Review

Mindfulness-Based Stress Reduction and Mindfulness-Based Cognitive Therapy – a systematic review of randomized controlled trials

Fjorback LO, Arendt M, Ørnbøl E, Fink P, Walach H. Mindfulness-Based Stress Reduction and Mindfulness-Based Cognitive Therapy – a systematic review of randomized controlled trials.

Objective: To systematically review the evidence for MBSR and MBCT.

Method: Systematic searches of Medline, PsycInfo and Embase were performed in October 2010. MBSR, MBCT and Mindfulness Meditation were key words. Only randomized controlled trials (RCT) using the standard MBSR/MBCT programme with a minimum of 33 participants were included.

Results: The search produced 72 articles, of which 21 were included. MBSR improved mental health in 11 studies compared to wait list control or treatment as usual (TAU) and was as efficacious as active control group in three studies. MBCT reduced the risk of depressive relapse in two studies compared to TAU and was equally efficacious to TAU or an active control group in two studies. Overall, studies showed medium effect sizes. Among other limitations are lack of active control group and long-term follow-up in several studies.

Conclusion: Evidence supports that MBSR improves mental health and MBCT prevents depressive relapse. Future RCTs should apply optimal design including active treatment for comparison, properly trained instructors and at least one-year follow-up. Future research should primarily tackle the question of whether mindfulness itself is a decisive ingredient by controlling against other active control conditions or true treatments.

L. O. Fjorback[1], M. Arendt[2], E. Ørnbøl[1], P. Fink[1], H. Walach[3]

[1]The Research Clinic for Functional Disorders and Psychosomatics, Aarhus University Hospital, Aalborg, [2]Unit for Psychiatric Research, Aarhus University Hospital, Aalborg, Denmark and [3]Institute for Transcultural Health Studies, European University Viadrina, Frankfurt, Germany

Summations

- Mindfulness-Based Stress Reduction is recommended as a useful method for improving mental health and reducing symptoms of stress, anxiety and depression.
- Mindfulness-Based Stress Reduction is recommended in medical disease management to improve health-related quality of life.
- Mindfulness-Based Cognitive Therapy is recommended for recovered recurrently depressed patients to prevent depressive relapse.

Considerations

- Results are generalizable only to individuals who have the interest and ability to participate in a Mindfulness-Based Stress Reduction/Mindfulness-Based Cognitive Therapy programme.
- Lack of long-term follow-up and active control groups are limitations in most Mindfulness-Based Stress Reduction studies.
- Mindfulness-Based Cognitive Therapy may increase the risk of relapse in patients with only two previous episodes.

Introduction

The literature on mindfulness is constantly expanding requiring updated reviews regularly. Mindfulness, defined as moment-to-moment non-judgemental awareness, is a skill that can be learned through practice, and it is believed to promote wellbeing (1). Mindfulness has received interest from clinicians and researchers because it seems to improve acceptance of symptoms that are difficult or impossible to change, install a cognitive metareflective capacity that enhances the degree of freedom of patients and help patients change their focus by emphasizing experience of the present moment. These potential mechanisms are not part and parcel of the established therapy programmes, and hence, mindfulness promises to offer something new to patients (2–4). Mindfulness-Based Stress Reduction (MBSR) (5) is a structured group programme that employs mindfulness meditation to alleviate suffering associated with physical, psychosomatic and psychiatric disorders. Participants are invited to focus with an interested, accepting and non-judgemental attitude on their pain, difficult sensations, emotions, cognitions and behaviour. This practice may lead to change in thoughts and behavioural patterns or in the attitudes towards thoughts, sensations and emotions. The improved self-observation may promote use of better coping skills (6). Mindfulness-Based Cognitive Therapy (MBCT) (7) is an adaptation of the MBSR programme. It incorporates elements of cognitive therapy facilitating a detached or decentred view of one's thoughts and is designed to prevent depressive relapse (6).

Since a first review in 2002, the interest in mindfulness-based interventions has increased (8). Baer (6) concludes that although the empirical literature includes many methodological flaws, mindfulness-based interventions may be helpful in the treatment of several disorders. A meta-analysis performed in 2004 shows effect sizes of approximately 0.5 on standardized measures of physical and mental wellbeing (9). The meta-analysis reviews both published and unpublished studies, and only three of the included controlled studies are actually published. Another review (10) concludes that MBSR is effective in reducing stress and anxiety whether it stems from chronic illness or other factors. However, the review is not systematic as there is no information on the number of included studies or inclusion criteria. An effect size analysis in clinical samples performed in 2010 (11) suggests that mindfulness-based therapy is moderately effective in improving anxiety and mood symptoms from pre- to post-treatment. However, the effect sizes for controlled studies are concluded to be unreliable and preliminary. All five reviews assess controlled and uncontrolled studies and do not exclude studies with few participants. A review by Tonneato et al. from 2007 assesses the impact of MBSR and MBCT on symptoms of anxiety and depression in clinical populations using a control group (12). They conclude that methodological variability in the reviewed studies precludes strong conclusions and that depression and anxiety do not reliably improve following MBSR. A meta-analysis of controlled studies performed in 2010 reports an overall small effect size of MBSR on mental health in adults with a chronic medical disease (13). In sum, the mindfulness literature is unclear about the evidence for MBSR/MBCT.

Aims of the study

The aim of the study is to perform a systematic literature review only of randomized controlled trials (RCT) on Mindfulness-Based Stress Reduction (MBSR) and Mindfulness-Based Cognitive Therapy (MBCT) with adequate sample size and only little variability from the original programmes to give recommendations for research, health care professionals and participants.

Material and methods

Description of mindfulness interventions

Mindfulness-Based Stress Reduction (5) consists of eight weekly 2–2½-h sessions and a whole-day retreat between week 6 and 7. The programme focuses on cultivating mindfulness through formal practices (sitting meditation, body scan and mindful yoga) and on integrating this capacity into everyday life as a coping resource for dealing with intensive physical symptoms and difficult emotional situations. It also includes group interactions concerning the challenges and achievements that the participants experience upon integrating mindfulness into their lives and stressful situations. Participants are asked to practice daily home assignments for 45–60 min a day (14).

Mindfulness-Based Stress Reduction is developed by Jon Kabat-Zinn, who emphasizes that MBSR is a complement to medical treatment, not a substitute of it (15).

Mindfulness-Based Cognitive Therapy (16) combines training in mindfulness (MBSR) with cognitive therapy and consists of eight weekly

2-h sessions. MBCT is similar to the MBSR programme, but it focuses more on thoughts. The participants learn to notice when they are ruminating and to identify specific thought patterns (7). MBCT is a prevention programme, not a treatment programme for acute depression. MBSR is intended to be delivered in heterogeneous groups while MBCT is designed to target homogenous group, but as the aim of the present review is to summarize the evidence lumping in chosen for inclusion and splitting in the conclusion.

Identification and selection

This review focuses on MBSR and MBCT because both treatments are well defined and mindfulness training is the key element. Mindfulness techniques are also used in other treatments (17, 18), but these interventions are not included as mindfulness training is not considered the main part of the treatment.

