



Title Registration Form **Campbell Collaboration Social Welfare Coordinating Group**

Title of review

(Suggested format: [*intervention/s*] for [*outcome/s*] in [*problem/population*] in [*location/situation*])

Example: behavioral therapy for reducing violence among adolescents in institutions)

Mindfulness Based Stress Reduction programs for improving health and wellbeing in adults

Background and objective of this review

(Briefly describe the problem and the intervention)

Half the consultations in primary care are due to stress-related problems (MacFarland 1985), and a large proportion of all medication is prescribed for problems related to stress, such as anxiety, depression, insomnia, headache, musculo-skeletal complaints, digestive problems and cardiovascular problems. Hence, reducing the harmful effects of stress through improved stress management may have substantial overall health benefits, including quality of life.

Mindfulness Based Stress Reduction (MBSR) was developed by John Kabat Zinn at the University of Massachusetts in 1979, and the program has since spread to several hundred health care institutions in North America and Europe. MBSR is also being used by a number of social services agencies, prisons, and schools.

The intervention consists of an eight week group training program, where the participants learn to use simple physical and mental exercises, to increase their ability to be fully present and aware of what is happening inside and outside of their mind and body on a moment-to-moment basis. These awareness exercises are performed with an accepting and non-reactive attitude to whatever is present, thereby discovering new ways to handle stress and life challenges.

A couple of relevant research reviews and meta-analyses have been published, but none of these have adhered to systematic review methods required by the Cochrane and Campbell Collaborations.

The **objective** of this systematic review is to assess the effectiveness of MBSR programs on somatic health conditions, psychological distress, and quality of life among adults experiencing a range of physical and psychosocial problems.

Define the population

(Who is included and who is excluded?)

The intervention has been tried in 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 all people, the review will include all populations that have tried the intervention. There are theoretical and empirical reasons for expecting a similar effect across target groups, varieties of the intervention and relevant outcomes. We will nevertheless distinguish between (1) primary and secondary interventions (expecting a larger absolute effect among patients with established health problems), and (2) two broadly defined patients groups (expecting a somewhat larger effect among patients with psychological distress compared to those with somatic problems only). We also expect a greater effect among those reporting compliance with exercising mindfulness practices.

Define the intervention/s

(What is given, by whom, and for how long? What are the comparison conditions?)

MBSR is an eight week training program consisting of weekly 2 to 2 1/2 hour group sessions lasting for eight weeks and one whole day session after seven weeks. The content consists of training attention and awareness using: 1) body scan exercises, 2) mental exercises focusing one's attention on breath, thoughts, feelings, and sensations 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 addition to the exercises, there is information (and discussion) on stress, stress management, and communication techniques. In each session, time is included for the group members to reflect together on what they experience. Between the sessions, members are strongly encouraged to practice the exercises for half an hour daily using CD's with guided exercises. The group usually has 10-30 members, led by one or two instructors.

Outcome/s

(What are the intended effects of the intervention? Primary and secondary outcomes should all be mentioned.)

Primary outcomes are reduced stress, and reduced stress-related somatic health problems and psychological distress. Secondary outcomes are improvements in quality of life, work ability, personal development (self-acceptance, empathy, emotion regulation and relationships), and increased mindfulness. Only studies that report measurements from validated measurement tools will be included.

Outcomes will typically be measured post treatment, and at 3 or 6 month, and at 12 month follow-up. Hopefully there are also long-term follow-ups.

Methodology

(What types of studies are to be included and excluded? Please describe eligible study designs, control/comparison groups, measures, and duration of follow-ups.)

Randomized controlled trials. For studies to be included they must contain sufficient information to make possible the calculation of the relative risk and/or standardized mean difference for primary outcome variables. Acceptable control groups are no intervention, waiting lists, other interventions, combination of other interventions, and services as usual.

Comparisons groups will have received other treatment interventions (e.g., cognitive therapy or educational interventions) or no treatment.

Review team

(List names of those who will be cited as authors on the final publication)

Lead reviewer This is the person who develops and co-ordinates the review team, discusses and assigns roles for individual members of the review team, liaises with the editorial base and takes responsibility for the on-going updates of the review	Name: Michael de Vibe Title: MD Affiliation: The Norwegian Knowledge Center for the Health Services Address: City: Oslo Postal Code: N-0130 Country: Norway Phone: +47 22 60 39 92 Mobile: +47 91 61 09 57 Email: Michael.deVibe@kunnskapssenteret.no
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Roles and responsibilities

Please give brief description of content and methodological expertise within the review team. It is recommended to have at least one person on the review team who has content expertise, at least one person who has methodological expertise and at least one person who has statistical expertise. It is also recommended to have one person with information retrieval expertise. Please note that this is the *recommended optimal* review team composition.

- Content: Michael de Vibe
- Systematic review methods: Arild Bjørndal
- Statistical analysis: Jan Odegard
- Information retrieval: Karianne Hammerstrøm

1. Potential conflicts of interest

(E.g., have any of the authors been involved in the development of relevant interventions, primary research, or prior published reviews on the topic?)

Michael de Vibe has done a research project on MBSR in Norwegian family practice published in the Norwegian Medical Journal in 2006 and is keenly interested in the intervention. None of the authors stand to gain financially from a positive or negative evaluation of MBSR.

2. Support

Do you need support in any of these areas: methodology and causal inference, systematic searches, coding, statistics (meta-analysis)?

We may need some advice on statistical methods for meta-analysis and coding.

3. Funding

Do you receive any financial support? If so, where from? If not, are you planning to apply for funding? Where?

The Knowledge Centre will provide necessary funding.

11. Preliminary timeframe

Approximate date for submission of Draft Protocol (please note this should be no longer than 6 month after title approval): 1.1.09

Title registration submission date: 1.7.08

Title approved 23rd Oct. 2008

References:

MacFarland BH et al. *Psychiatric disorders in primary care*. Archives of general psych. 1985;42:583-590.