance the effects of MBSR interventions. To achieve this, qualitative design studies may prove to be valuable in gaining insight into participant perception and help to identify ways to involve participants more, thus strengthening the effects. However, when evaluating actual effects, RCTs must remain the preferred design; further uncontrolled studies are not needed. Longer follow-up periods are also required in order to assess and address long-term effects. Better reporting of randomised controlled trials is also urgently needed and future research should include head-to-head comparisons with other interventions. Well-designed primary studies ought to explore the effects of the length of the intervention as well as reported home practice. As this field rapidly evolves, we anticipate further combinations of both applied and basic approaches. Investigations of changes in brain and body functions may, for example, be embedded within trials. Such designs could potentially shed new light on mechanisms and interventions for change. New trials should include measures of mindfulness, preferably using the Five Facet Mindfulness Questionnaire (Baer,

2006). All trialists should attempt to share data, as many topics related to mechanisms may be explored in individual patient data meta-analyses.

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8 Differences between the protocol and the review

The use of the robust standard error approach in the analysis was not described in the protocol. This was because the method was published after the protocol had been accepted.

The suggested sensitivity analysis was processed using subgroup analysis (which relates to risks of bias and the application of ITT-analysis). We did not impute any missing information as attrition rates were low, and because neither risk of bias scores nor whether ITT-analysis was done, influenced the results.

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

Only seven studies measured mindfulness (in two different ways) and we chose not to perform the suggested moderator analysis.

With hindsight we should probably have avoided the mixture of concepts ´subgroup analysis´, ´moderator analysis´, and ´sensitivity analysis´. We had some real subgroups (e.g. clinical vs. non-clinical target groups), some study level variables (e.g. risk of bias) and variables on the individual level (e.g. compliance and self-reported practice). While it seemed meaningful to investigate heterogeneity in effects by means of subgroup analysis for the first two groups (as described in the main text), in our judgement the latter variables can be treated as moderators in a meaningful way only if access to individual patient data is possible.

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11 Tables

11.1 CHARACTERISTICS OF INCLUDED STUDIES

Alterman 2004

Methods	RCT
Participants	Drug abusers in resident treatment for >2 months, Exclusion criteria: schizophrenia and borderline personality disorders, AIDS, hepatitis, regular mind-body practice in 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 the following seven areas: medical, employment, alcohol, drug, legal, family-social and psychiatric. In addition, the following were also measured: 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 five month follow-up period, and a positive trend for psychological problems, but no other group differences and no difference in urine toxicology
Notes	Analysis by repeated measures of variance to look for group and time interactions. Because statistical power was low, 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	Unclear risk	Not specified

Bias	Authors' judgement	Support for judgement
(selection bias)		
Blinding (performance bias and detection bias)	High risk	University technicians administered interview at post-intervention and follow-up but not at baseline stage
Incomplete outcome data (attrition bias)	Low risk	Only three people dropped out of each group
Selective reporting (reporting bias)	High risk	No SD given
Other bias	High risk	Treatment staff administered interview at baseline, technical staff at other times

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	Attention control, depression, affect, anxiety, anger, rumination, worry, mindfulness and four 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 (ITT) analysis not conducted as the number of dropouts in each group was equal (n=7). Greater negative affect, depression and anger rumination in MBSR group at baseline. Therefore multivariate ANOVA undertaken 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 was the same (n=7) hence the most conservative estimate of post-test scores would not have affected group mean differences post-test
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

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 use of more accepting/yielding mode of control $p<0.03$. Increase in measure of self as source of control $p<0.008$. Increased scores on the outcome of spiritual experiences $p<0.03$
Notes	Intention to treat (ITT) analysis not reported. ANOVA analysis was performed using change scores as dependent variable and baseline values as covariates. Wrote to author but further data unavailable

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation	Low risk	Coin flipping (confirmed after request for further information sent to author)

Bias	Authors' judgement	Support for judgement
(selection bias)		
Allocation concealment (selection bias)	Unclear risk	Person who did the coin flipping not specified
Blinding (performance bias and detection bias)	High risk	Most likely not blinded given that 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)	Unclear risk	Missing raw data from all facets of SCI (Sense Of Control Index)
Other bias	Low risk	No other bias detected

Bränström 2010

Methods	RCT
Participants	71 patients with varying cancer diagnoses who were not currently undergoing radiation or chemotherapy treatment
Interventions	MBSR vs. wait-list control MBSR: 8 x 2 hours per week, without all-day session
Outcomes	Stress, anxiety and depression, impact on event scale, mood states and mindfulness. Home-based meditation practice. All measured both before MBSR and one month after completion
Key conclusions	Significant decrease in stress, post-traumatic avoidance symptoms, and increased profile of mood states. Significant increase in mindfulness – this mediated the effects
Notes	Wrote to author who confirmed that the figures in Table 2 of the publication were generated using Intention to treat (ITT) analysis (32 persons in the MBSR group and 39 persons in the control group)

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Software used for random selection procedure
Allocation concealment (selection	Low risk	

bias)		
Blinding (performance bias and detection bias)	Unclear risk	No blinding of group assignment
Incomplete outcome data (attrition bias)	Low risk	Intention to treat (ITT) analysis
Selective reporting (reporting bias)	Low risk	All reported, six month follow-up to be reported later
Other bias	Low risk	No other bias detected

Carson 2004

Methods	RCT
Participants	White couples either married or cohabitating >2 years, non-distressed (<58 on the global marital satisfaction inventory and <65 on the brief symptom inventory), not practising yoga or meditation regularly
Interventions	MBSR vs. wait-list control MBSR: 8 x 2.5 hours per week + 7 hour 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	Favourable 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 practised 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, wrote to author
Blinding (performance bias and detection bias)	Unclear risk	Not specified,wrote to author
Incomplete outcome data (attrition bias)	Low risk	Equal dropout numbers 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). Trend for depersonalisation (p=0.063), but no significant difference in distress
Notes	More people with elevated distress in control group (7/13) than MBSR group (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	Unclear risk	Not specified

and detection bias)		
Incomplete outcome data (attrition bias)	High risk	Missing data for the two dropouts in the intervention group not accounted for
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Unclear risk	Large baseline difference in distress between intervention and treatment group not analysed

Creswell 2007

Methods	RCT
Participants	HIV-infected adults with psychological distress
Interventions	MBSR vs. 1-day MBSR control MBSR: 8 x 2 hours per week, 6-hour 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 predicted outcome and accounted for two-thirds of effect on CD4+T lymphocytes levels.
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 blinded to participant condition
Incomplete outcome data (attrition bias)	Low risk	Intention to treat (ITT) analysis conducted

Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Davidson 2003

Methods	RCT
Participants	41 right-handed employees in a biotechnology corporation
Interventions	MBSR vs. wait-list control MBSR: 8 x 2 hours per week, 6-hour 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 in EEGs of MBSR group members, 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)	Unclear 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 enrolled. Programme completed by 37 persons who stutter (29 males and 8 females)
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 reduced suffering from stress and related tension and fatigue, reduced anxiety about speech situations and more confidence in approaching speech situations. MBSR group felt more in control and used more problem-focussed coping
Notes	Follow-up data cannot be used in meta-analysis because follow-up done in parallel with the wait-list group receiving MBSR. Wrote to author and received additional information. Attendance recorded, but not duration of practice time

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Done by main experimenter using coin flipping
Allocation concealment (selection bias)	High risk	
Blinding (performance bias and detection bias)	Low risk	Questionnaires received anonymously in sealed envelopes by second investigator
Incomplete outcome data (attrition bias)	High risk	
Selective reporting (reporting bias)	Low risk	All outcomes addressed
Other bias	High risk	Did not use intention to treat analysis; 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, 6-hour 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 crossover of wait-list control group who then received MBSR. Same results as the intervention group after 6 months follow-up. 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	Used 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

Grossman 2010

Methods	RCT, randomised in blocks of 4-6
Participants	150 patients with mild to moderate multiple sclerosis
Interventions	MBSR vs. usual care MBSR: 8 weeks x 2.5 hours per week, 7-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, indicating 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. Intention to treat (ITT) 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 who was blinded to all patient information
Blinding (performance bias and detection bias)	Low risk	Outcome measures entered into database by personnel blinded to group assignment
Incomplete outcome data (attrition bias)	Low risk	All outcomes addressed
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	No other bias detected

Jain 2007

Methods	RCT
Participants	104 healthcare/medical students
Interventions	MBSR vs. waiting-list control vs. relaxation training MBSR: 4 x 1.5 hours per week, 6-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 the effect on distress was mediated through this. No effect noted on spiritual experiences. Effect of practice duration on outcome for distress and positive mood
Notes	Intention to treat (ITT) analysis performed

Risk of bias table

Bias	Authors' judgement	Support for judgement

Random sequence generation (selection bias)	Low risk	Computer program used to stratify participants for sex and student status
Allocation concealment (selection bias)	Low risk	Computerised 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 (ITT) analysis performed
Other bias	Low risk	No other bias detected

Klatt 2009

Methods	RCT
Participants	48 university faculty and staff
Interventions	MBSR vs. wait-list control MBSR: 6 x 1 hour per week, 20 minutes of home practice
Outcomes	Stress, sleep, mindfulness, salivary cortisol
Key conclusions	The MBSR group experienced significant stress reduction and an increase in mindfulness, despite receiving a short MBSR course. No effect on salivary cortisol
Notes	Intention to treat (ITT) 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	Low risk	Small amount of missing data

Bias	Authors' judgement	Support for judgement
bias)		
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 generalised social anxiety
Interventions	MBSR vs. GBCT (12-week group based cognitive therapy) vs. control MBSR: 8 x 2.5 hours per week, 7.5-hour all-day session
Outcomes	Anxiety, illness severity, social interaction and interpersonal sensitivity, self-rated disability, depression, quality of life
Key conclusions	Patients receiving both MBSR and GBCT improved, but those who received GBCT had greater effects on social anxiety, and equal effects in terms of improving mood, functionality, and quality of life compared to the MBSR group.
Notes	For those with serious problems, a 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: Intention to treat (ITT) analysis, and analysis of completer sample (including patients who completed and attended at least 80% of the sessions). Expectation maximisation method used to impute missing values
Selective reporting	Low risk	All outcomes reported

(reporting bias)		
Other bias	Low risk	No other bias detected

Lengacher 2009

Methods	RCT
Participants	84 women over 21-years of age diagnosed with breast cancer Stage 0-III who had undergone surgery and received adjuvant radiation and/or chemotherapy and had completed their treatment within the last ten months
Interventions	MBSR vs. wait-list control MBSR: 6 x 2 hour sessions per week, adapted for breast cancer survivors. Attendance and home practice measured. 70% considered compliant, one of the seven groups received only five sessions due to the occurrence of a tropical storm
Outcomes	Concerns about recurrence, anxiety, depression, life orientation, stress, spirituality, symptoms
Key conclusions	MBSR sign improved psychological distress, fear of recurrence and QOL. Extent of practice influences overall benefit. Attendance alone showed a favourable effect on psychological status
Notes	Adjusted means given, wrote to author to obtain unadjusted means and SD values. Symptoms measured by the MDASI – not reported in study