Studies were identified by systematic searches of Medline, PsychInfo and Embase from 1980 to October 2010. Titles, abstracts and full texts of the identified papers were screened for eligibility by one reviewer. All abstracts were read, and when an indication of mindfulness and RCT was found, the entire article was retrieved. References of selected papers were checked for additional eligible papers. The following criteria were applied for selection:

Keywords: Mindfulness-Based Stress Reduction, Mindfulness-Based Cognitive Therapy and Mindfulness Meditation.

Inclusion criteria: RCT, adults, published in English, MBSR or MBCT.

Slightly modified MBSR interventions with reduced treatment time (7–8 weekly 1½ to 2½-h sessions) for patients with cancer, older adults with chronic low back pain and medical students are included (19–22).

Exclusion criteria: Exploratory studies and studies with 32 or less participants. We chose a minimum of 33 patients to reduce the risk of type 2 error. According to Cohen (23), an 80% change of detecting a medium-to-large treatment effect with a two-tailed t-test at $\alpha = 0.05$ requires 33 participants per sample.

Data extraction

Data were extracted from eligible papers on study population, design, intervention, duration of follow-up and measurement and outcomes of physical and mental health.

Analysis

To examine the effects on physical and mental health, studies were grouped according to study population in non-clinical populations (Table 1) and clinical populations with physical illness (Table 2) or psychiatric disorders (Table 3). The aims and conclusions of the included trials are given in the text, and the outcomes are displayed in the tables. Then, the possible effect of mindfulness interventions was studied for different outcomes such as stress, anxiety and depression (Table 4). Finally, the quality of the RCTs is evaluated (Table 5).

Results

The search produced 72 different articles, of which 17 MBSR and 4 MBCT studies were included. The main reasons for exclusion were too few participants and the intervention not being the standard MBSR or MBCT programme.

Non-clinical populations (Table 1)

Nyklicek et al. (24) concluded that increased mindfulness may mediate the positive effects of MBSR intervention. The aim was to compare the effects of MBSR to a waiting list control condition while examining potentially mediating effects of mindfulness.

Davidson et al. (25) suggested that MBSR may produce demonstrable effects on brain and immune function. The aim was to measure the effects of MBSR on brain and immune function. We do not know whether the EEG-observed significant increases in left-sided anterior activation - a pattern previously associated with positive affect - are of any practical or clinical relevance, and not all brain scientists agree that increases in left-sided anterior activation are associated with positive affect (26).

Williams et al. (27) concluded that self-selected community residents can improve their mental and physical health by participating in an MBSR programme. The purpose was to determine whether participants in an MBSR intervention experienced decreases in the effect of daily hassles, psychological distress and medical symptoms. The results were based only on completers defined as subjects who completed the control or intervention programme and completed all the questionnaires.

Shapiro et al. (21) suggested that the short-term results give strength to the hypothesis that mindfulness can be thought of as 'preventive medicine'

Table 1. Effect of Mindfulness-Based Stress Reduction (MBSR) in non-clinical populations

Author, year	Participants	Intervention	Control group	Follow-up	Measures	Results	Effect-size
Nyklicek et al. (24)	Self-selected community residents reporting symptoms of distress Recruited in local papers. $N = 60$ mean age 46, 63% females	MBSR: 8 weekly, 2.5- to 3-h classes along with a silent 7-h retreat in week 6 $N = 29$	Waiting-list $N = 31$	End of treatment	Perceived Stress Scale	Group × time effect Psychological wellbeing d-difference 6.17 $P = 0.016$ MBSR: preM = 32.44, SD = 6.46; postM = 25.39, SD = 7.54 Control: preM = 31.37, SD = 6.46; postM = 28.1, SD = 7.51	Only within group effect sizes
					Maastricht Questionnaire	Vital exhaustion d-difference 13.72 $P = 0.001$ MBSR preM = 27.74, SD = 8.02; postM = 18.51, SD = 9.75 Control preM = 27.27, SD = 7.99; postM = 25.34, SD = 9.79	
					WHOQoL-bref	Quality of life d-difference 2.77 $P = 0.009$ MBSR preM = 2.98, SD = 0.69; postM = 3.37, SD = 0.63 Control preM = 2.97, SD = 0.69; postM = 3.07, SD = 0.63	
					Global Mood Scale	Positive affect d-difference 8.23 $P = 0.006$ MBSR preM = 14.18, SD = 7.05; postM = 18.76, SD = 6.84 Control preM = 16.38, SD = 7.04; postM = 16.9, SD = 6.83 No significant group × time effect Negative affect d-difference 1.77 $P = 0.189$ MBSR preM = 20.49, SD = 8.67; postM = 14.68, SD = 9.21 Control preM = 20.39, SD = 8.69; postM = 17.13, SD = 9.21	
Davidson et al. (25)	Healthy employees Recruited from a biotechnology corporation. 48 were randomized, $N = 41$ completed some of the measures for at least 2 assessments, mean age 36, 70% females	MBSR: 8 weekly, 2.5- to 3-h classes along with a silent 7-h retreat in week 6 $N = 25$	Waiting-list $N = 16$	End of treatment and 4 months	EEG	Group × time effect MBSR had greater left-sided activation (C3/C4) end of treatment $P < 0.05$ and 4-month follow-up $P < 0.01$	Not possible to calculate, no SE for change scores
					Antibody titers	MBSR had greater rise in antibody titers $P < 0.05$	
					State trait anxiety	MBSR had greater reduction in anxiety $P < 0.01$ MBSR preM = 40, SE = 1.7; postM = 35, SE = 1.3 Control preM = 39, SE = 3; postM = 40, SE = 2.5	
					Positive and negative affect	No significant group × time effect	

Table 1. Continued

Author, year	Participants	Intervention	Control group	Follow-up	Measures	Results	Effect-size
Williams et al. (27)	Self-selected community residents Recruited via local papers. 103 were randomized, N = 62 completed all questionnaires, mean age 42, 72% females	MBSR: 8 weekly, 2.5-h classes along with a silent 8-h retreat in week 6 plus 1-h preprogramme and postprogramme interviews N = 35	Educational Materials N = 27	End of treatment and 3 months	Daily Stress Inventory	Group × time effect Daily hassles P = 0.045 MBSR preM = 2.77, SE = 0.3; postM = 2.25, SE = 0.27 Control preM = 3, SE = 0.35; postM = 2.85, SE = 0.35	Mean effect size all mental health scales 0.56 Mean effect size all physical health scales 1.01
					Symptom checklist (SCL90) (MSCL)	Psychological distress P = 0.049 MBSR preM = 0.57, SE = 0.15; postM = 0.28, SE = 0.07 Control preM = 0.67, SE = 0.2; postM = 0.61, SE = 0.2 Medical symptoms P = 0.01 MBSR preM = 17, SE = 3; postM = 10, SE = 2.5 Control preM = 18, SE = 4; postM = 17, SE = 4	
Shapiro et al. (21)	Medical and premedical students were actively recruited. N = 78 53% females, mean age?	MBSR: 7 weekly, 2.5-h sessions or waiting-list N = 37	Waiting-list N = 41	End of treatment	Symptom checklist (SCL90)	Group × time effect MBSR group had less depression P < 0.006 MBSR preM = 0.85, SD = 0.58; postM = 0.57, SD = 0.58 Control preM = 0.76, SD = 0.63; postM = 0.89, SD = 0.71	Mean effect size all mental health scales 0.62
					State trait anxiety	MBSR group had less State Anxiety P < 0.05 MBSR preM = 39.8, SD = 11; postM = 37.2, SD = 12.4 Control preM = 39.1, SD = 9.4; postM = 42.8, SD = 11.6 MBSR group had less trait anxiety P < 0.002 MBSR preM = 40.9, SD = 8.9 postM = 35, SD = 8.8 Control preM = 41, SD = 9.9 postM = 40.5, SD = 10.1	
					Index of Core Spiritual Experiences	MBSR group had increases in spirituality P < 0.02 MBSR preM = 2.57, SD = 0.64 postM = 2.8, SD = 0.57 Control preM = 2.6, SD = 0.76, postM = 2.6, SD = 0.68	
					Empathy construct rating scale	MBSR group had increases in empathy P < 0.05 MBSR preM = 77, SD = 27.6 postM = 83.5, SD = 24.4 Control preM = 76, SD = 22.7 postM = 73, SD = 21.6	

