THE CAMPBELL COLLABORATION

Mindfulness Based Stress Reduction (MBSR) for improving health and social functioning in adults (Protocol)

Review information

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What's new

Date / Event	Description

History

Date / Event	Description

Abstract

Background

Objectives

Search methods

Selection criteria

Data collection and analysis

Results

Authors' conclusions

Plain language summary

[Plain language title]

[Summary text]

Background

Description of the condition

Psychological well-being is important for our health and our ability to function well in society. We will, however, all encounter challenging situations in the course of our life, whether it is bereavement, poverty, divorce or other life events that upset our balance. When such situations of psychological distress prevail over time, it may affect our health.

The mechanism whereby psychological distress may cause illness is being increasingly understood (Cohen 2007, Rosengren 2004). Recently a large prospective study of 10 000 public servants in London over 14 years concluded that 5-10% of cardiovascular disease seemed to be caused by job-stress (Chandola 2008). Likewise there is mounting evidence that traumatic life events increase the risk for chronic somatic and psychological problems that affect health and quality of life (Kirkengen 2008).

Parallell with the important understanding of the interconnectedness of the bio-psycho-social aspects of human life, the interest in mind-body interventions have increased steadily in Western societies. In 1999 and again in 2004 the U.S. government gave substantial funding through the National Institute of Health for research on mind-body interactions and health. Mindfulness based interventions are one approach to stress management and among these Mindfulness Based Stress Reduction (MBSR) is a well-defined programme that has been offered as an intervention in many studies (Grossman 2004).

The MBSR intervention is usually directed towards people with chronic physical and mental illnesses, such as chronic pain, heart disease, cancer, fibromyalgia, rheumatoid arthritis, anxiety, depression, eating disorders, attention deficit disorder, insomnia and burn-out. In addition it has been tried out on various non-clinical populations such as students, therapists, prison inmates and impoverished inner city dwellers (Grossman 2004).

Description of the intervention

MBSR is a group-based intervention programme (Kabat-Zinn 1990). It was developed at the University of Massachusetts Medical Center in 1979 as an intervention to relieve stress and better cope with illness and it is now being offered at several hundred health care institutions in the US and Europe (Santorelli 1999).

MBSR is an eight week programme in mindfulness training. The standard program has weekly sessions of 2 - 2 1/2 hours and one all day session after six to seven weeks. Some use shorter weekly sessions (30 - 90 minutes) and some omit the all day session. The weekly sessions have standardized core elements consisting of different mental and physical mindfulness exercises: 1) body-scan

exercises, 2) mental exercises focusing one's attention on the breath, 3) physical exercises with focus on being aware of bodily sensations and one's own limits during the exercises, and 4) practicing being fully aware during everyday activities by using the breath as an anchor for the attention. Essential to all parts of the program is developing an accepting and non-reactive attitude to what one experiences in each moment. The intervention derives it roots from ancient Buddhist practices of Vipassana (insight) meditation and yoga exercises but has been adapted, and is described in western terminology free from any particular religious affiliation (Kabat-Zinn 1990).

In addition to the exercises there is information (and discussion) on stress, stress management, and how to apply mindfulness to interpersonal communication. In each session time is included for the group members to reflect together on what they experience when they practice mindfulness. Between the sessions participants are strongly encouraged to practice the exercises for 30-45 minutes daily listening to audiotapes with guided exercises in body-scan, sitting mindfulness exercise focusing on the breath and yoga stretching exercises. The group usually has 10-30 members and is lead by one or two instructors (Kabat-Zinn 1990).

How the intervention might work

The MBSR programme provides systematic training in mindfulness as a self-regulation approach to stress reduction and emotion management. It is thought to have effect by fostering increased awareness for what is happening in each moment, with an accepting attitude, without getting caught up in habitual thoughts, emotions and behaviour patterns. The increased awareness then gives rise to new ways to respond and cope in relation to oneself and the world around. Findings from some studies indicate that MBSR can alter the function of the brain that is responsible for affect regulation and the areas that govern how we react to stressful impulses, and this in turn may normalize body functions such as breathing, heart rate and immune function (Davidson 2003, Lazar 2005).