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)	High risk	Outcome assessors not blinded to follow-up from baseline
Incomplete outcome data (attrition bias)	Low risk	One dropout from each group, unlikely to introduce bias
Selective reporting (reporting bias)	Unclear risk	They mention that they did not report symptoms from the MDASI, but not why

Other bias	Unclear risk	Did not use correction for large numbers of outcomes

Moritz 2006

Methods	RCT
Participants	165 people with emotional distress measured using the Profile of Mood States (POMS)
Interventions	MBSR vs. home-based spirituality programme (8 x 1.5 hours audiotape sessions per week + daily 45-minute audiotape practice) vs. wait-list control MBSR: 8 x 1.5 hours per week, daily 45-minute audiotape practice
Outcomes	Profile of mood state and health-related quality of life
Key conclusions	At post-intervention, significant effect of both interventions: significantly more for spirituality group than MBSR group. Post-intervention effect of MBSR maintained at four weeks, where both interventions' effects were equal but still significantly different from those in the wait-list group
Notes	Baseline differences (not significant) with more mental distress in spirituality group. Adherence and practice greater in spiritual group

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer program used
Allocation concealment (selection bias)	Low risk	Done by biostatistician. Allocation list available only to an administrator who was 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 (ITT) analysis performed
Selective reporting (reporting bias)	Unclear risk	Subscale scores for SF36 at four weeks post-intervention not reported
Other bias	Low risk	No other bias detected

Morone 2008

Methods	RCT

Participants	37 participants with chronic lower back pain, aged >65 years
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 program used
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 (ITT) analysis method with last value carried forward
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Murphy 1995

Methods	RCT
Participants	31 male inmates with a history of alcohol abuse and aggression
Interventions	MBSR vs. progressive relaxation training (PRT: 6 x 2-hour sessions held over 5-week period) MBSR: 6 x 2 hours held over 5-week period
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 intervention on sub-measure of egocentrism (called negative self-focussed attention). At one-month follow-up, a slight decrease in aggressive response in MBSR group 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	All outcomes reported
Other bias	Low risk	No other bias detected

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	Unclear risk	Not specified

(selection bias)		
Blinding (performance bias and detection bias)	High risk	Partly: research assistant collected majority of data but PANAS was collected by co-therapist
Incomplete outcome data (attrition bias)	High risk	Equal numbers of dropout from each group, reasons for dropout addressed
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Nyklicek 2008

Methods	RCT
Participants	60 people experiencing regular distress
Interventions	MBSR vs. wait-list control MBSR: 8 x 2.5 hours per week, 6-hour all-day session, 40-minute home practice
Outcomes	Perceived stress, exhaustion, positive and negative affect, quality of life, mindfulness
Key conclusions	MBSR decreased distress, exhaustion and negative affect. MBSR increased QoL to a lesser extent. 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 program used
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 Programme – 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 had the same significant effect on stress, forgiveness and the same trend on reducing rumination. No effect on hope
Notes	Authors state that they did perform intention to treat (ITT) analysis, but not all randomised participants included (only 44)

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer program used
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 dropouts were not significantly associated with pre-test values or covariates on any outcome
Selective reporting (reporting bias)	Low risk	No other bias detected
Other bias	High risk	EPP and MBSR groups analysed together. 5 participants crossed over between intervention and control groups after randomisation

Plews-Ogan 2005

Methods	RCT
Participants	30 patients with chronic musculoskeletal pain
Interventions	MBSR vs. massage (one hour a week for 8-week period) 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. 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 dropouts 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

Pradhan 2007

Methods	RCT
Participants	63 rheumatoid arthritis patients not in remission
Interventions	MBSR vs. wait-list control MBSR: 8 x 2.5 hours per week, 6-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 follow-up at four months
Notes	Post-intervention and frequency of practice (but not time spent) were related to outcome, but not at six months follow-up. Better results obtained with one of the three instructors involved (who was also 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	Conducted by research director who had no direct patient contact (using Mienert clinical trials assignment procedure)
Blinding (performance bias and detection bias)	Low risk	All rheumatoid arthritis disease activity assessors and lab personnel blinded
Incomplete outcome data (attrition bias)	Low risk	Intention to treat (ITT) 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

Robert-McComb 2004

Methods	RCT
Participants	20 women with cardiovascular disease
Interventions	MBSR vs. wait-list control MBSR: 8 x 2 hours per week
Outcomes	Physical health, catecholamines, cortisol, breathing rate, oxygen consumption, tidal volume, and heart rate
Key conclusions	Significant effect on breathing pattern with increased ventilatory efficiency during exercise. No effect on hormone resting levels
Notes	Data from study first published by Tacon in 2002

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection	Unclear risk	Random selection with number 1 & 2 but unclear how it was done

Bias	Authors' judgement	Support for judgement
bias)		
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)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Sephton 2007

Methods	RCT
Participants	91 women with fibromyalgia
Interventions	MBSR vs. wait-list control MBSR: 8 x 2.5 hours per week, 6-hour all-day session
Outcomes	Functional impairment, pain, sleep, depression
Key conclusions	MBSR alleviated symptoms of depression in fibromyalgia patients and reduced somatic symptom scores. Participants who meditated experienced greatest reduction in depressive symptoms at the end of the study ($p<.05$). Attendance had no significant effect on outcome
Notes	Follow-up immediately after intervention and after two months. Attendance 69%. 87.5% meditated regularly at post-intervention and 73% at two months follow-up

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment	Unclear risk	Not specified

(selection bias)		
Blinding (performance bias and detection bias)	Low risk	Data entry personnel blinded
Incomplete outcome data (attrition bias)	Low risk	Two analyses performed. In one, the last observation was carried forward and used for missing data
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Shapiro 1998b

Methods	RCT (confirmed by author)
Participants	78 medical and pre-medical 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, by different experimenters. Results measured at student 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 healthcare 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 control group. Changes in self-compassion significantly predicted positive changes in perceived stress but not changes in satisfaction with life
Notes	Intention to treat (ITT) analysis not conducted, significant 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 and also by co-therapist
Incomplete outcome data (attrition bias)	Unclear risk	Large dropout rate, no intention to treat (ITT) analysis
Selective reporting (reporting bias)	Unclear risk	All outcomes reported
Other bias	Unclear risk	No other bias detected

Speca 2000

Methods	RCT

Participants	109 cancer patients
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 a significant effect on all outcome measures
Notes	Those who dropped out had greater baseline anxiety and depression. The best predictor of improvement was the number of sessions attended (this explained 13.2% of the variance)

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Fixed randomisation scheme using a table of random numbers
Allocation concealment (selection bias)	Low risk	Allocation concealed by using numbers to identify participants. The investigator did not know the association between the individual participants and the numbers used to identify them
Blinding (performance bias and detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Low risk	Intention to treat (ITT) analyses for dropouts imputed; last value carried over. 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 (CFS)
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 lost to follow-up
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	High risk	Before study inclusion, study population had attended varying numbers of psychiatric sessions. Baseline differences not accounted for in the analysis

Tacon 2003b

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 hormone resting levels
Notes	Data from exercise tests and hormone measurements published in separate article by Robert-McComb in 2004

Risk of bias table

Bias	Authors'	Support for judgement

	judgement	
Random sequence generation (selection bias)	Unclear risk	Random selection using numbers 1 & 2, unclear how this was done
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 experiencing 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 (ITT) 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	Unclear risk	Not specified

detection bias)		
Incomplete outcome data (attrition bias)	Low risk	Small amounts of missing data
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	Large imbalance at baseline, but adjusted for by using ANCOVA analysis

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 level of 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 using hierarchical regression)
Notes	Only full data on SOC variable supplied; same study as Sephton published in 2007

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 between treatment and control groups
Selective reporting (reporting	Unclear risk	Full data on perceived stress and depression not

Bias	Authors' judgement	Support for judgement
bias)		provided
Other bias	Low risk	No other bias detected

Williams 2001

Methods	RCT
Participants	103 community volunteers who were stressed
Interventions	MBSR vs. treatment-as-usual control (also given unspecified educational material) MBSR: 8 x 2.5 hours per week, 8-hour all-day session
Outcomes	Daily stress, distress and medical symptoms
Key conclusions	MBSR group showed significant reduction in stress, distress, and medical symptoms
Notes	Used a 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	Note all outcome data reported
Other bias	Low risk	No other bias detected

11.2 CHARACTERISTICS OF EXCLUDED STUDIES

Study	Reason for Exclusion
Abbey 2003	Not an RCT
Abbott 2006	Unobtainable
Alexander 1989	Not MBSR
Allen 2006	Not a primary study
Alterman 2004	Not an RCT
American 2007	Not a primary study
Arias 2006	Not a primary study
Arnold 2001	Not a primary study
Arthur 2006	Not a primary study
Astin 2003a	Measures effect of MBSR in combination with Qi-Gong
Astin 2003b	Not a primary study
Astin 2004	Not a primary study
Bahrke 1978	Not MBSR
Barrows 2002	Not a primary study
Berking 2007	Not a primary study
Biegel 2009	Not an RCT
Bishop 2002	Not a primary study
Boerstler 1987	Not a primary study
Brach 1992	Not MBSR
Brandon, 1985	Not MBSR
Brazier 2006	Not MBSR
Britton 2007	Unobtainable, author contacted
Bruckstein 1999	Not an RCT. Participants themselves could choose which group to participate in.
Bruning 1987	Not MBSR
Butler 2006	Not MBSR
Bögels 2008	Not an RCT

Study	Reason for Exclusion
Carson 2006	Not a primary study
Chang 2003	Not MBSR
Cohen-Katz 2004	Not a primary study
Coulter 2002	Not a primary study
Davies 2008	Not a primary study
Deepak, 1994	Not MBSR
Delmonte 1985	Not a primary study
Delmonte 1990	Not a primary study
Diamond 1987	Not a primary study
Dosh 2002	Not a primary study
Ebell 2001	Not a primary study
Edwards 2003	Not a primary study
Ernst 2008	Not an RCT
Ferren 2004	Not an RCT
Fjorback 2008	Not a primary study
Flanzbaum 2003	Not an MBSR
Foley 2006	Unobtainable
Galantino 2005	Not an RCT
Garland 2007	Not an RCT
Garland 2010	Not an RCT
Gaston 1991	Not MBSR
Gazella 2005	Not a primary study
Goodman 2004	Primary study reported in Plews-Ogan (2005)
Greene 1988	Not MBSR
Grossman 2004	Not a primary study
Grossman 2007	Not an RCT
Hall 1999	Not MBSR
Hart 2007	Not a primary study
Hassed 2004	Not MBSR