Effect sizes refers to: Cohen's d an effect size of 0.2–0.3 might be a 'small' effect, around 0.5 a 'medium' effect and 0.8 to infinity, a 'large' effect.
Williams and Shapiro: Mean effect sizes of all mental and physical health were calculated in meta-analysis Grossman et al. (9).

Table 2. Effect of Mindfulness-Based Stress Reduction (MBSR) in clinical populations with somatic conditions

Author, year	Participants	Intervention	Control group	Follow-up	Measures	Results	Effect-size
Grossman et al. (9)	Patients with multiple sclerosis Referred themselves after having received information via the outpatient neurology clinic at the University Hospital Basel $N = 150$ mean age 47 79% females	MBSR: 8 weekly, 2-h classes along with a silent 7-h retreat in week 7, a personal intake interview and post intervention interview $N = 76$	Treatment as usual $N = 74$	End of treatment and 6 months	Health-related quality of life HAQUAMS	Group × time effect MBSR change end of treatment 0.18 (0.09–0.27) $P = 0.0002$ TAU change end of treatment −0.09 (−0.2 to 0.01)	0.86
						MBSR change 6-month follow-up 0.13 (0.00–0.25) $P = 0.04$ TAU change 6-month follow-up −0.05 (−0.16 to 0.07)	0.51
					Quality of life in chronic disorders PQOLC	MBSR change end of treatment 2.54 (1.91–3.17) $P = 0.00000$ TAU change end of treatment −0.57 (−1.29 to 0.015)	0.43
						MBSR change 6-month follow-up 1.77 (0.97–2.58) $P = 0.003$ TAU change 6-month follow-up 0.1 (−0.83 to 0.64)	0.28
					Depression CES-D	MBSR change end of treatment 5.29 (3.5–7.07) $P = 0.00000$ TAU change end of treatment −0.1.43 (−3.47 to 0.61)	0.65
						MBSR change 6-month follow-up 4.63 (2.51–6.75) $P = 0.03$ TAU change 6-month follow-up 0.86 (−1.07 to 2.78)	0.36
					Fatigue MFIS	MBSR change end of treatment 6.65 (4.14–9.16) $P = 0.0001$ TAU change end of treatment −0.1 (−2.26 to 2.05)	0.41
							adjusted
						MBSR change 6-month follow-up 6.58 (3.63–9.53) TAU change 6-month follow-up −0.10 (−2.26 to 2.05)	0.38
							adjusted
					Anxiety STAI	MBSR change end of treatment 3.95 (2.31–5.59) $P = 0.001$ TAU change end of treatment −0.22 (−1.89 to 1.46)	0.39
							0.39
						MBSR change 6-month follow-up 3.68 (1.84–5.52) TAU change 6-month follow-up 0.13 (−1.62 to 1.88)	0.33

Table 2. Continued

Author, year	Participants	Intervention	Control group	Follow-up	Measures	Results	Effect-size
Foley et al. (29)	Cancer patients Recruited through local media and clinical staff at the Sydney Cancer Center. $N = 115$ mean age 55, 77% females	Mindfulness-Based Cognitive Therapy (MBCT): 8 weekly, 2-h classes along with a silent 7-h retreat in week 7 $N = 55$	Waiting-list $N = 60$	End of treatment	Current levels of depression HAM-D	Group × time effect $P \le 0.001$ MBCT preM = 16.02, SD = 7.28; postM = 6.26, SD = 5.43 Control preM = 14.38, SD = 8.12; postM = 10.27, SD = 6.93	Only within group effect sizes
					Current levels of anxiety HAM-A	Group × time effect $P = 0.002$ MBCT preM = 15.58, SD = 9.79; postM = 5.58, SD = 5.13 Control preM = 14.37, SD = 9.932; postM = 8.90, SD = 8.39	
					Distress DASS-21	Group × time effect $P \le 0.001$ MBCT preM = 16.98, SD = 10.57; postM = 10.67, SD = 6.98 Control preM = 16.13, SD = 10.88; postM = 15.52, SD = 10.71	
					Quality of life FACT-G	No significant group × time effect MBCT preM = 71.62, SD = 14.81; postM = 78.80, SD = 14.87 Control preM = 71.38, SD = 14.67; postM = 74.18, SD = 13.30	
					Mindfulness FMI	Group × time effect $P \le 0.001$ MBCT preM = 18.31, SD = 7.65; postM = 23.29, SD = 7.17 Control preM = 17.98, SD = 6.81; postM = 18.65, SD = 6.44	0.5
Mularki et al. (30)	Patients with chronic obstructive lung disease Recruited from two medical centre sites using posted advertisement or clinical referral $N = 86$ mean age 67 50% females	Mindfulness-based breathing therapy: standard MBSR plus with supplemental relaxation response training during the first 2 weeks. $N = 44$ mean age 70.6	Support group designed to match time spent and attention by a team of professional facilitator $N = 42$ mean age 64	End of treatment	Self-reported dyspnea Changes in functional limitation (6 min walk test) Mindfulness Perceived stress	36 did not complete the study, most dropouts never attended a single session. No differences in major outcomes between the MBBT intervention and the support group by either intention to treat analysis ($n = 49$) or within the subset completed at least 75% of the sessions ($n = 36$)	
Wong et al. (31)	Patients with chronic pain for at least 3 months $N = 100$	MBSR: 8 weekly, 2-h classes along with a silent 7-h retreat in week 7	Education programme groups	End of treatment 3 and 6 months	Self-reported pain Amount of sick leave Mood status (POMS, Depression scale, STAI) Health-related quality of life (SF-12)	No group × time effect After intervention, patients in both groups had significant improvements in pain intensity, anxiety and quality of life which was sustained until 6 months postintervention	