Why it is important to do this review

MBSR is becoming more widespread and it is important to find out if it works, for whom, and under what circumstances. It is also essential to look at the body of knowledge on effect evaluation of MBSR in order to guide future research. An HTA-report from 2007 (ending the search in 2005) identified five broad categories of meditation practices of which mindfulness meditation was one (Ospina 2007). Meta-analyses were focused upon effects on hypertension, cardiovascular disease and substance abuse, not specifically studying MBSR. Other broad reviews concerning meditation have focused on particular target groups like patients with anxiety and children with attention deficit disorder (Krisanaprakornkit 2007, Krisanaprakornkit 2008). Some reviews have dealt with

the effects of MBSR in particular on specific groups like cancer patients (Smith 2005, Matchim 2007), and anxiety and mood symptoms (Toneatto 2007). Grossman et al. reviewed effects of MBSR on health (ending the search in 2002) including all controlled trials (Grossmann 2004). The latter group of reviews have included studies with various types of design. More studies have been published that can shed new light on the possible effects of MBSR (Carmody 2008). Our intention is to build on earlier systematic reviews, and provide an up to date review of randomised trials of the effects of MBSR on health and social functioning for various target groups.

Objectives

To assess the effects of MBSR on health and social functioning in adults.

Methods

Criteria for considering studies for this review

Types of studies

Randomized controlled trials (RCTs), if carried out well, provide the most unbiased estimate of effect of all comparative designs. Studies of meditative techniques for psychosocial conditions are especially prone to bias introduced by any form for self-selection to intervention or control. Moreover, there is likely to be a sufficient number of RCTs of adequate size to include in meta-analyses. Hence, we will only include RCTs.

Types of participants

MBSR has been tried out on a variety of target groups. Since MBSR is a general method for self-regulation based on the ability to be attentive and aware that is common to most people, the review will include all populations (> 18 years of age) that have received the intervention.

Types of interventions

We will include studies on MBSR training programmes based on the elements set out in the protocol by John Kabat-Zinn (Kabat-Zinn 1990). To be included the intervention must contain all four core elements of MBSR: 1) body-scan exercises, 2) mental exercises focusing one's attention on the breath, 3) physical exercises with focus on being aware of bodily sensations, and 4) practicing being fully aware during everyday activities. As long as these elements are taught we will include studies with varying duration and intensity of the MBSR course. We will exclude studies that combine MBSR with other therapeutic approaches, such as cognitive therapy.

Acceptable control groups are no intervention, waiting lists, other interventions, combinations of other interventions and services as usual. We will include comparisons of different variations of MBSR; e.g. a short versus a long course.

Types of outcome measures

Primary outcomes are health as measured by reduction in stress, psychological distress, stress-related somatic health problems, and wellbeing as measured by improvement in quality of life and psychological wellbeing. Secondary outcomes are improvements in social functioning such as work ability and personal development (e.g. self-acceptance, empathy, coping and relationship satisfaction). Moderator variables are compliance (measured through number of sessions attended and the degree to which participants actually practice), and increased mindfulness. Only studies that report measurements on outcomes from standardised scales, e.g. Becks Depression Inventory - BDI, will be included. We will check whether original or adapted versions of the different scales were used.

Primary outcomes

- There are a variety of ways to measure the primary outcomes. There is often a strong correlation between measures of health, illness and wellbeing, and many inventories can be understood to measure the same underlying process (Koivumaa-Honkanen 2004). A detailed listing of which scales and subscales used in various studies considered for meta-analysis is necessary together with a critical view on how they are labelled (a measure of quality of life may be labelled a measure of health in another study). Care will be taken to meta-analyse only measurements on scales that have been shown to measure the same underlying phenomenon. Commonly used measures are symptom checklists reporting either global measures or subscales. Examples of these are SCL90, SCL25, SCL5, SF36 and SF12. Some of these are used as a measure of health-related quality of life (e.g. SF36) while others have been used as a measure of psychological distress (e.g. SCL5). Many scales that measure specific aspects of psychological distress are also used, like anxiety (Spielberger State and Trait Anxiety - STAI), depression (Becks Depression Inventory - BDI) and burnout (Maslach Burnout Inventory - MBI). In addition there are scales measuring other aspects of psychological distress such as worry, rumination, fear, anger, hope and mood. A positive aspect of quality of life is measured by scales of psychological wellbeing, that often include a cognitive evaluation of satisfaction with life in addition to evaluating the degree of positive feelings of happiness and the absence of unhappy feelings.