Study	Reason for Exclusion
Haynes 2007	Unobtainable
Health & Medicine 2008	Not an RCT
Hebert 2001a	Not MBSR: several sessions lead by psychiatrist which addressed issues of coping with breast cancer
Hellman 1990	Not MBSR
Hildenbrand 1986	Not a primary study
Hodges 2000	Not a primary study
Horrigan 2006	Not a primary study
Horrigan 2007	Not a primary study
Horton-Deutsch 2003	Not a primary study
Horton-Deutsch 2007	Not an RCT
Humphrey 1999	Not MBSR
Issel 2007a	Not a primary study
Issel 2007b	Not an RCT
Ivanovski 2007	Not a primary study
Jackson 2004	Unpublished, unobtainable
Jacobs 2003	Not an RCT
Jaltuch 1997	Unobtainable
Jha 2007	Not an RCT
Johnson 2004	Not MBSR
Kabat-Zinn 1985	Not an RCT
Kabat-Zinn 1986	Unobtainable
Kabat-Zinn 1992	Not an RCT
Kabat-Zinn 1998	Not MBSR (used only audiotapes)
Kindlon 1983	Not MBSR
Koerbel 2007	Not a primary study
Krisanaprakornkit 2006	Not a primary study
Krisanaprakornkit 2007	Not a primary study
Kroese 2005	Not a primary study
Kron 2004	Not a primary study

Study	Reason for Exclusion
Kron 2007	Not a primary study
Lee 2007	Not MBSR
Linden 2001	Not an RCT
Loganathan 2007	Not MBSR
Lombart 1998	Not an RCT
Lundh 2005	Not a primary study
Luskin 2000	Not a primary study
Lynch 2004	Not an RCT
Mackenzie 2006	Not an RCT
Manzoni 2008	Not a primary study
Maras 1984	Not an RCT
Marcus 2001	Not an RCT
Marcus 2007	Not an RCT
Massion 1997	Unobtainable
Matchim 2007	Not a primary study
McCarberg 1999	Not MBSR
McMillan 2002	Not MBSR
Medical Devices 2008	Not an RCT
Melnyk 2005	Not a primary study
Michalak 2006	Not a primary study
Michalsen 2002	Not an RCT
Moghaddam 2007	Not MBSR
Monk-Turner 2003	Not an RCT
Monti 2005	Not MBSR: the art therapy component went beyond standard forms of MBSR intervention and was not simply an adaptation
Morone	Primary study reported in Morone 2008
Morone 2006	Primary study reported in Morone 2008
Morone 2007	Not a primary study
Mulligan 2004	Not a primary study
Murphy 1986	Not MBSR

Study	Reason for Exclusion
Murphy 1996	Not a primary study
Napoli 2005	Not MBSR
Neale 2007	Not a primary study
Nielsen 2006	Not an RCT
Ormrod 1991	Not MBSR
Ortner 2007	Not MBSR
Ott 2006	Not a primary study
Ozcelik 2007	Unobtainable
Palmkron 2008	Not a primary study
Papp 2001	Not a primary study
Paradies 2006	Not a primary study
Patel 1985	Not MBSR
Paterniti 2008	Not an RCT
Pauzano-Slamm 2005	Not an RCT
Pearl 1994	Not an RCT
Perkins 1998	Combination of MBSR and progressive relaxation
Phelps 2005	Unobtainable
Poulin 2005	Not an RCT
Poulin 2008	Not an RCT
Praissman 2008	Not a primary study
Proulx 2003	Not a primary study
Rainforth 2007	Not a primary study
Ramel 2004	Not an RCT
Randolph 1999	Not an RCT
Rhead 1983	Not an RCT
Robinson 2003	Not an RCT
Rosdahl 2003	Not an RCT
Rosenzweig 2003	Not an RCT
Roth 2004	Not an RCT

Study	Reason for Exclusion
Sagula 2004	Not an RCT
Salmon 2004	Not a primary study
Saxe 2001	Not an RCT
Schmidt 2008	Not an RCT
Schure 2008	Not an RCT
Severtsen 1986	Not MBSR
Shapiro 1998a	Primary study reported in Shapiro 1998b
Shapiro 2002	Unobtainable
Shapiro 2003	Quasi-experimental due to pre-intervention measures being given after randomisation; the two treatment options were not equivalent and affected answers to pre-intervention protocol
Shapiro 2007	Not an RCT
Shigaki 2006	Not a primary study
Singh 2002	Not an RCT
Singh 2004	Not an RCT
Singh 2006a	Not an RCT
Singh 2006b	Not an RCT
Smith 2004	Not a primary study
Smith 2005a	Not a primary study
Smith 2005b	Unobtainable
Smith 2007	Unobtainable
Smith 2008	Not an RCT
Snaith 1998	Not a primary study
Solloway 2007	Not an RCT
Soskis 1989	Not an RCT
Spanos 1980	Not an RCT
Spence 2006	Not MBSR
Starks 2007	Unobtainable
Stauffer 2008	Not an RCT
Tacon 2003a	Not a primary study

Study	Reason for Exclusion
Tacon 2004	Not an RCT
Tate 1994	Not an RCT
Toneatto 2007	Not a primary study
Tremblay 2008	Not a primary study
von Weiss 2002	Not a primary study
Walach 2007	Not an RCT
Weiss 2005	Not an RCT
Wilson 2000	Unobtainable
Winbush 2007	Not a primary study
Åsberg 2006	Not a primary study

11.3 STUDY CHARACTERISTICS

Study name	Population	Outcome/inventories (see Table 14.2 for explanations)	Number randomised	Follow-up (months)	MBSR hours	Practice per day (min)	Attendance %	ITT/ non-ITT
Alterman 04	Substance abusers	ASI, SF-36-Vit, SF-36 Ph, SF-36 Me, SAS, LOT, LAP-R, PANAS-Pos	31	3	23			Non-ITT
Anderson 07	General	BAI, Anx Sens I, BDI, TMS, Anger Rum S, N Anger I, RSQ, PANAS, Penn State Worry	86		16	18	65	Non-ITT
Astin 97	Students	INSPIRIT, SCI, GSI	28		16	18		Non-ITT
Bränstöm 10	Cancer	HADS, FFMS,PSOM, PSS, IES-R	85		16		73	ITT
Carson 04	Ordinary couples	IRI, LOT, INSPIRIT,GSI	114	3	27	32	80	Non-ITT
Cohen-Katz 05	General	MAAS, MBI	27		26			Non-ITT
Creswell 08	HIV positive	CD4+T lymphocytes	67		22		57	Non-ITT
Davidson 03	General	STAI Trait, AB titre	41		26	7		Non-ITT
de Veer 09	People with stutter	SSC, SESAS, PSI, LCB, PSS, S-24	46		20		80	Non-ITT
de Vibe 06	Chronic illness and stress	WHOQOL-BREF, SCL-5, SHC	144		26		81	Non-ITT

Study name	Population	Outcome/inventories (see Table 14.2 for explanations)	Number randomised	Follow-up (months)	MBSR hours	Practice per day (min)	Attendance %	ITT/ non-ITT
Grossman 10	Multiple sclerosis	STAI, CES-D, HAQUAMS, PQOLC, MFIS fatigue	150	6	27	30	92	ITT
Jain 07	Students	DER, INSPIRIT, PSOM, GSI	69		12	45		Non-ITT
Klatt 09	University staff	GI SleepQ, PSS, MAAS	48		6	17	80	Non-ITT
Koszycki 07	Social anxiety	LSAS, CGI, SIAS, SPS, IPSM, LSRDS, BDI, QoLI	53		28		94	ITT
Lengacher 09	Cancer	STAI, CES-D, LOT, PSS, SF36 PhyS, SF36 MentalS	84		12	30	80	ITT
Moritz 06	Distress	POMS, SF36 PhyS, SF36 MentalS	109	1	12	18	65	ITT
Morone 08	Chronic low back pain	CPAQ, McGPQ, SF-36	37		12	32	84	Non-ITT
Murphy 95	Prisoners	STAXI, Egocentricity, salivary cortisol	31		12			Non-ITT
Murrey 04	Students	CUSI, CSI, NMRS, PANAS	27		12	35		Non-ITT
Nyclicek 08	Distress	WHOQOL-BREF, MAAS, PANAS, PSS, MQ	60		26			ITT
Oman 08	Students	PSS, RRQ, H Forgiveness S, ADHS	31	2	12		83	Non-ITT
Plews-Ogan 05	Chronic muscular-	SF-12 mentalS, PUS	20	1	20		79	Non-ITT

Study name	Population	Outcome/inventories (see Table 14.2 for explanations)	Number randomised	Follow-up (months)	MBSR hours	Practice per day (min)	Attendance %	ITT/ non-ITT
	skeletal pain							
Pradhan 07	Rheumatoid arthritis	SCL-90 dep, MAAS, PWS, GSI, DAS28	63	4	26	8	85	ITT
Sephton 07	Fibromyalgia	BDI, SOC	91	2	26		69	ITT
Shapiro 05	Health professionals	MBI, SCS, PSS, SWLS	38		16			Non-ITT
Shapiro 98	Students	STAI, SCL-90 depr, ECRS, INSPIRIT, GSI	78		18			Non-ITT
Speca 00	Cancer	POMS, SOSI	109		11		85	ITT
Surawy 05	Chronic fatigue syndrome	HADS, CFS, SF-36	18		20		75	Non-ITT
Tacon 03	Cardiovascular disorder	STAI , CECS, PF-SOC, Catecholamines, Cortisol, SF-36, HR, TV, Vent	20		16			Non-ITT
Vieten 08	Mood disturbance	STAI, CES-D, MAAS, ARM, PANAS, PSS	34		16	11	90	Non-ITT
Williams 01	Stress	Daily Stress I, GSI, MSCL	103	3	28		83	Non-ITT

Total number randomised: 1,942

11.4 MEASUREMENT SCALES, ABBREVATIONS

Measurement Scales, Abbreviations
AB titre=Influenza Antibody Titre
Anger Rum S=Anger Rumination Scale
Anx Sens I=Anxiety Sensitivity Index
ARM=Affect Regulation Measure
ASI=Addiction Severity Index
BAI=Beck Anxiety Index
BDI=Beck Depression Inventory
CECS=Courtauld Emotional Control Scale
CES-D=Centre for Epidemiologic Studies Depression Scale
CFS=Chalder Fatigue Scale
CGI=Clinical Global Impression
CPAQ=Chronic Pain Acceptance Questionnaire
CSI=Coping Strategi Index
CUSI=Coping Using Sex Inventory
DAS28=Disease Activity Scale
DER=Daily Emotion Report
DSI=Daily Stress Inventory
ECRS=Empathy Construct Rating Scale
FFMS=Five Facet Mindfulness Scale
GI SleepQ=Pittsburgh Sleep Quality Index
GSI=General Severity Index from the Hopkins Symptom Checklist-90
HADS=Hospital Anxiety and Depression Scale
HAQUAMS=Hamburg Quality of Life Questionnaire in Multiple Sclerosis
HFS=Heartland Forgiveness Scale
HR=Heart Rate
IES-R=Impact of Event Scale-Revised (sub-scales for intrusion, avoidance and hyperarousal)
INSPIRIT=Index of Core Spiritual Experience