Table 2. Continued

Author, year	Participants	Intervention	Control group	Follow-up	Measures	Results	Effect-size
Creswell et al. (33)	HIV-infected adults reporting symptoms of psychological distress Recruited through HIV/AIDS community agencies. N = 67 were randomized N = 48 attended at least one class, mean age 41, 10% females	MBSR: 8 weekly, 2-h classes along with a silent 7-h retreat in week 7 N = 41 (Intention to treat) N = 33 (Attended at least one study class)	1-day stress reduction MBSR program N = 26 (Intention to treat) N = 15 (Attended class)	End of treatment	Disease activity CD4 + Lymphocytes (Log 10)	Group × time effect P = 0.02 MBSR preM = 618, SE = 47; postM = 628, SE = 52 Control preM = 757, SE = 70; postM = 572, SE = 71 ITT analyses showed the same pattern P = 0.08	0.64
Morone et al. (20)	Older adults with chronic low back pain Recruited via adult pain clinics, flyers and newspapers. N = 37 mean age 75, 57% females	MBSR: 8 weekly 1 -h sessions N = 19	Waiting-list N = 18	End of treatment	Pain SF-36 Pain Scale	No significant group × time effect P = 0.31 MBSR preM = 35.5, SD = 6; postM = 39.9, SD = 7.7 Control preM = 35.7, SD = 7.2; postM = 38.8, SD = 8.3	Only within group effect sizes
					Physical function SF-36 Physical Function Scale	Group × time effect P = 0.03 MBSR preM = 42, SD = 10.9; postM = 45.7, SD = 9.2 Control preM = 35.7, SD = 7.2; postM = 38.8, SD = 8.3	
					Pain acceptance Questionnaire Total Score	Group × time effect P = 0.008 MBSR preM = 72.2, SD = 13.4; postM = 75.5, SD16 Control preM = 68.1, SD = 20.3; postM = 64.8, SD = 23.0	
					Quality of life SF-36 global Health composite	No significant group × time effect P = 0.27 MBSR preM = 40.4, SD = 9.0; postM = 44.7, SD = 8.9 Control preM = 40.3, SD = 10.4; postM = 42.9, SD = 10.7	
Pradhan et al. (34)	Rheumatoid arthritis patients Recruited via newspaper, health fairs and rheumatologists. N = 63 mean age 54, 86% females	MBSR: 8 weekly, 2.5-to 3-h classes along with a silent 7-h retreat in week 6 + 3 refresher classes over the following 4 months N = 31	Waiting-list N = 32	End of treatment and 6 months	Depressive symptoms (SCL-90-R)	No significant differences between groups at two months. No significant group × time effect P < 0.08 (at 6 months) MBSR Change M = −0.26, SE = 0.08; Control −0.06, SE = 0.08	0.5
					Psychological distress (SCL-90-R)	Group × time effect P < 0.04 (at 6 months) MBSR Change M = −0.17, SE = 0.05; Control −0.03, SE = 0.05	
					Wellbeing Psychological Well-Being Scale	Group × time effect P < 0.03 (at 6 months) MBSR Change M = −5.55, SE = 3.44; Control −5.47, SE = 3.38	
					Disease activity Score in 28 joints	No effect on disease activity P = 0.45 MBSR Change M = −0.3, SE = 0.17; Control −0.12, SE = 0.16	
					Mindfulness Attention Awareness scale	No significant group × time effect P < 0.09 MBSR Change M = 0.45, SE = 0.15; Control.09, SE = 0.14	

Table 2. Continued

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Author, year	Participants	Intervention	Control group	Follow-up	Measures	Results	Effect-size
Sephton et al. (35)	Women with fibromyalgia Recruited via news-papers, TV. N = 91 mean age 48	MBSR: 8 weekly, 2.5- to 3-h classes along with a silent 7-h retreat in week 6 N = 51	Waiting-list N = 40	End of treatment and 2 months	Depressive Symptoms (BDI: Beck Depression Inventory)	Group × time effect P = 0.002 MBSR preM = 15.7, SE = 7.1; postM = 12.4, SE = 7.4; 2-month follow-up M = 13.3, SE = 7.5 Control preM 14.7, SE = 6.9; postM = 15.1, SE = 8.1; 2-month follow-up M = 14.8, SE 8.1	0.64
Monti et al. (32)	Woman with cancer Referred from cancer centres and hospitals N = 111 mean age 53	Mindfulness-based art therapy: MBSR and aspects of art therapy N = 56	Waiting-list N = 55	End of treatment	Symptoms of distress (SCL-90-R) Overall; Anxiety; Depression; Quality of life (SF-36) Physical composite score; Mental composite score	Group × time effect Change in means (control-MBAT) 0.16 (0.08,0.24) P < 0.001; 0.16 (0.02,0.29) P < 0.022; 0.19 (0.07,0.30) P < 0.001; No Group × time effect P < 0.19 −2.23 (−5.6, 1.15); −4.45 (−8.32, −0.58)	0.3; 0.23; 0.26
Hebert et al. (37)	Women with breast cancer Enrolled from hospitals N = 172 mean age 50	MBSR N = 50	Nutrition education N = 51 or usual care N = 56	4 and 12 months	Total energy Kcal/d	Group × time effect P < 0.0002 4-month follow-up nutrition education M = −74.8, SE = 74.1 vs no change in other groups 12-month follow-up M = −33.9, SE = 79.2	
Speca et al. (19)	Cancer patients Referred from clinical staff or leaflets in clinic. N = 90 mean age 51 (27–75), 79% female	MBSR: 7 weekly, 90-min sessions N = 53	Waiting-list N = 37	End of treatment	Profile Of Mood States; Anxiety; Depression; Anger; Vigour; Confusion; Total POMS; Symptoms of Stress Inventory SOSI	Group × time effect MBSR M = −4.8, SE = 5.6; Control M = −0.4, SE = 5.2 P < 0.01; MBSR M = −6.2, SE = 8.3; Control M = −0.4, SE = 9.5 P < 0.05; MBSR M = −3.9, SE = 4.8; Control M = −0.1, SE = 7.1 P < 0.05; MBSR M = 4.1, SE = 6.8; Control M = 0.4, SE = 4.6 P < 0.05; MBSR M = −2.5, SE = 4.2; Control M = 0.3, SE = 3.9 P < 0.05; MBSR M = −24.1, SE = 25.1; Control M = −2.1, SE = 28.6 P < 0.01; Group × time effect P < 0.05 MBSR M = −31.3, SE = 32.4; Control M = −12.3, SE = 30.26	Mean effect size all: mental health scales 0.54

Sephton and Pradhan Effect sizes were calculated in meta-analysis Bohlmeijer et al. (13).
Speca Effect size = 0.54 Mean effect sizes of all mental and physical health were calculated in meta-analysis Grossman et al. (28).