- Other outcome measures of stress-related somatic health problems include inventories for sleep, pain intensity, pain acceptance, and bodily

reactions like salivary cortisol and immune function (antibody response to vaccination or number of T lymphocytes).

- All reported adverse effects

Secondary outcomes

- Social function. We are interested in seeing whether there are studies reporting on the effect of MBSR on social functions like work ability or activities of daily living, although we do not expect to find many studies that measure this.
- Personal development. Measurements for personal development can be for example empathy, self-acceptance, coping, forgiveness or spirituality.
- Satisfaction with the intervention
- Cost

Moderator variables

- Compliance is measured by the length (number of hours of the MBSR course, the attendance at the MBSR course and the degree of reported mindfulness exercise. This will allow us to see if it is possible to establish a dose-response relationship between the intervention and the outcomes.
- Mindfulness. In the last ten years a number of measurement scales for the degree of mindfulness has been developed. One of the most used is the MAAS- mindfulness awareness and attention scale. The effect of mindfulness training on health is thought to occur by increasing the ability to be mindful that is to be present in the actual moment at hand.

Lists of outcome measures which are included or excluded will be published.

Outcomes will typically be measured post-intervention, and at 3 or 6 month, at 12 month follow-up and longer if there is sufficient data. We will also document service cost if data on this is included in the primary studies. Included studies must contain sufficient information to make possible the calculation of the relative risk and/or standardized mean difference for primary outcome variables.

Search methods for identification of studies

Electronic searches will be made of bibliographic databases as well as searching on open web-sites. Reference lists of articles will be examined. Attempts will be made to look for studies in the so called 'grey literature'. We will also search for on-going studies. There will be no publication, geographic, or language restrictions. Searches will cover the following sources.

Electronic searches

MEDLINE

AMED (Allied and Complementary Medicine)

PsycINFO

EMBASE

Ovid Nursing Full Text Plus

British Nursing Index and Archive

Cochrane Library, 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

Search terms

Search terms for MEDLINE (modified as necessary for other databases) will be as followed:

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

Searching other resources

We will also search for ongoing studies in ClinicalTrials.gov. Furthermore, we will make contact with MBSR developers, practitioners and independent researchers to identify unpublished reports, ongoing studies and studies that did not come up in our search.

Data collection and analysis

Selection of studies

Two reviewers will independently read the titles and available abstracts to exclude obviously irrelevant reports. Any citation deemed potentially relevant by at least one reviewer will be retrieved in full text. Multiple reports of the same study will be linked together. Two reviewers (one content expert and one with methodological competence) will independently read all retrieved studies to determine whether they meet our selection criteria (described above and in Appendix 1). Readers will not be blinded as to journal name, author names, author affiliation or results. Disagreements will be resolved by consensus with a third author with methodological expertise. We will list potentially relevant, but excluded studies with an explanation as to why they were not included.

We will correspond with investigators, where necessary, to clarify study eligibility.

Data extraction and management

Information on study design and implementation, sample characteristics, intervention characteristics, and outcomes will be extracted from studies and entered into a paper form, see Appendix 2. If important information is missing, we will contact authors of the particular study to obtain the data. A coding list is incorporated in the data extraction form and will be piloted on two papers at the outset of the data collection phase (may result in minor adjustments). Two reviewers will independently extract data from all studies, one is a content specialist and the other has methodological expertise. If differences between raters occur, these will be discussed in order to refine coding schemes. Persisting disagreements that cannot be resolved by discussing with a third reviewer will be addressed by contacting the study authors. If this is unsuccessful, the disagreement will be recorded in the review. Multiple reports from the same study will be coded separately before combining information across reports.

Assessment of risk of bias in included studies

The risk of bias will be described in the "Risk of bias" table included in RevMan and the risk will be judged according to criteria set out in chapter 8 in the Cochrane Handbook (Higgins 2008). We will describe and judge sequence generation, allocation concealment, performance bias, blinding of assessors, incomplete outcome data, selective outcome reporting and other sources of bias like trial ended early. The nature of the intervention makes blinding of the participants and the course instructors impossible, but outcome assessors and those involved in the randomization process can be blinded. With regard to incomplete outcome data, we will assess dropout rates and the use of intention to treat (ITT) analysis.