Measurement Scales, Abbreviations
IPSM=Interpersonal
IRI=Individual Relaxation Index
ITT= Intention to treat analysis
LAP-R=Reker's Life Attitude Profile-Revised
LCB=Locus of Control of Behaviour Scale
LOT=Life Orientation Test
LSAS=Liebowitz Social Anxiety Scale (Fear and Avoidance sub-scales)
LSRDS=Liebowitz Self-Rated Disability Scale
MAAS=Mindfulness Attention Awareness Scale
MBI= Maslach Burnout Inventory (sub-scales for Emotional Exhaustion, Depersonalization and Personal Accomplishment)
McGPQ=McGill Pain Questionnaire Short Form
MBSR=Mindfulness Based Stress Reduction
MQ=Maastrict Questionnaire
MSCL=Medical Symptom Checklist
N Anger I=Novaco Anger Inventory
NMRS=Negative Mood Regulation Scale
PANAS-Pos=Positive and Negative Affect Scale – Positive
PF-SOC=Problem-Focused Styles of Coping
POMS=Profile of Mood States Scale
PQOLC=Profile of Health-Related Quality of Life in Chronic Disorders
PSI=Perceptions of Stuttering Inventory
PSOM=Positive States of Mind
PSS=Perceived Stress Scale
P State Worry=Penn State Worry
PUS=Pain Unpleasantness Scale
PWS=Positive Well-Being Scales
QoLI=Quality of Life Inventory
Vital Exhaustion,
RRQ= Rumination and Reflection Questionnaire

Measurement Scales, Abbreviations
RSQ=Rumination Scale of the Response Styles Questionnaire
S-24=Attitude towards speech situations
SAS=Hovden Spirituality Assessment Scale
SCI=Shapiro Control Index
SCL-5=Hopkins Symptom Checklist-5
SCL-90 dep=Hopkins Symptom Checklist 90 Depression sub-scale
SCS=Self-Compassion Scale
Sensitivity Measure,
SESAS=Self-Efficacy Scale for Adults who Stutter
SF-12 mentalS=Health Survey Questionnaire-Mental summary score
SF36 PhysS=Health Survey Questionnaire – Physical Summary Score
SF36 mentalS=Health Survey Questionnaire – Mental Summary Score
SF-36-Vit=Health Survey Questionnaire-Vitality sub-scale
SHC=Ursin Subjective Health Complaints
SIAS=Social Interaction Scale
SOC=Sense of Coherence
SOSI=Symptoms of Stress Inventory
SPS=Social Phobia Scale
SSC=Speech Situation Checklist
STAI Trait=Spielberger State-Trait Anxiety Inventory
SWLS=Satisfaction With Life Scale
TV=Tidal Volume
Vent=Ventilation,
WHOQOL-BREF= World Health Organization Quality of Life Scale Brief version

11.5 EFFECT SIZES AND OUTCOMES

Outcomes	Studies	Measurement scales (some scales reported outcomes using many subscales)	Hedges' g-values	95% CI	Heterogeneity
Anxiety (10 studies, 12 outcomes)	Anderson, Bränstöm, Davidson, de Veer, Grossman, Langacher, Shapiro 98, Surawy, Tacon, Vieten	BAI, HADS, Anxiety about speech, STAI trait, STAI state	0.53	0.43-0.63	Tau^2: 0.0 I^2: 0%
Depression (9 studies, 9 outcomes)	Anderson, Bränstöm, Grossman, Langacher, Pradhan, Sephton, Shapiro 98, Surawy, Vieten	BDI, HADS, CES-D, SCL90-D	0.54	0.35-0.74	Tau^2: 0.03 I^2: 32%
Stress/distress (20 studies, 28 outcomes)	Astin, Bränstöm, Carson, Cohen-Katz, de Veer, de Vibe, Grossman, Jain, Klatt, Langacher, Moritz, Morone, Nyklicek, Plews-Ogan, Pradhan, Shapiro 98, Shapiro 05, Speca, Vieten, Williams	GSI, PSS, MBI, SCL-5, MFIS-F, SF36-M, Vital exh, SOSI, DSI	0.56	0.44-0.67	Tau^2: 0.009 I^2: 11%
Other measures of mental health (12 studies, 30 outcomes)	Anderson, Astin, Bränstöm, Carson, de Veer, Jain, Klatt, Langacher, Moritz, Nyklicek, Speca, Vieten, Williams	Anx Sens I, Anger Rum S, N Anger I, PANAS, P State Worry, RSQ, IES-R, IRI, LOT, S-24, SESAS, DER, GI SleepQ, POMS, ARM	0.48	0.34-0.61	Tau^2: 0.0 I^2: 0%
Mental health	All studies	All of Anxiety, Depression, Stress and Other	0.53	0.46-0.61	Tau^2: 0

Outcomes	Studies	Measurement scales (some scales reported outcomes using many subscales)	Hedges' g-values	95% CI	Heterogeneity
(26 studies, 79 outcomes)		mental health outcomes			I^2: 0%
Personal development (12 studies, 21 outcomes)	Astin, Bränstöm, Carson, de Veer, Jain, Morone, Murrey, Pradhan, Sephton, Shapiro 98, Shapiro 05, Tacon	INSPIRIT, SCI, PSOM, PSI, LCB, CPAQ, CUSI, CSI, PWBS, SOC, ECRS, SCS, CECS, PF-SOC,	0.50	0.35-0.66	Tau: 0.02 I^2: 14%
Quality of Life (4 studies, 11 outcomes)	de Vibe, Grossman, Nyklicek, Shapiro 05	WHOQOLBREF, HAQUAMS, PQOLC, SWLS,	0.57	0.17-0.96	Tau^2: 0.07 I^2: 47%
Somatic outcomes (10 studies, 18 outcomes)	Davidson, de Vibe, Lengacher, Mortitz, Morone, Plews-Ogan, Pradhan, Surawy, Tacon, Wiliams	AB titre, SHC, McGPQ, SF36-Ph, PUS, DAS28, CFS, HR, TV, Vent, MSCL	0.31	0.10-0.52	Tau^2: 0.01 I^2: 11%
Mindfulness (7 studies, 11 outcomes)	Anderson, Bränström, Cohen-Katz, Klatt, Nyklicek, Pradhan, Vieten	MAAS, FFMS	0,70	0.05-1.34	Tau^2: 0.4 I^2: 82%

11.6 SUBGROUP ANALYSIS

Comparisons	Study N	Effect size difference (95% CI), p-value
Non-clinical vs. clinical populations	26	0.12 (-0.06, 0.30), p=0.17
Clinical psychological vs. clinical somatic populations	16	0.01 (-.03, 0.23), p=0.94
Studies without intention to treat (ITT) analysis vs. studies with ITT analysis	26	0.12 (-0.28, 0.03), p=0.12
Decrease in effect size for each additional month of follow-up from 0-6 months	26	-0.03 (-0.05, 0.00), p=0.03
Increase in effect size for each unit increase in risk of bias score	26	0.03 (-0.08, 0.03), p=0.32
Increase in effect size for each one hour increase in MBSR course	26	0.01 (0.00, 0.02), p=0.15
Increase in effect size for each percentage point increase in MBSR attendance between 65% and 92%	18	0.01 (0.00, 0.02), p=0.005
Increase in effect size for each minute of MBSR practice between 7 and 45 minutes/day	13	0.00 (-0.01, 0.02), p=0.48

11.7 CORRELATION MATRIX AT POST-INTERVENTION

	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	0.61	0.35	0.05	0.50	-0.23	26
Clin.Som/Clin.Psych	Not Appl	1.00	-0.45	0.03	0.19	0.21	-0.71	16
ITT/NonITT	0.61	-0.45	1.00	0.47	-0.02	0.10	0.07	26
Risk of bias	0.35	0.03	0.47	1.00	0.13	0.17	0.05	26
MBSR hours	0.47	0.19	-0.02	0.13	1.00	0.29	-0.02	26
Attendance hours	0.50	0.21	0.10	0.17	0.29	1.00	0.06	18
Practice minutes	-0.23	-0.71	0.07	0.05	-0.02	0.06	1.00	13

Correlation matrices for the covariates in the 8 bivariate analyses. These are based on all of the effect sizes, though separated into one set at the end of the intervention and another for all values of follow-up time.

12 Appendices

12.1 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 criterion 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:				

12.2 CODING AND DATA EXTRACTION FORM

CODING AND DATA EXTRACTION FORM: MBSR REVIEW	
Reference ID: Study ID:	Reviewer 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:

PATICIPANTS

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:
- Oncological:
- 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 page number):

STUDY SAMPLE

11. Number of cases	MSBR n =	Control n =	Total	Notes & pp.

in sample	(Add columns as required)	(Add columns as required)	n =	no.
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 programme 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 What does the scale measure, e.g. stress, depression, or a combination of these? Direction of scale. Is the scale described as validated? Cite	Timing of measurement State exact times within the categories below			
		<3 months	3-6 months	>6-12 months	>12 months

	how the study has described this outcome
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 p, df, t, f, and Other
	Median Mean (SD) (SMD) (SE)	Median Mean (SD) (SMD) (SE)	Median Mean (SD) (SMD) (SE)	Median Mean (SD) (SMD) (SE)	
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					

22. Outcome bias

Are there outcomes that were measured but not reported?
If 'Yes', are the reasons for this 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:

12.3 SEARCH TERMS

Ovid MEDLINE(R) 1950 to July Week 1 2008
10.07.08

1 Meditation/
2 meditat$.ti,ab.
3 mindfulnes$.ti,ab.
4 mbsr$.ti,ab.
5 or/1-4
6 randomized controlled trial.pt.
7 controlled clinical trial.pt.
8 randomized.ab.
9 placebo.ab.
10 drug therapy.fs.
11 randomly.ab.
12 trial.ab.
13 groups.ab.
14 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
15 humans.sh.
16 14 and 15
17 5 and 16

AMED (Allied and Complementary Medicine) 1985 to July 2008
10.07.2008

1 Meditation/
2 meditat$.ti,ab.
3 mindfulnes$.ti,ab.
4 mbsr$.ti,ab.
5 o/1-4

PsycINFO 1806 to July Week 2 2008
10.07.2008

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$3 or mask$3)).tw.
31 (clinic$ adj (trial? or stud$3)).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

EMBASE 1980 to 2008 Week 27

10.07.2008

1 Meditation/
2 meditat$.ti,ab.
3 mindfulnes$.ti,ab.
4 mbsr$.ti,ab.
5 or/1-4
6 Clinical Trial/
7 Randomized Controlled Trial/
8 Randomization/
9 Double Blind Procedure/

10 Single Blind Procedure/
11 Crossover Procedure/
12 PLACEBO/
13 placebo$.tw.
14 randomi?ed controlled trial$.tw.
15 rct.tw.
16 random allocation.tw.
17 randomly allocated.tw.
18 allocated randomly.tw.
19 (allocated adj2 random).tw.
20 single blind$.tw.
21 double blind$.tw.
22 ((treble or triple) adj blind$).tw.
23 Prospective study/
24 or/6-23
25 Case study/
26 case report.tw.
27 Abstract report/
28 Letter/
29 Human/
30 Nonhuman/
31ANIMAL/
32 Animal Experiment/
33 30 or 31 or 32
34 33 not (29 and 33)
35 or/25-28,34
36 24 not 35
37 5 and 36

Ovid Nursing Full Text Plus 1950 to July Week 1 2008
10.07.2008

1 Meditation/
2 meditat$.ti,ab.
3 mindfulnes$.ti,ab.
4 mbsr$.ti,ab.
5 or/1-4

British Nursing Index and Archive 1985 to July 2008
10.07.2008

1 meditat$.ti,ab.
2 mindfulnes$.ti,ab.
3 mbsr$.ti,ab.
4 or/1-3

Wiley, Cochrane Library Issue 2, 2008

10.07.2008

#1 MeSH descriptor Meditation explode all trees

#2 (meditat* or mindfulnes* or mbsr$):ti,ab

#3 (#1 OR #2)

SIGLE

11.07.2008

Search term: mbsr

Search term: mindfulness-based

Web of Science®

14.07.2008

3

#2 AND #1

Databases=SCI-EXPANDED, SSCI, A&HCI Timespan=All Years

2

Topic=(randomized) OR Topic=(placebo) OR Topic=(randomly) OR Topic=(trial) OR Topic=(groups) OR Topic=(controlled)

Databases=SCI-EXPANDED, SSCI, A&HCI Timespan=All Years

1

Topic=(meditat*) OR Topic=(mindfulnes*) OR Topic=(mbsr*)

Databases=SCI-EXPANDED, SSCI, A&HCI Timespan=All Years

SveMed+

14.07.2008

S1 Explodesökning på Meditation

S2 mindfulnes$

S3 mbsr$

S4 oppmerksomhetstrening$

S5 uppmärksamhetsträning$

S6 s1 or s2 or s3 or s4 or s5

Google

11.07.2008

Hits only entered if unique to this search (i.e. not retrieved in other databases)

We went through the first 100 hits.

research OR evaluation OR evaluations OR outcome OR outcomes OR effect OR effects OR trial OR trials OR study OR studies "mindfulness based stress reduction"

CSA ERIC

06.11.2008

TI=(meditat* or mindfulnes* or mbsr*) or AB=(meditat* or mindfulnes* or mbsr*)
Limited to: Publication Type is PT=(142 reports: evaluative) or PT=(143 reports: research)

CSA Sociological Abstracts

06.11.2008
(TI=(meditat* or mindfulnes* or mbsr*) or AB=(meditat* or mindfulnes* or mbsr*)) and((TI=(random* or control* or trial*) or TI=(group* or placebo* or experiment* or evaluat*) or TI=(prospectiv* or (compar* within 2 (trial* or study or studies)))) or(AB=(random* or control* or trial*) or AB=(group* or placebo* or experiment* or evaluat*) or AB=(prospectiv* or (compar* within 2 (trial* or study or studies)))))

CSA Social Services Abstracts

06.11.2008
TI=(meditat* or mindfulnes* or mbsr*) or AB=(meditat* or mindfulnes* or mbsr*)

OVID International Bibliography of the Social Sciences

10.11.2008
1 Meditation/
2 meditat$.tw.
3 mindfulnes$.tw.
4 mbsr$.tw.
5 or/1-4
6 random$.tw.
7 control$.tw.
8 trial$.tw.
9 group$.tw.
10 placebo$.tw.
11 experiment$.tw.
12 evaluat$.tw.
13 ((prospectiv$ or compar*) adj2 (trial* or study or studies)).tw.
14 or/6-13
15 14 and 5

ProQuest

13.11.2008
(mindfulnes* or mbsr) and (random* or control* or trial* or group* or placebo* or experiment* or evaluat*)

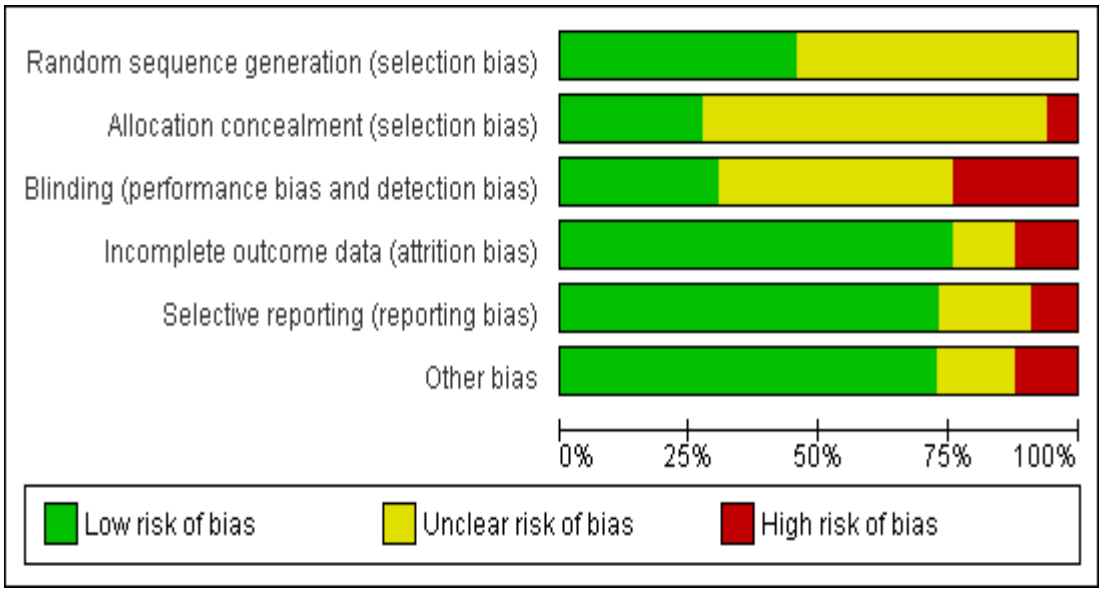
Dissertation Abstracts

15.10.2008

Mindfulness-based

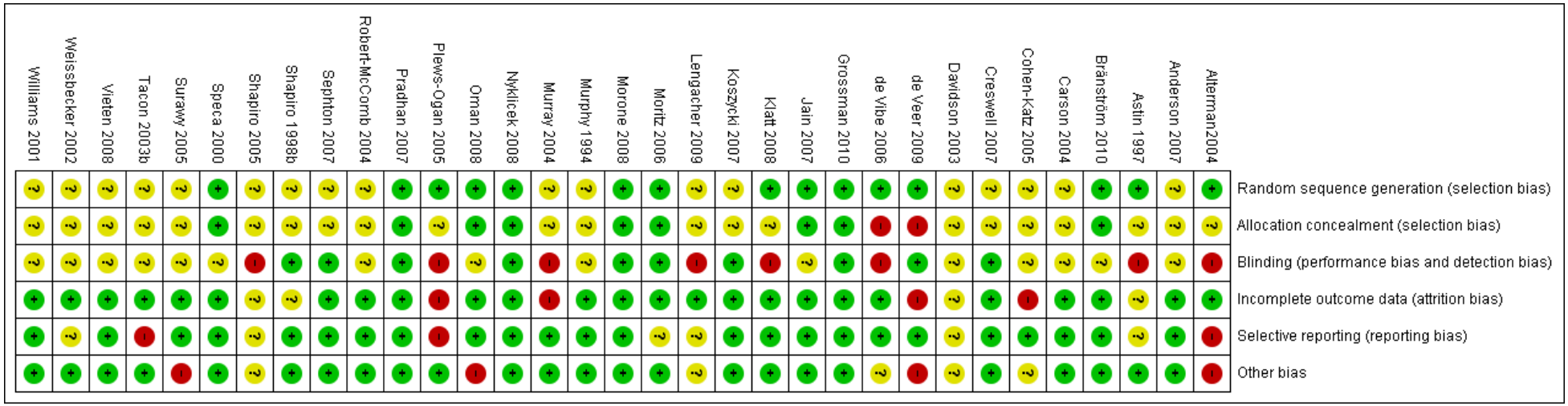
13 Figures

13.1 METHODOLOGICAL QUALITY GRAPH



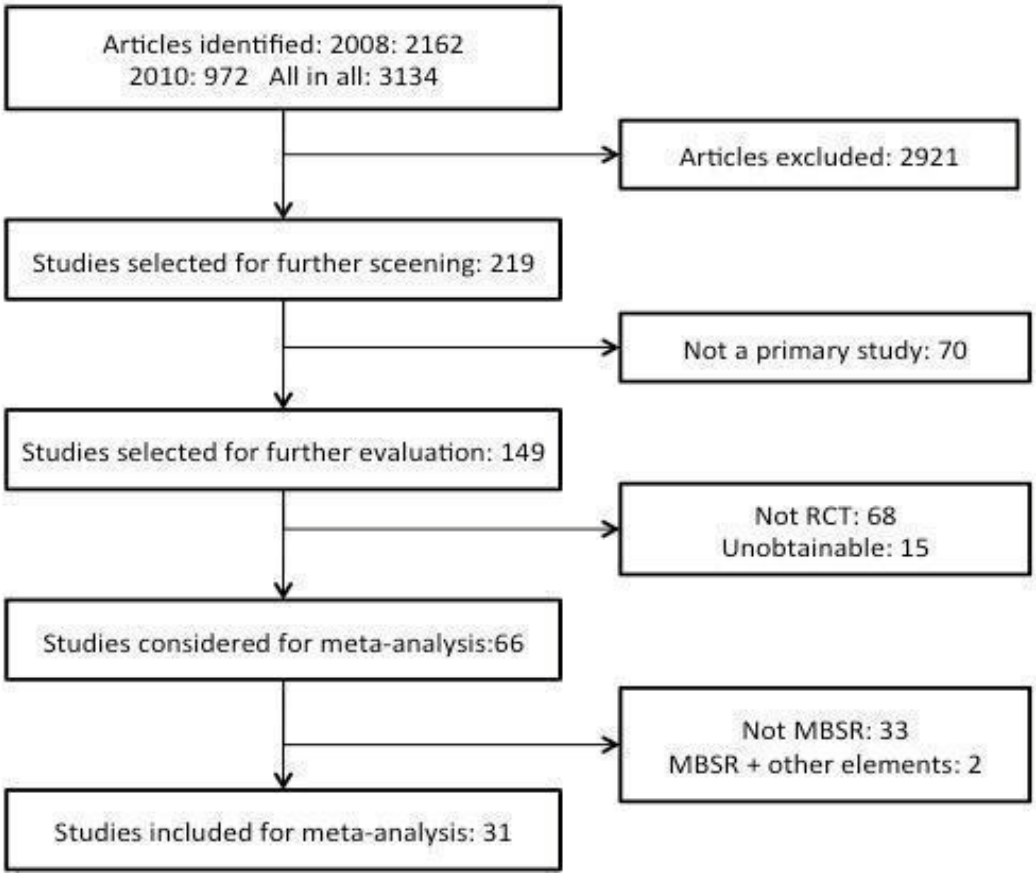
Review authors' judgements about each methodological quality item (shown as percentages across all included studies)

13.2 METHODOLOGICAL QUALITY SUMMARY



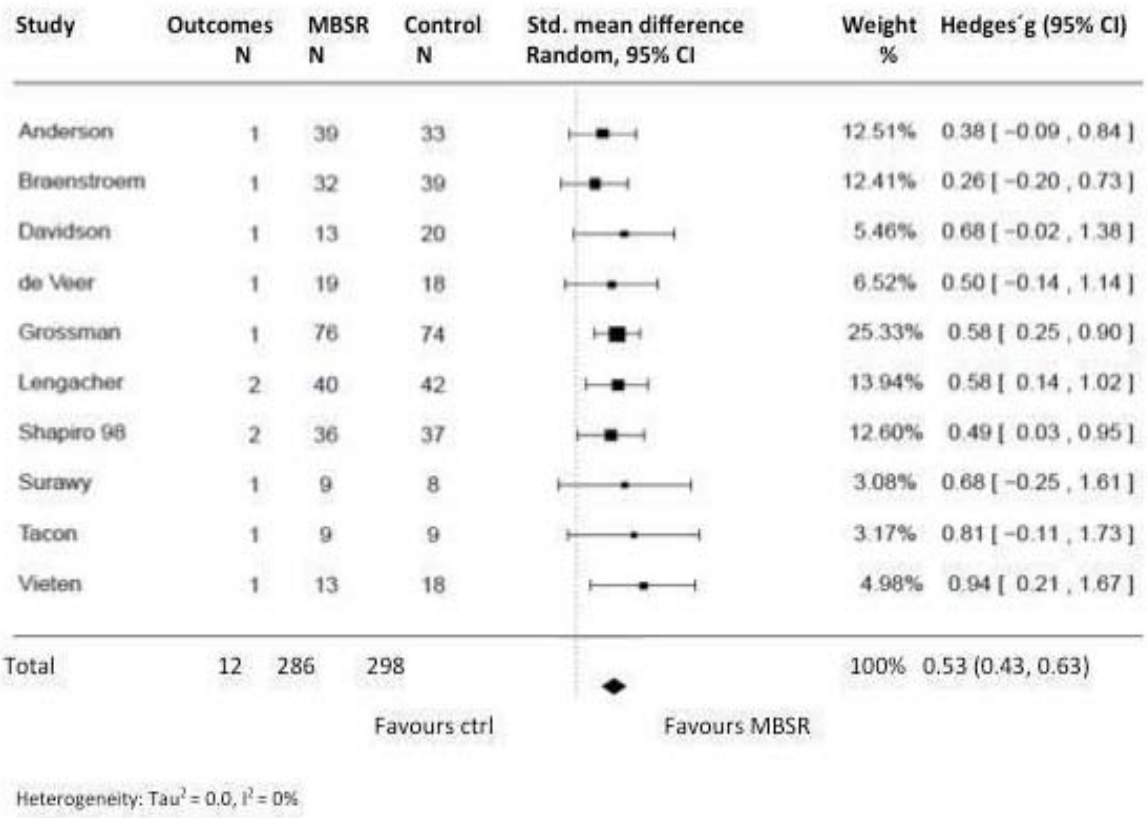
Review authors' judgements about each methodological quality item for each included study

13.3 SEARCH RESULTS AND INCLUSION OF STUDIES



13.4 EFFECTS ON ANXIETY SCORES (USING ROBUST SE)

Figure 4
Review: MBSR for improving health, quality of life and social functioning in adults
Comparison: MBSR vs WL or TAU
Outcome: Composite Anxiety Score

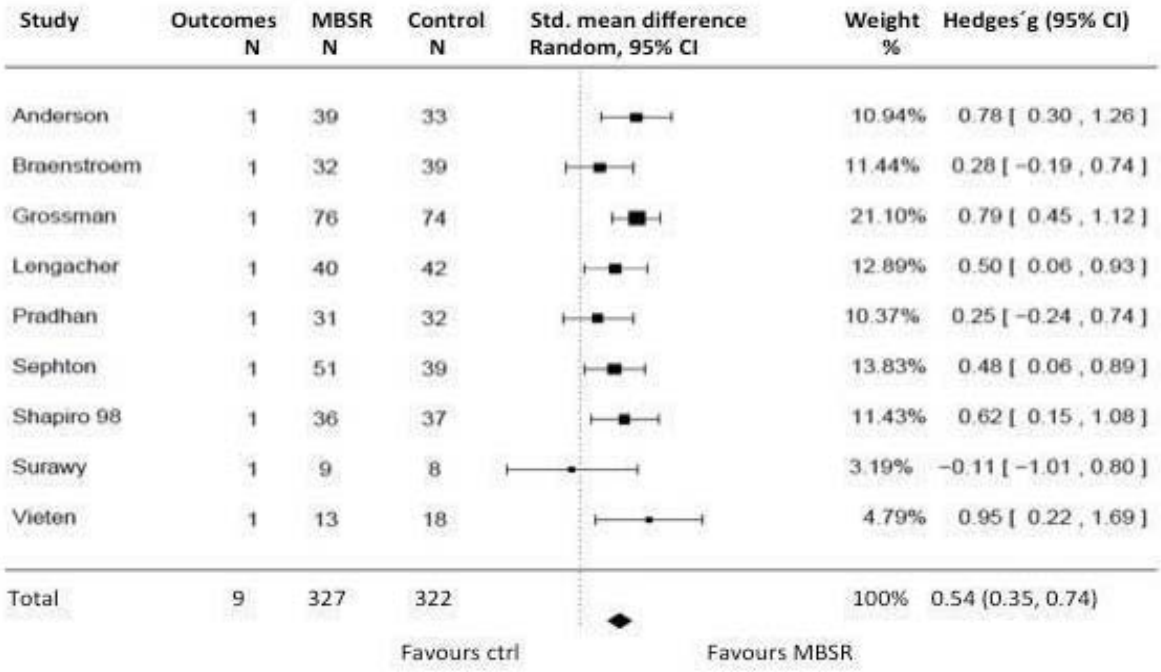


Heterogeneity: $Tau^2 = 0.0$, $I^2 = 0\%$

13.5 EFFECTS ON DEPRESSION SCORES (USING NORMAL SE)

Figure 5
Review: MBSR for improving health, quality of life and social functioning in adults
Comparison: MBSR vs WL or TAU

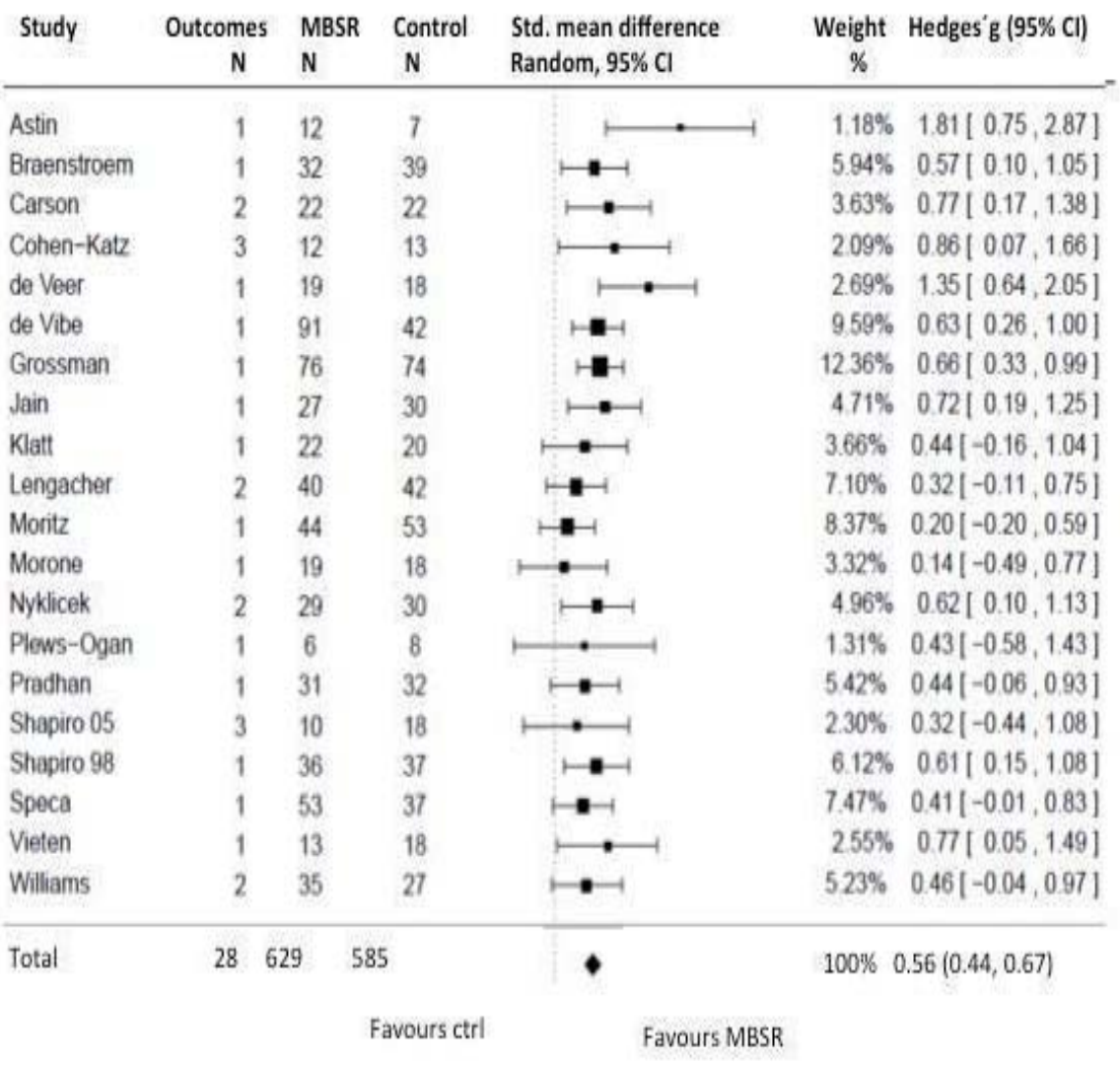
Outcome: Composite Depression Score



Heterogeneity: $Tau^2 = 0.03$, $I^2 = 32\%$

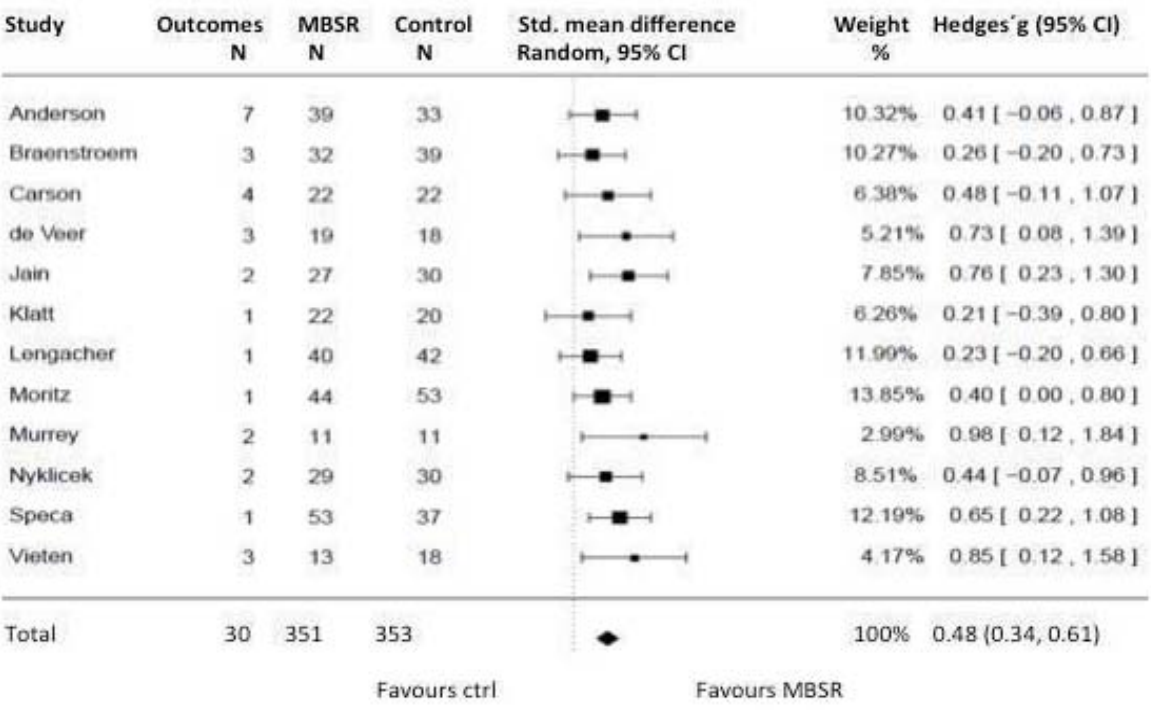
13.6 EFFECTS ON STRESS SCORES (USING ROBUST SE)

Figure 6
Review: MBSR for improving health, quality of life and social functioning in adults
Comparison: MBSR vs WL or TAU
Outcome: Composite Stress Score



13.7 EFFECTS ON OTHER MENTAL HEALTH SCORES (USING ROBUST SE)

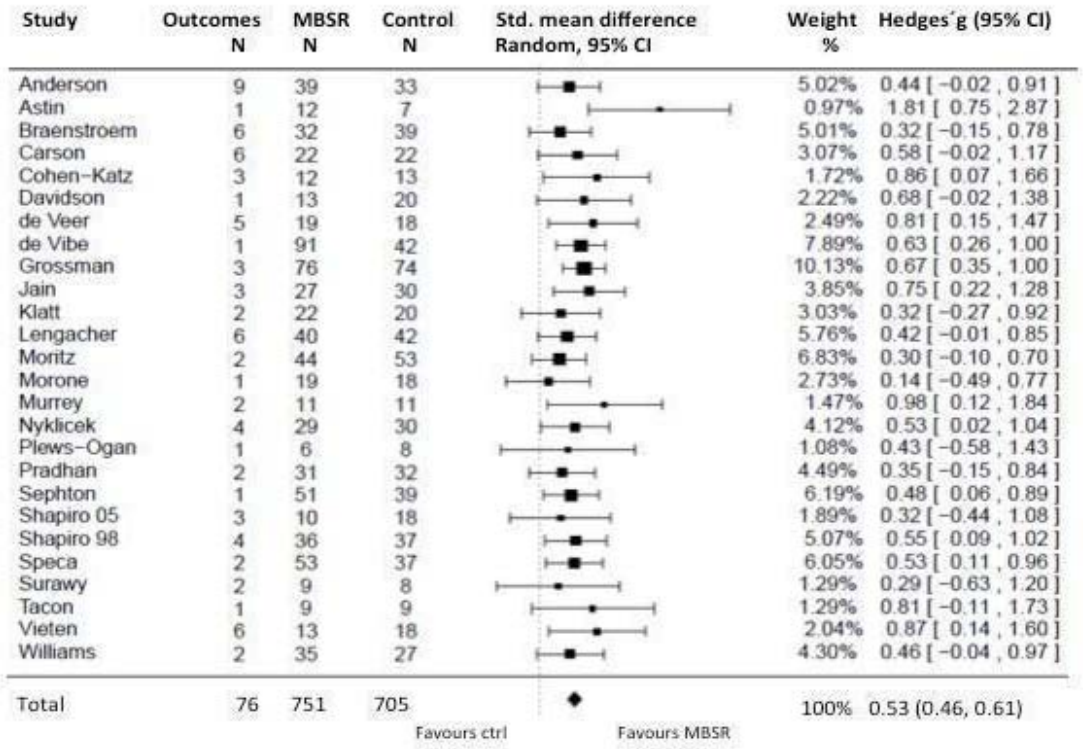
Figure 7
Review: MBSR for improving health, quality of life and social functioning in adults
Comparison: MBSR vs WL or TAU
Outcome: Composite Other Mental Health Score



Heterogeneity: $Tau^2 = 0.0$, $I^2 = 0\%$

13.8 EFFECTS ON COMPOSITE MENTAL HEALTH SCORE (USING ROBUST SE)

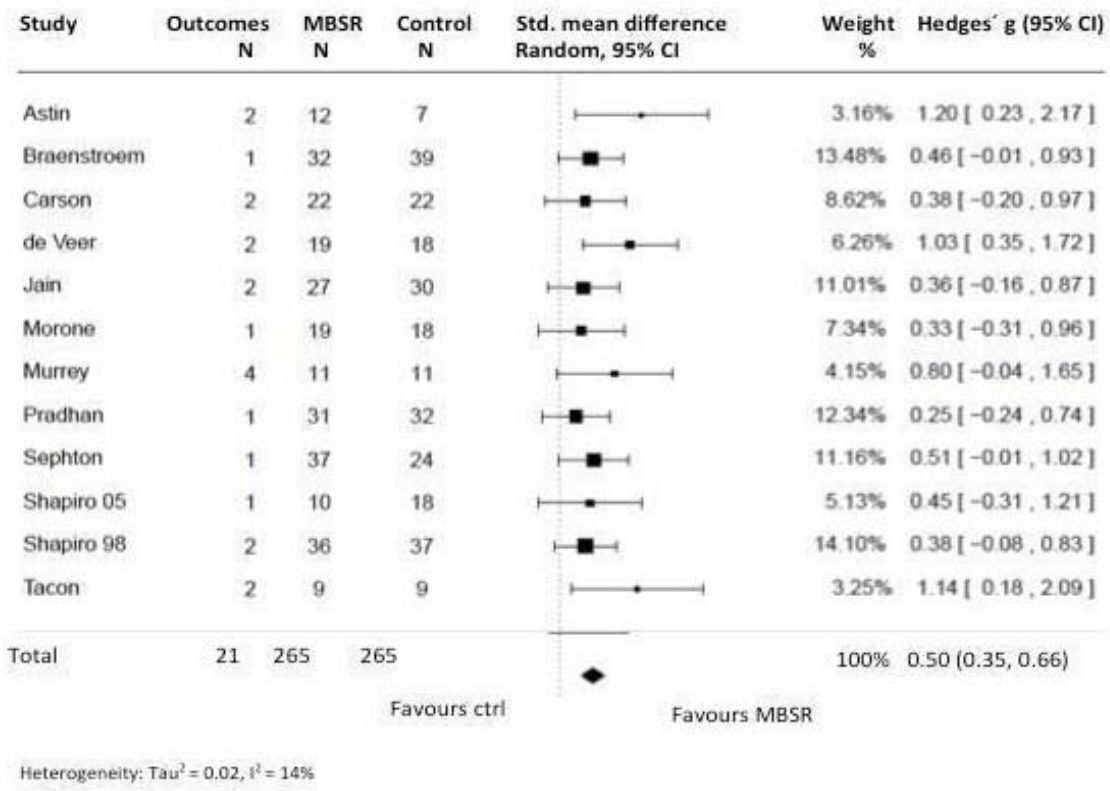
Figure 8
Review: MBSR for improving health, quality of life and social functioning in adults
Comparison: MBSR vs WL or TAU
Outcome: Composite Mental Health Score



Heterogeneity: $tau^2 = 0.0$, $I^2 = 0\%$

13.9 EFFECTS ON PERSONAL DEVELOPMENT SCORES (USING ROBUST SE)

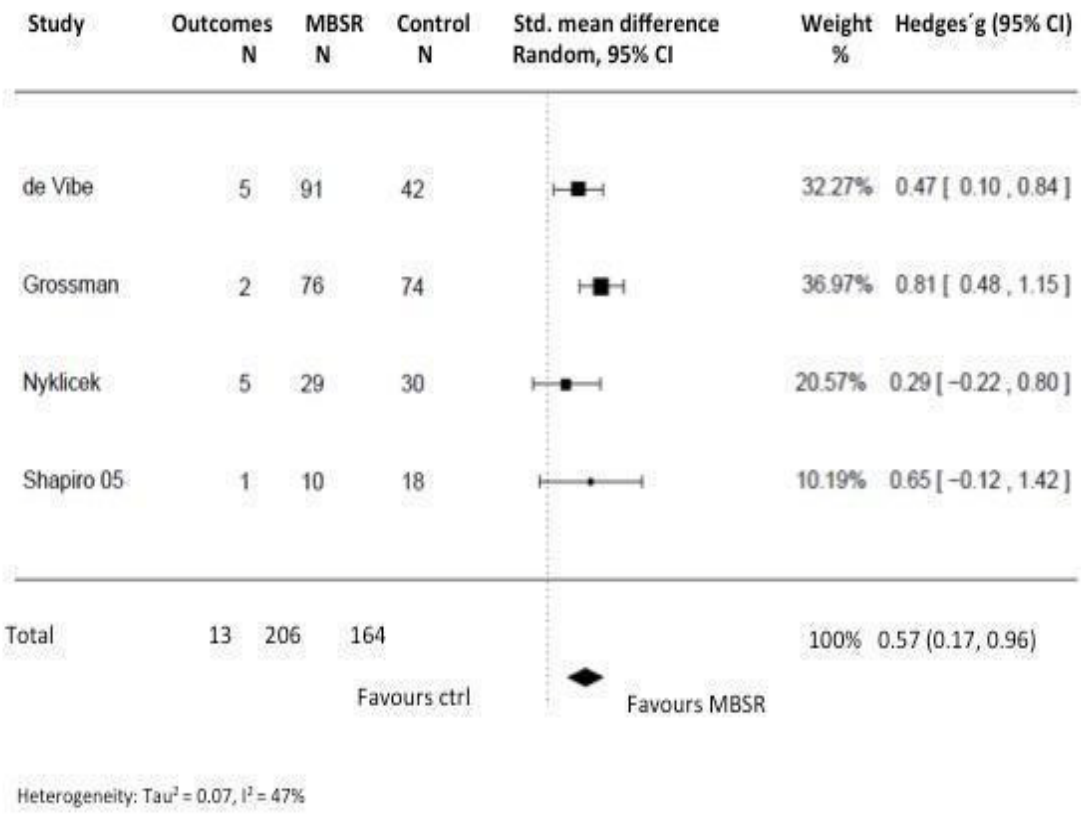
Figure 9
Review: MBSR for improving health, quality of life and social functioning in adults
Comparison: MBSR vs WL or TAU
Outcome: Composite Personal Development Score



Heterogeneity: $Tau^2 = 0.02$, $I^2 = 14\%$

13.10 EFFECTS ON QUALITY OF LIFE SCORES (USING ROBUST SE)

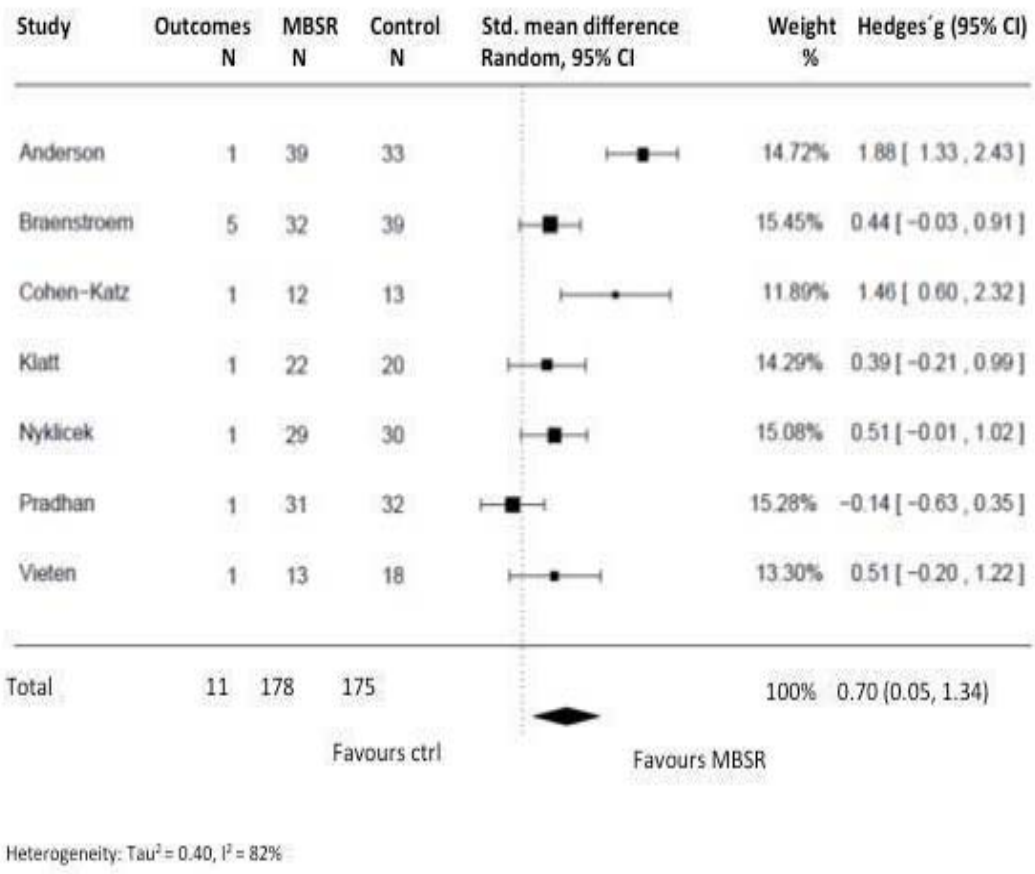
Figure 10
Review: MBSR for improving health, quality of life and social functioning in adults
Comparison: MBSR vs WL or TAU
Outcome: Composite Quality of Life Score



Heterogeneity: $Tau^2 = 0.07$, $I^2 = 47\%$

13.11 EFFECTS ON MINDFULNESS MEASURES (USING ROBUST SE)

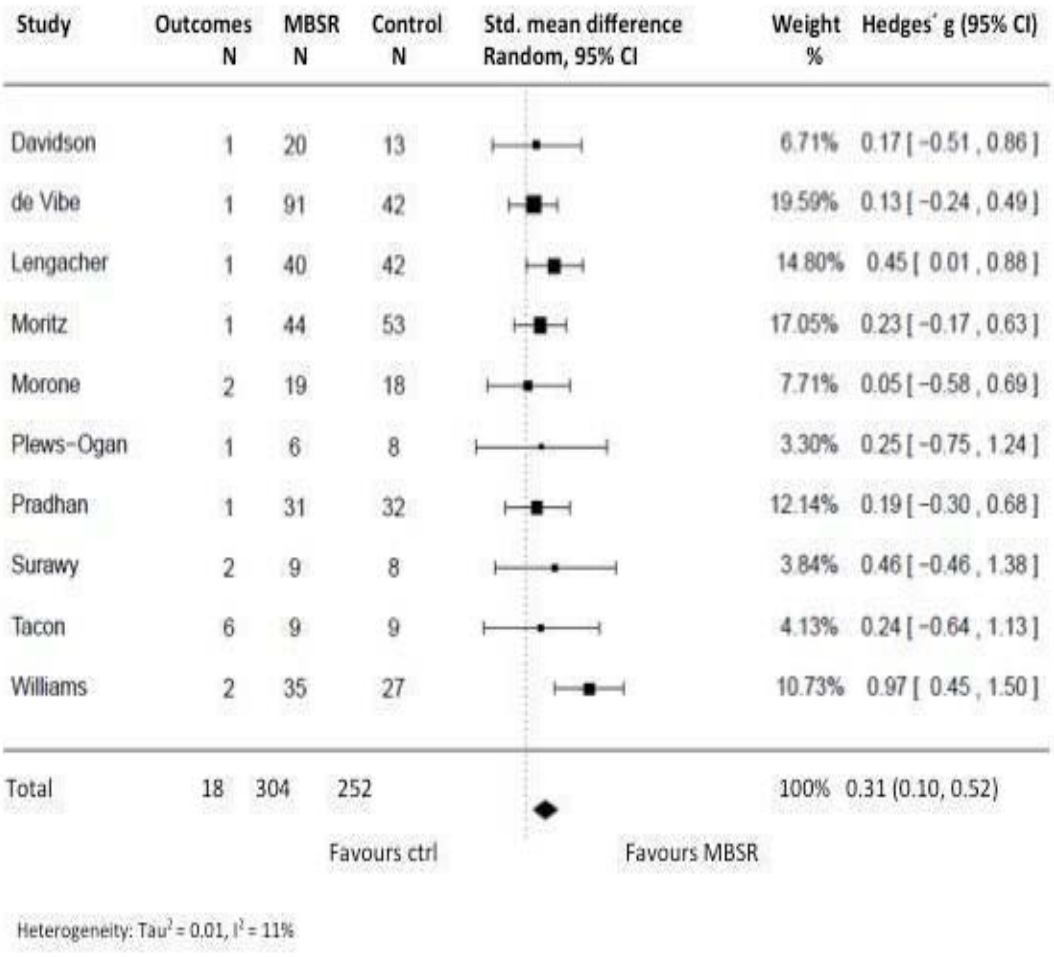
Figure 11
Review: MBSR for improving health, quality of life and social functioning in adults
Comparison: MBSR vs WL or TAU
Outcome: Composite Mindfulness Score



Heterogeneity: $Tau^2 = 0.40$, $I^2 = 82\%$

13.12 EFFECTS ON SOMATIC HEALTH SCORES (USING ROBUST SE)

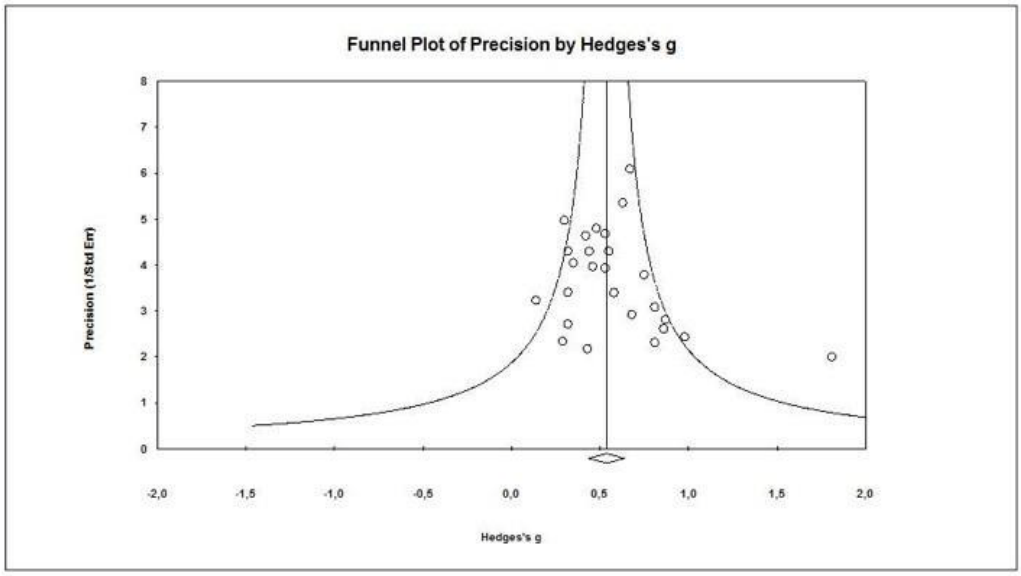
Figure 12
Review: MBSR for improving health, quality of life and social functioning in adults
Comparison: MBSR vs WL or TAU
Outcome: Composite Somatic Health Score



Heterogeneity: $Tau^2 = 0.01$, $I^2 = 11\%$

13.13 FUNNEL PLOT OF PRECISION VERSUS EFFECT SIZES

Composite Mental Health Outcome Hedges`g from 26 RCT studies on MBSR



Fail safe N (Rosenthal): Number of missing studies that would bring the p value to > 0.05 = 689
Fail safe N (Orwin) : Number of missing studies with zero effect, that would reduce Hedges` g to < 0.2 = 44
Egger´s test: Intercept 0.95 (CI -0,24, 2,15)

13.14 GRADE SCORES

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 79 mental health outcomes in 26 studies using robust SE	0.53	(0.46, 0.61)	1456	⊕⊕⊕⊕ **high**[1,2,3,4,5,6]
Stress Outcome Pooled estimate of 28 stress outcomes in 20 studies using robust SE	0.56	(0.44, 0.67)	1214	⊕⊕⊕⊕ **high**[1,2,3,5]
Anxiety Outcome Pooled estimate of 12 anxiety outcomes in 10 studies using robust SE	0.53	(0.43, 0.63)	584	⊕⊕⊕⊖ **moderate**[2,3,5,8]
Depression Outcome Pooled estimate of 9 depression outcomes in 9 studies using standard SE	0.54	(0.35, 0.74)	649	⊕⊕⊕⊖ **moderate**[2,8]
Somatic Health Outcome Pooled estimate of 18 somatic health outcomes in 10 studies using robust SE	0.31	(0.10, 0,52)	556	⊕⊕⊕⊖ **moderate**[7]
Personal development Outcome Pooled estimate of 21 personal development outcomes in 12 studies using robust SE	0.50	(0.35, 0.66)	530	⊕⊕⊕⊖ **moderate** [6]
Quality of Life Outcome Pooled estimate of 13 personal development outcomes in 4 studies using robust SE	0.57	(0.17, 0.96)	370	⊕⊕⊖⊖ **low**[8,9]

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] 14 studies did not specify sequence generation. 22 studies did not specify whether concealment of allocation was adequate. 15 studies did not report on blinding. Not rated down as there was no significant influence of increasing risk of bias score on the effect size, p=.29
[2] Results consistent across studies using different populations and different lengths of MBSR intervention, [3] $\tau^2 = 0.0$ and $I^2 = 0\%$ for mental health and anxiety and 0.009 and 11% for stress, showing low heterogeneity. [4] All studies in 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] 23 studies without reporting bias, [7] Very different somatic outcomes used, and wider CIs, more studies with similar outcomes necessary to assess certain effect [8] Relatively few studies, [9] $\tau^2 = 0.065$ and $I^2 = 47\%$ showing risk of heterogeneity