Table 3. Effect of Mindfulness-Based Stress Reduction (MBSR) in clinical populations with psychiatric disorders

Author, year	Participants	Intervention	Control group	Follow-up	Measures	Results	Effect-size
Koszycki et al. (38)	Patients with DSM-IV generalized social anxiety disorders Recruited via media. $N = 53$ mean age 37–38, 72% females	MBSR: 8 weekly, 2.5-h classes along with a silent 7-h retreat in week 6 $N = 26$	12 weekly 2.5-h sessions of cognitive behavioural therapy (CBT) $N = 27$	End of treatment	Social interacting (SIAS) Social phobia scale (SPS) CGI- Illness severity Liebowitz Social Anxiety Scale	Group × time interaction CBT had greater improvement in decreasing social anxiety symptoms. Equally efficacious in improving function, mood, wellbeing. CBT preM = 46.1, SE = 8.9; postM = 30.2, SE = 10.8 $P = 0.057$ MBSR preM = 44.6, SE = 10.6; postM = 34.1, SE = 14.9 CBT preM = 33.3, SE = 13.2; postM = 15.4, SE = 8 P = 0.006 MBSR preM = 34.0, SE = 14; postM = 24.6, SE = 16.4 CBT preM = 4.7, SE = 0.7; postM = 3 SE = 1, P = 0.005 MBSR preM = 5, SE = 0.8; postM = 3.9, SE = 0.8 CBT preM = 34.3, SE = 8.6; postM = 17.4, SE = 8.3 P = 0.009 MBSR preM = 39.1, SE = 8.9; postM = 25.3, SE = 9	Only within group effect sizes
Moritz et al. (22)	Emotionally distressed patients (> 40 POMS) Recruited from primary care clinics. $N = 165$ mean age 44, 84% females	MBSR: 8 weekly, 1.5-h classes $N = 56$ 76% female	An 8-week audiotaped spirituality home-study programme $N = 54$ 95% females, or a waiting-list control group $N = 55$ 80% females	End of treatment and 4 weeks	Profile of Mood Scale (POMS) Health survey, Mental component (SF-36, MCS)	Group × time interaction. Greatest improvement in the spirituality group at the end of treatment. MBSR equally efficacious at 4 weeks follow-up P values refer to comparison to spirituality group Control Mean change scores = −10.3, SE = 4.0 P < 0.001 MBSR Mean change scores = −22.6, SE = 4.0 P = 0.034 Spirituality Mean change scores = −43.1, SE = 3.9 Group × time interaction. Greatest improvement in the spirituality group at the end of treatment MBSR equally efficacious at 4 weeks follow-up Control Mean change scores = 4.7, SE = 1.6 P < 0.001 MBSR Mean change scores = 7.1, SE = 1.6 P = 0.029 Spirituality Mean change scores = 14.4, SE = 1.6	Only within group effect sizes

Table 3. Continued

Author, year	Participants	Intervention	Control group	Follow-up	Measures	Results	Effect-size
Teasdale et al. (39)	Recovered recurrently depressed patients Recruited from community health care facilities and media. N = 145 mean age 41–44, 73–78% females	Mindfulness-Based Cognitive Therapy (MBCT): 8 weekly, 2-h sessions + 4 follow-up meetings N = 76 Patients with 3 or more past episodes N = 49	treatment as usual (TAU) N = 69 Patients with 3 or more past episodes N = 50	1 year	Time to onset of relapse of depression, over the 60-week study period	Group × time interaction MBCT reduced relapse from 66% to 37% in patients with 3 or more previous episodes P < 0.01 but in patients with only 2 recent episodes, relapse non-significantly increased from 31% to 56% at 1-year follow-up P > 0.1	0.59
Ma et al. (40)	Recovered recurrently depressed patients Recruited from general practice and newspapers. N = 75 mean age 43–46, 73–79% females	MBCT: 8 weekly, 2-h sessions + 2 follow-up meetings N = 38 Patients with 3 or more past episodes N = 28	TAU N = 37 79% female Mean age 46 Patients with 3 or more past episodes N = 27	1 year	Time to onset of relapse of depression, over the 60-week study period	Group × time interaction MBCT significantly reduced relapse from 78% to 36% in patients with 3 or more previous episodes P = 0.002 but in patients with only 2 recent episodes, relapse non-significantly increased from 20% to 50% at 1-year follow-up P = 0.321	0.88
Bondolfi et al. (41)	Unmedicated patients in remission from recurrent depression (≥3 episodes) Recruited via general practice, psychiatrists and media. N = 60 mean age 46–49, 69–74% females	MBCT: 8 weekly, 2-h sessions + 4 follow-up meetings N = 31	treatment as usual (TAU) N = 29	14 months	Time to onset of relapse of depression, over the 60-week study period Among those who relapsed (n = 19)	No Group × time interaction P = 0.78 MBCT relapse rate 29% TAU relapse rate 34% Group × time interaction P = 0.006 MBCT Time to relapse mean 204 days [35–330] TAU Time to relapse mean 69 days [15–191]	Not possible to calculate 0.77
Kuyken et al. (42)	Medicated patients in full or partial remission from recurrent depression (≥3 episodes) Recruited from general practice. N = 123 mean age 49, 47% females	MBCT: 8 weekly, 2-h sessions + 4 follow-up meetings and support to discontinue antidepressant medication N = 61	Antidepressant medication N = 62	15 months	Time to onset of relapse of depression Residual depressive symptoms hamilton Quality of life WHO brief Physical Psychological	No Group × time interaction P = 0.07 ITT (P = 0.05 PPT) MBCT relapse rate 47% Active control relapse rate 60% Group × time interaction P = 0.02 MBCT Mean 5.83 [4.49–7.3] 1 month post-treatment to 7.05 [5.53–8.74] at 15 Active control 7.75 [5.86–9.34] 1 month post-treatment to 8.69 [6.64–10.5] at 15 Group × time interaction P = 0.04 physical and P = 0.01 psychological MBCT Mean 24.08 [22.62–25.53] 1-month follow-up to 23.97 [22.63–25.3] at 15 Active control 22.86 [21.34–24.39] 1-month follow-up to 22.93 [21.18–24.69] at 15 MBCT Mean 18.88 [17.88–19.89] 1-month follow-up to 18.61 [17.65–19.57] at 15 Active control 17.47 [16.24–18.7] 1-month follow-up to 17.36 [15.93–18.78] at 15	Not possible to calculate

Table 4. The effect of Mindfulness-Based Stress Reduction and Mindfulness-Based Cognitive Therapy on selected symptoms

Outcome	Participants	Control group	Measures	Significant group × time interaction	Pre–post effect size
Perceived stress and / or psycho-logical distress	103 Community residents	Educational materials	DSI, SCL-90-R	+	0.56
	78 Medical / premedical students	Waiting-list	GSI	+	0.62
	60 Residents reporting distress	Waiting-list	PSS	+	0.64
	63 Patients with rheumatoid arthritis	Waiting-list	SCL-90-R	+	0.5
	90 Cancer patients	Waiting-list	SOSI	+	0.51
	115 Cancer patients	Waiting-list	DASS-21	+	0.6
	111 Cancer patients (women)	Waiting-list	SCL-90-R	+	0.3
	86 Chronic obstructive lung disease patients	Support group	PSS	−	
Depressive symptoms	78 Medical /premedical students	Waiting-list	SCL-90-R	+	0.62
	63 Patients with rheumatoid arthritis	Waiting-list	SCL-90-R	−	0.48
	91 Females with fibromyalgia	Waiting-list	BDI	+	0.64
	90 Cancer patients	Waiting-list	POMS	+	0.71
	115 Cancer patients	Waiting-list	HAM-D	+	1.34
	111 Cancer patients (women)	Waiting-list	SCL-90-R	+	0.26
	150 Patients with multiple sclerosis	TAU	CES-D	+	0.65
	100 Chronic pain patients	Education group	POMS	−	?
	165 Emotionally distressed patients	Spirituality, Waiting-list	POMS	−	0.85
	53 Patients with social anxiety	CBT	BDI	−	0.67
	145 Recurrently depressed patients	TAU	Relapse of depression		
	3 or more previous episodes			+	0.59
	up to 2 previous episodes			−	
	75 Recurrently depressed patients	TAU	Relapse of depression		
	3 or more previous episodes			+	0.88
	up to 2 previous episodes			−	
	60 Recurrently depressed patients	TAU	Relapse of depression	−	?
			Time to relapse	+	0.77
	123 Recurrently depressed patients	Antidepressant medication	Relapse of depression	−	?
			Hamilton (residual symptoms)	+	?
Anxiety symptoms	78 Medical /premedical students	Waiting-list	STA	+	0.62
	41 Healthy employees	Waiting-list	STA	+	?
	90 Cancer patients	Waiting-list	POMS	+	0.82
	115 Cancer patients	Waiting-list	HAM-A	+	1.14
	111 Women with cancer	Waiting-list	SCL-90-R	+	0.23
	150 Patients with multiple sclerosis	Usual care	STAI	+	0.39
	100 Chronic pain patients	Education group	STAI	−	?
	53 Patients with social anxiety	CBT	LSAS-Fear	−	1.44
			LSAS-Avoidance		1.54

+, significant group × time interaction; −, No significant group × time interaction; TAU, Treatment as usual; GSI, General Severity Index; SCL-90-R, The Symptom Checklist-90-Revised; PSS, Perceived Stress Scale; SOSI, Symptoms of Stress Inventory; DSI, Daily Stress Inventory; BDI, Becks Depression Inventory; POMS, Profile of Mood States; STA, State Trait Anxiety Inventory; LSAS, Liebowitz Anxiety Scale; DASS-21, Depression, anxiety stress scale, short form; CES-D, Centre for epidemiologic studies depression scale; CBT, cognitive behavioural therapy.

for future doctors, helping them to cultivate a way of being that fosters healing and growth in their own lives as well as skills to help others. The aim of the study was to assess the efficacy of MBSR.

Table 1 presents the results of the four included MBSR studies in non-clinical populations. Mental health improved in all four studies, and MBSR improved outcomes of physical health in the two studies measuring physical health.

Clinical populations with physical illness (Tabel 2)

Grossman et al. (28) examined effects of MBSR among individuals with multiple sclerosis and found evidence of improved health-related quality of life and wellbeing compared to treatment as usual and suggested that the results may also have treatment implications for other chronic disorders that diminish health-related quality of life.

Foley et al. (29) evaluated the effectiveness of MBCT for individuals with a diagnosis of cancer and concluded that the observed improvements represent clinically meaningful change and provide evidence for the provision of MBCT within oncology settings. This is an MBCT/MBSR programme, but in the present review, it is grouped as MBSR because it contains the same elements including a daylong retreat session.

Mularski et al. (30) suggested that Mindfulness Breathing Therapy in patients with chronic obstructive lung disease (COPD) is unlikely to be an important therapeutic option for patients with COPD. The aim was to test the efficacy of Mindfulness Breathing Therapy on improving

Table 5. Quality of the included studies

	Jadad score	ITT	Primary outcome/power cal-culation	Study provided evidence to support the aim/effect size	Therapist competence and number of therapist	Number of therapist	Description of concomiant treatment	Adherence to the treatment manual	Description of homework practice	Total score
Nyklicek et al. (24)	3	+	−, +	+, +	?	?	−	−	+	6
Davidson et al. (25)	2	−	−	+	+	−	−	+	−	3
Williams et al. (27)	2	−	−, +	+	?	?	−	−	+	3
Shapiro et al. (21)	3	?	−	+	?	−	−	−	−	2
Grossman et al. (28)	3	+	+, +	+, +	+	−	+	−	+	9
Foley et al. (29)	3	+	−, +	+, +	+	−	−	−	+	7
Wong et al. (31)	2	+	+	−	?	?	−	−	+	3
Mularski et al. (30)	3	+	+,+	−	+, ≥2	+	−	−	+	8
Cresswell et al. (33)	3	+	+	+	+	?	−	−	−	5
Morone et al. (20)	2	+	−	+, +	+	−	−	−	+	6
Pradhan et al. (34)	2	+	−, +	+	+, ≥2	+	−	−	+	7
Monti et al. (32)	3	+	−, +	+	+	−	−	−	−	6
Sephton et al. (35)	2	+	+, +	+, +	+	−	−	−	+	6
Speca et al. (19)	3	−	+	+	?	?	−	−	+	4
Hebert et al. (37)	2	?	+	?	+	?	−	−	−	2
Koszycki et al. (38)	2	+	+	+, +	+	−	−	−	−	5
Moritz et al. (22)	3	+	+, +	+	?	?	−	−	+	6
Teasdale et al. (39)	3	+	+, +	+, +	+, ≥2	+	+	+	−	11
Ma et al. (40)	3	+	+, +	+, +	+	?	+	+	−	9
Kuyken et al. (42)	2	+	+, +	+	+	−	+	+	−	7
Bondolfi et al. (41)	3	+	+, +	ss	+, ≥2	+	+	+	+	10

symptoms and health-related quality of life in patients with COPD. A high dropout (40%) is a limitation in this study.

Wong et al. (31) aimed to compare the effectiveness of MBSR with a multidisciplinary education programme based on principles for management of chronic pain that could adjust for the confounding effects of group attention and therapist time. Wong concluded that MBSR was not effective per se for improving quality of life or mood symptoms as significant improvements were observed in both groups. The high dropout rate, a low proportion of subjects who completed all 10 sessions and practiced daily for the recommended amount of time might have contributed to the negative results.

Monti et al. (32) tested the efficacy of Mindfulness-Based Art Therapy in women with cancer. After an observed reduction in symptoms of distress and improved health-related quality of life, they concluded that data support a possible future role for psychosocial treatment option for patients with cancer.

Creswell et al. (33) provided initial evidence that MBSR can buffer CD4 + T lymphocyte declines in an ethnically diverse sample of HIV-1-infected adults. The aim was to test whether MBSR could do that. Additional analyses suggested that the MBSR treatment effects on CD4-T lymphocytes are independent of antiretroviral medication use.

Morone et al. (20) conducted a pilot study to assess the feasibility of recruitment and adherence to an MBSR programme for older adults with chronic low back pain and to develop initial estimates of treatment effects. The completion rate for the intervention group was 68% and 78% for the control group after they crossed over to the MBSR programme. Because it was a pilot study, they explored participant outcome on a variety of outcome measures. As a result, they did not consider any one of the measures as primary.

Pradhan (34) suggested that MBSR may complement medical disease management by improving psychological distress and strengthening wellbeing in patients with rheumatoid arthritis. The objective was to assess the effect of MBSR on depressive psychological status and disease activity.

Sephton et al. (35) showed that MBSR alleviated depressive symptoms in patients with fibromyalgia. The aim was to test the effects of MBSR on depressive symptoms in patients with a physician-verified fibromyalgia diagnosis. All findings persisted when pain, sleep and antidepressant medication use were controlled for. Functional impairment, pain and sleep quality were measured prior to randomization. The results of these outcomes were not reported.

Speca et al. (19, 36) concluded that the modified MBSR programme was effective in decreasing mood disturbance and stress symptoms in both male and female patients with a wide variety of cancer diagnoses, stages of illness and ages. The objective of this study was to assess the effects of

participation in MBSR on mood disturbance and symptoms of stress in cancer out-patients. All patients were assessed six months after programme completion in a pre- and postintervention design, and these improvements were maintained at six-month follow-up.

Hebert et al. (37) compared the effectiveness of an intensive dietary intervention on diet and body mass in women with breast cancer to an MBSR programme or usual supportive care. Results indicated that MBSR did not make women with breast cancer consume less fat. Psychosocial variables included measures of self-reported emotional wellbeing, and data on anxiety, depression, self-esteem and psychological distress were also obtained. None of these results were reported.

Table 2 shows the results of the 11 included MBSR studies in clinical populations with physical illnesses. Nine studies reported changes in mental health, and six showed significant improvements compared to the control group. Six reported changes in physical health, and two demonstrated significant improvements. Disease activity was assessed in three studies, and no effect was found in rheumatoid arthritis and COPD patients, whereas a positive effect was found in patients with HIV.

Clinical populations with psychiatric disorders (Table 3)

Koszycki et al. (38) concluded that Cognitive Behavioural Group Therapy (CBGT) is the treatment of choice in generalized social anxiety disorders and suggested that MBSR may have some benefit in the treatment of these disorders. The aim was to evaluate the efficacy of MBSR compared to a first-line psychological intervention for social anxiety disorder. Both treatment groups improved, but patients receiving CBGT had lower scores on measures of social anxiety. Both interventions were comparable in improving mood, functionality and quality of life (these results are not displayed in the table).

Moritz et al. (22) suggested that a home study–based spirituality educational programme can affect mental health by improving mood and quality of life within the same range as reported by other mood intervention programmes such as cognitive behavioural therapy and MBSR. The objective was to evaluate the efficacy of a home study–based spirituality educational programme on mood disturbance in emotionally distressed patients. The mindfulness intervention followed the modified programme developed for patients with cancer (19), which is modelled on the MBSR programme (5). Only 57% of the participants in

the MBSR group completed the treatment, which is 20–40% lower than the figures reported by the other included MBSR/MBCT studies.

Teasdale et al. (39) suggested that MBCT offers a promising cost-efficient psychological approach to preventing relapse in recovered, recurrently depressed patients. The aim was to evaluate MBCT. The patients were stratified according to recency of recovery from the last episode of depression and number of previous episodes (two vs. more than two).

Ma et al. (40) concluded that MBCT is an effective and efficient way to prevent depressive relapse in recovered depressed patients with three or more previous episodes. One aim was to see whether the relapse prevention effects of MBCT observed by Teasdale could be replicated. To determine whether patients with only two previous episodes were from the same base population as those with three or more episodes, they also compared these two groups according to age at onset of their first episode of major depression and, along with a group of never-depressed controls, according to measures of childhood experience. MBCT was most effective in preventing relapses that were not preceded by life events. Relapses were more often associated with significant life events in the two-episode group. This group also reported less childhood adversity and later first depression onset than the three-or-more-episode group, which suggests that these groups represented distinct populations.

Bondolfi et al. (41) concluded that further studies are required to determine which patient characteristics, beyond the number of past depressive episodes, may predict differential benefits from this MBCT therapeutic approach. The study tested the hypothesis that MBCT would reduce the risk of depressive relapse in an independent replication trial across both language and culture. The trial was conducted in Switzerland, where there is high availability of mental health care and patients have direct access to psychiatrists, which may impact on the global management of recurrent depression.

Kuyken et al. (42) suggested that MBCT produces comparable outcomes in people using antidepressant medication in terms of relapse/cost-effectiveness and superior outcomes concerning residual depressive symptoms, psychiatric comorbidity and the physical and psychological domains of quality of life. The aim was to examine whether MBCT provided an alternative approach to antidepressant medication in preventing depressive relapse. The participants had a history of three or more previous episodes of depression, had been treated with a therapeutic dose of antidepressant

medication over the last six months and were either in full or in partial remission. The patients were randomized to traditional antidepressant medication or MBCT that included support to taper/discontinue antidepressant medication.

The results of the six included MBSR/MBCT studies in clinical populations with psychiatric disorders are presented in Table 3. When compared to active control conditions, the improvements were significantly higher in the mindfulness condition in one study and significantly higher in active control conditions in two studies at the end of treatment, but when 4-week follow-up was assessed, mindfulness and active control conditions were equal.

Mindfulness-Based Stress Reduction and Mindfulness-Based Cognitive Therapy on selected outcomes (Table 4)

When compared to a control group, MBSR significantly reduced perceived stress and/or psychological distress in seven studies (19, 21, 24, 27, 29, 32, 34). MBSR did not reduce stress in one study (30). MBSR/MBCT alleviated depressive symptoms in ten studies (19, 21, 28, 29, 32, 35, 39–42). Depressive symptoms were not alleviated significantly more than control group in four studies (22, 31, 34, 38). MBSR improved anxiety in six studies (19, 21, 25, 28, 29, 32). And anxiety was not improved more than the active control condition in two studies (22, 38).

Quality of the included randomized controlled trials

The Psychotherapy Outcome Study Methodology Rating Scale consists of 22 items, of which some are chosen along with the Consort guidelines to evaluate the quality of the RCTs (43, 44). Waiting list control group is the weakest possible control and the design used in most of the included MBSR studies. MBCT/MBSR was compared to treatment as usual (TAU) in four studies. It is difficult to clearly define TAU as it can change over time, and TAU patients usually get markedly less hours of treatment than participants. A treatment method that in previous research has been found effective for a specific disorder is the most stringent comparison condition to use, but this design is only used in two studies (38, 42) (Table 5).

To avoid confounding therapist and treatment condition, treatment should be delivered by more than one therapist; four included studies reported use of two or more therapists. To conclusively determine whether authors actually apply the treatment they describe, independent assessors should rate recorded sessions for adherence to the treatment manual and competence of the therapists. This is reported only in the MBCT studies (39–42). Authors should indicate how the sample size was determined. If a formal power calculation was used, the authors should identify the primary outcome on which the calculation was based. The APA Division 12 Task Force (45) has defined an adequate sample size as 'about 30 per group', and 14 of the 21 included studies met that recommendation. Only about half of the included studies reported power calculation, primary outcome and effect sizes. The quality was also assessed by the Jadad score that depends on the description of randomization, blinding and dropouts. A Jadad score of 3 was reached in 12 studies.

Overall, studies provided evidence supporting that:

i) MBSR is superior to waiting list in improving mental health in self-selected clinical and non-clinical populations and

ii) MBCT can reduce the risk of depressive relapse among referred and self-selected recovered, recurrently depressed patients with three or more previous episodes.

The sum of mindfulness homework practice was not related to outcome change in four studies (24, 25, 34, 41), while patients who meditated more had better outcomes than those who did not in two studies (19, 35). One study found no association between number of sessions attended and outcome (33), while another (19) found better outcomes for patients attending more sessions. Mindfulness questionnaires were used in three studies. Increase in mindfulness correlated significantly with improvements in mental health in two studies (24, 29), whereas the effects of mindfulness were in the predicted direction, but failed to reach significance in another study (34). So, overall, the literature shows an effect, but we do not know if this is a result of specific skills taught by the programmes, meditation practice or increases in mindfulness measured by mindfulness questionnaires.

Compliance

The review showed that most patients randomized to the mindfulness interventions (75–97%) did complete treatment, which was defined as attending at least four or five sessions.

Limitations

Most studies did not include active control groups. The stress-reducing effect of mindfulness treatment may not have come out as strong if the treatments

were compared with other stress-reducing interventions. Among MBSR studies, nine studies only assessed end of treatment results, and six studies reported one- to six-month post-treatment results. The lack of active control groups and long-term follow-up periods constitutes a limitation of many of the assessed studies. Publication bias cannot be ruled out because most studies have shown positive results.

Risks

The popularity of mindfulness interventions involves the risk that the techniques may be misunderstood or inappropriately applied. The developers behind both MBSR and MBCT address this issue and state that several years of practice is required before teaching which might have economical implications. If the interventions are delivered by teachers without adequate experience or qualifications, this could explain a poor outcome. The instructors' different levels of experience may explain some of the variation between studies and even between teachers within the same study. Experience in MBSR (one teacher having over 20 years of meditation practice and 10 years of teaching experience) was found to be the only predictive variable in one study (34). For patients with only two recent episodes of depression, relapse non-significantly increased following MBCT, which could be due to motivation factors, but also a result of a real risk. Patients with three or more episodes might be more marginalized and may benefit from unspecific group factors, whereas the two-episode patients may be better off using their own network. None of the studies reported any side effects to MBSR/MBCT, but it is well known that participants can experience an increase in symptoms because of the awareness training. And according to the mindfulness literature, mindfulness has to be integrated in the teacher in order for the teacher to provide sufficient support (46).

Discussion

Based on a systematic review of RCTs on MBSR and MBCT, the following can be concluded: evidence supports that MBSR improves mental health in non-clinical (21, 24, 25, 27) and clinical populations (19, 20, 22, 28, 29, 32–35, 38), but it remains unclear whether it can also improve physical health. In clinical populations with physical illness, MBSR complements medical disease management by relieving psychological distress and strengthening wellbeing (19, 28, 29, 32, 35,

36, 47). In clinical populations with psychiatric disorders, MBSR has some benefit as it reduces symptoms of distress, anxiety and depression or teaches patients coping skills to handle these symptoms (22, 38). MBCT is an effective and efficient way to prevent relapse in recovered, depressed patients with three or more previous episodes (39–42). Overall, studies showed medium effect sizes, and improvement fell within the range reported in other psychosocial interventions.

The APA Division 12 Task Force has developed criteria that therapies must fulfil to be considered well established and empirically supported (45). MBSR meets these criteria in the following way: 15 included MBSR studies reported mental health outcomes, and 13 studies found MBSR to be more effective than a waiting list or educational materials and equivalent to a home-based spirituality programme, educational group and cognitive behavioural therapy (CBT). Experiments are conducted with treatment manuals, and effects have been demonstrated by different investigators in large and clearly specified samples. MBSR thus meets criteria for the 'well-established' designation.

Mindfulness-Based Cognitive Therapy also approached the 'well-established' designation regarding prevention of depressive relapse. Methodologically, the reviewed studies are strong, and they show MBCT to be superior to TAU and equivalent to continuing antidepressant medication when compared to MBCT plus support to discontinue antidepressants in preventing relapse. Treatment manuals and large and clearly specified samples of formerly depressed patients are used, and the studies are conducted by independent investigators. MBCT did not prevent depressive relapse in patients with only two previous episodes, and the number of past episodes of depression is a determined characteristic that may predict differential benefit from MBCT.

Thus, we now know that the two manuals MBSR and MBCT are effective for some people, but the literature does not clarify the mechanisms whereby they are efficacious. If mindfulness training is specifically responsive to the effects of treatment, the mechanisms by which MBSR/MBCT achieve these benefits remain unclear. Enhancement of sense of control and accuracy of perception, or increased tolerance, acceptance, patience and courage to deal with unpredictable life events may play a role (28). Unlike many health promoting and cognitive behavioural approaches (6), mindfulness training focuses solely on cultivating inner resources, rather than changing what is wrong with the person. This is shown in the study comparing MBSR with CBT for patients

with DSM-IV generalized social anxiety disorders (38). Both treatment groups improved, but patients receiving CBT had lower scores on measures of social anxiety. The interventions were comparable in improving mood, functionality and quality of life. Thus, patients in the mindfulness group may still have symptoms, but experience less impairment. As the mechanisms in mindfulness are cognitive decentring and acceptance, mindfulness can possibly be reached through other activities than meditation, such as being in the nature, through art, talking to a friend. Mindfulness is indeed important, but other elements such as learning to concentrate, taking half an hour off each day, group support are also important. Future research should primarily tackle the question of whether mindfulness itself is a decisive ingredient by controlling against other active control conditions or true treatments.

Generalizations can be made to individuals who choose mindfulness as an intervention, and for them it seems to work. Because of the need for active participation, it is desirable that mindfulness is actively chosen. Bias is inherent in self-selected samples, and the results can be extrapolated only to patients or participants who are interested in and able to participate in the intervention. The inconsistent association between home practice and outcomes may be because of relatively small numbers of participating subjects and lack of long-term follow-up periods.

A limitation was that we did not include unpublished studies and we included studies with Jahad scores lower than three. In a systematic review, all papers on the topic in question with a Jadad score of three or less can be excluded to avoid that the meta-analysis itself suffers under the limitations of the included studies (48). As the mindfulness studies are not double-blinded, a Jadad score of maximum three can be achieved, which was the case in 11 of the 21 included studies.

Recommendations for future research

Future RCTs of MBSR and MBCT should use optimal design including the use of an active treatment as comparison and properly trained instructors, and they should include follow-up of at least one year and describe attrition. In clinical populations, it is recommended to test the combination of mindfulness treatment and specialized treatment for the specific medical disorder in question. It is recommended to explore the effect of longer treatment times as several of the strong studies reviewed included 3–4 reinforcement classes.

Recommendations for health care professionals and participants

Individuals who have the interest and ability to participate in an MBSR/MBCT programme learn how to actively participate in their health and wellbeing. MBSR is a useful method for improving mental health and reducing symptoms of stress, anxiety and depression or help individuals to better cope with these symptoms. MBSR complements medical disease management by improving psychological distress and wellbeing, and MBCT reduces the risk of depressive relapse.

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