Measures of treatment effect

We expect to encounter continuous data, typically in the form of measurements on a scale. We will extract data on final value scores. When available we will include in the analysis estimates of the treatment effect adjusted by taking into account baseline measurements. If standard deviations are not reported we will attempt to calculate them from standard errors, confidence intervals, t-values or p-values that relate to the differences between means in two groups. A few outcomes may be dichotomous and we will extract numbers for these outcomes (sample size will also have been collected). We will calculate effect measures using odds ratios for dichotomous data and standardized mean differences for continuous data.

If studies report multiple measures of the same construct at different points in time, we will conduct separate meta-analyses for outcomes measured at different points in time.

Unit of analysis issues

We will assess the unit of analysis of all the trials and determine whether individuals were randomized in groups or individually. We do not expect to find cluster-randomised trials. If we do, we will check for unit-of-analysis errors. For trials that use randomization by groups, results will be presented with proper control for clustering as set out in the Cochrane Handbook. To do this we need information about intra-class correlation coefficient (ICC). To determine the ICC we will use estimates in the primary trials on a study-by-study basis. If such information is not available we will use external estimates as described in the Cochrane Handbook.

Dealing with missing data

In the event of missing data, we will contact research authors in order to try to retrieve missing information due to incomplete reporting. We will address the potential impact of the missing data on the findings of the review in the

assessment of risk of bias and in the discussion section. In the case of missing information on standard deviations for continuous outcomes we will impute data in order to include these studies in a sensitivity analysis.

Assessment of heterogeneity

We will measure heterogeneity both informally (checking overlap of confidence intervals) and statistically by the chi-square test and the I-squared statistics (Higgins 2002). Care will be taken in the interpretation of the chi-squared test, because of its low power. Expecting some heterogeneity that cannot readily be explained, we will use a random-effects meta-analysis model.

Assessment of reporting biases

We will investigate possible reporting biases by means of funnel plots and testing for funnel plot asymmetry using Egger´s test. If we find important asymmetries, possibly due to small-study effects (the tendency for effect sizes from small studies to deviate from effect sizes from large studies), we will undertake a sensitivity analysis using the "trim and fill" method to correct for the asymmetry (Egger 1997).

Data synthesis

For mental health we will group results from measurement scales separately for anxiety, depression and stress/distress. If a study offers multiple measures of the same construct we will average the effect sizes from these outcomes. In a second level of analyses we will integrate all standardized effect sizes for mental health within single studies by calculating the mean. We will then synthesize these effect sizes for "mental health" across studies. It is a common view among clinicians that anxiety, depression and psychological distress are different constructs. However, studying the questions in inventories (which are overlapping), and measuring correlation (which is always high), one becomes doubtful of whether it holds true that the usual way of measuring e.g. anxiety and depression really taps into different constructs. The described two meta-analyses is an explicit attempt to look at this difficult issue both ways. As for physical health and social functioning, most measures will clearly represent separate constructs (e.g. blood pressure and pain). If the sample size varies between scales measured in a single study (that measures the same construct), we will weigh them for sample size when calculating the average score.

Inverse variance methods will be used to pool SMDs across studies, so that each effect size is weighted by the inverse of its variance in an overall estimate of effect size. Confidence intervals of 95% will be used for individual study data and pooled estimates. Binary outcomes will be analysed by calculating odds ratios with 95% confidence intervals.

We expect that all trials include measurements at the end of treatment. We also hope for medium-term follow-up (typically at three to six months), and possibly longer (if data are available).

Subgroup analysis and investigation of heterogeneity

We will perform the following subgroup analysis to explore possible differences in outcome effects:

- Clinical and non-clinical populations (expecting a larger effect among patients with established health problems).
- Psychological and somatic conditions (expecting a somewhat larger effect among participants with psychological distress compared to those with somatic problems only).
- Effect of length of MBSR intervention (expecting a greater effect of standard MBSR vs shorter MBSR interventions).
- Effect of compliance (expecting a greater effect on those who attend the course and practice mindfulness exercises).

Sensitivity analysis

We intend to perform the following sensitivity analysis:

- Removing the studies with large risk of bias to see whether an analysis of the studies with low risk of bias gives a different result.
- Analysing only studies that report data from an ITT analysis.
- Including studies where we have imputed missing information.

Results

Description of studies

Results of the search

Included studies

Excluded studies

Risk of bias in included studies

Allocation

Blinding

Incomplete outcome data

Selective reporting

Other potential sources of bias

Effects of interventions

Discussion

Summary of main results

Overall completeness and applicability of evidence

Quality of the evidence

Potential biases in the review process

Agreements and disagreements with other studies or reviews

Authors' conclusions

Implications for practice

Implications for research

Acknowledgements

Contributions of authors

Arild Bjørndal suggested the review to Michael de Vibe who has the content expertise. Michael de Vibe wrote the first draft of the protocol. Karianne Hammerstrøm, who is a research librarian, developed the search strategies. Arild Bjørndal wrote the other methods sections of the protocol and Krystyna Kowalski designed the forms. Karianne Hammerstrøm will carry out the searches. Michael de Vibe, Karianne Hammerstrøm and Krystyna Kowalski will select studies and extract data with Arild Bjørndal acting as arbitrator. All authors will contribute to the analyses. Michael de Vibe and Arild Bjørndal will write a first draft of the review.

Declarations of interest

Michael de Vibe has done a research project on MBSR in Norwegian family practice published in the Norwegian Medical Journal in 2006 and is a MBSR instructor. He is also doing an intervention study of MBSR among students with Arild Bjørndal as his mentor. Krystyna Kowalski is a part-time hatha yoga teacher. None of the authors stand to gain financially from a positive or negative evaluation of MBSR

Differences between protocol and review
Published notes
Characteristics of studies
Characteristics of included studies
Footnotes
Characteristics of excluded studies
Footnotes
Characteristics of studies awaiting classification
Footnotes
Characteristics of ongoing studies
Footnotes
Summary of findings tables
Additional tables
References to studies
Included studies
Excluded studies
Studies awaiting classification
Ongoing studies
Other references
Additional references

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Other published versions of this review

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Data and analyses

Figures

Figure 2

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

Sources of support

Internal sources

- No sources of support provided

External sources

- No sources of support provided

Feedback

Appendices

1 Study Inclusion and Exclusion Form MBSR Review

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

	Additional comments:				

2 Coding and Data Extraction Form MBSR Review

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: - Musculosceletal: - Psychological: - Oncology: - Respiratory: - Rheumatological: - Other (specify): If non-clinical, specify: Both clinical and non-clinical, specify:
10. Are exclusion criteria for study participation mentioned? NO: YES: If yes, describe (cite pg. no.):

STUDY SAMPLE				
11. Number of cases in sample	MSBR n= (Add columns as required)	Control n= (Add columns as required)	Total n=	Notes & pp. 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 program and control groups at baseline?

Yes (describe differences):

No:

Not reported:

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

Yes (describe differences):

No:

Not reported:

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

Yes (describe differences):

No:

Not reported:

15. Was intention to treat analysis used by investigators?

Yes:

No:

Not reported :

If yes, describe:

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

20. OUTCOME CHARACTERISTICS

Instrument/unit	**Outcome definition**	**Timing of measurement**			
	What does the scale measure, e.g. stress, depression, or a combination? Direction of scale. Is	State exact times within the categories below			
		<3months	3-6 months	> 6-12 months	>12 months

		the described as validated? Cite how the study has described this outcome.				
1.						
2.						
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9.						
10.						

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

Outcome		Intervention group 1		Control 1		Between group analysis
		Baseline	Final	Baseline	Final	Values for
		Median Mean (SD) (SMD) (SE)	Median Mean (SD) (SMD) (SE)	Median Mean (SD) (SMD) (SE)	Median Mean (SD) (SMD) (SE)	p df t f other
1.						
2.						
3.						
4.						
5.						
6.						

7.						
8.						
9.						
10.						

22. Outcome bias
Are there outcomes that were measured but not report? If yes, are reasons reported?
23. Miscellaneous:
Specific source of funding - Pharmaceutical industry: - Internal funds: - Professional org.: - Other industry: - Government: - Other (specify):
Key conclusions of study authors:
Special comments by study authors:
Comments by reviewers:
Reference to other studies:
Contact details of the authors:
Need to contact authors: If yes list issue(s), content and date contacted:
Additional comments: