

Research report

# Mindfulness meditation practise as a healthcare intervention: A systematic review

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## a b s t r a c t

*Background:* Mindfulness may be viewed as a supra-cognitive state of consciousness focussed on the decentred, objective and compassionate observation of transient mental and physical phenomena that may be attained through meditation practices. Mindfulness meditation is thought to be beneficial in the management of various physical and mental health conditions.

*Objective:* To assess the effectiveness of mindfulness meditation practice as a healthcare intervention.

*Methods:* Systematic computerised and hand literature searches for randomised controlled trials and evaluation using methodological quality criteria.

*Results:* The higher quality studies analysed in this review have demonstrated replicated statistically significant improvements in spirituality and positive health measures and decreases in depressive relapse, depressive recurrence and psychological distress.

*Conclusions:* Despite the lack of specific, reliable and validated mindfulness measures, mindfulness shows potential as a positive healthcare intervention and continued investigation is warranted. Further research using improved methodology and utilising specific mindfulness outcome measures in trials with long-term follow up, larger populations and a wider demographic range is recommended.

## 1. Introduction

Mindfulness is a core construct of Buddhist teachings and lies at the heart of meditation.<sup>1</sup> Meditation has been described as “a family of self regulation practices that focus on training attention and awareness in order to bring mental processes under greater voluntary control and thereby foster general mental well-being and development and/or specific capacities such as calm, clarity and concentration.”<sup>2</sup> Formal and informal meditation practices whether they be sitting, walking, lying or in daily activity form a mental and attitudinal framework in which mindfulness may be established.<sup>3</sup>

Mindfulness is a state of consciousness in which the participant maintains a single pointed awareness focussed on mental, interoceptive and exteroceptive experiences; a quality of “bare attention” is attained where all elaborative and judgmental processes are suspended.<sup>4</sup> Mindfulness is distinct from purposive outcome orientated self-management strategies. For example in relaxation exercises there is a definite aim or end point to be attained,

however, mindfulness is characterised by a ‘beginners mind’ in which there is an inquisitive, embracing observation and a complete acceptance of all experience devoid of striving or attachment to any goal.<sup>3</sup> Mindfulness has been characterised as a ‘crucible’ within which profound cognitive and behavioural changes may occur.<sup>5</sup>

The two principal strategies used to operationalise mindfulness as a healthcare intervention are Mindfulness Based Stress Reduction (MBSR) and Mindfulness Based Cognitive Therapy (MBCT). MBSR<sup>6</sup> was developed by John Kabat-Zinn at the Department of Behavioural Medicine at the University of Massachusetts Medical Centre to address the cognitive and somatic dimensions of unmanaged stress associated with chronic pain and illness. In 1997 there were more than 240 programmes offering MBSR<sup>7</sup> and since then interest has expanded exponentially.<sup>4,8</sup>

MBSR is a multi-component group intervention programme consisting of 8 weekly two-hour group sessions and a final 8-hour whole day retreat. MBSR includes periods of sitting meditation and self-directed body scans to facilitate the impartial observation of sensation. Hatha yoga is included to generate increased musculo-skeletal awareness and balance. Home practice and exercises are prescribed and are recorded in self-administered logbooks and diaries.



MBCT<sup>9</sup> integrates aspects of Cognitive Behavioural Therapy (CBT) and MBSR. MBCT is intended to impart skills that empower patients in remission from recurrent major depression. MBCT teaches individuals to disengage from habitual depression-related ruminative mental patterns and adopt a more “decentred” perspective, where thoughts and feelings are viewed as transient negative or positive events rather than accurate representations of an objective reality. MBCT is delivered in 8 two-hour group trainings. Daily homework includes taped, guided or unguided exercises to promote mindfulness and additional exercises are designed to facilitate the incorporation of awareness skills in daily life.

There is an emerging debate on how the construct of mindfulness, embedded in an ancient spiritual and cultural heritage, may be evaluated by contemporary scientific analysis.<sup>2,4,10–12</sup> The task of developing a scientific understanding of mindfulness is made problematic by the diffuse definitions that occur in the current literature where mindfulness is characterised as a collection of various techniques, a psychological process and sometimes as a distinct outcome in its own right.<sup>13</sup> The development of a contemporary theory of mindfulness has been advocated as a spur to empirical work,<sup>11</sup> but the utility of that work may in part depend on the development and use of validated mindfulness measures to assess outcomes in complex mindfulness based interventions.<sup>14</sup> Moreover, when discussing mindfulness scholars must enter the “shadowy world of consciousness,”<sup>15</sup> a notoriously difficult area.<sup>16,17</sup>

It has been suggested that the non-judgmental observation of thoughts and their associated emotional sequelae may permit a state of detachment that could lead to the reduction of behaviours with adverse health implications.<sup>18</sup> Mindfulness meditation has been shown to reduce habitual responding,<sup>19</sup> and addictive behaviours have been modified in both injecting drug users and binge eaters.<sup>20,21</sup> Recently there has been an increase in the application of mindfulness techniques to a range of clinical and non-clinical populations including those suffering from cardiovascular disease, diabetes, prostate cancer and dermatomyositis.<sup>22–25</sup>

A growing number of studies appear to support the effectiveness of MBSR in a diverse range of patient populations. Some MBSR studies that have involved chronic pain<sup>26,27</sup> have shown statistically significant improvements in self-reported pain, psychological, and other medical symptoms that were largely maintained at follow up.<sup>18</sup>

Mindfulness based interventions have been used with those who have clinically defined psychiatric syndromes such as depression and substance abuse included in the Diagnostic and Statistical Manual of Mental Disorders 4th edition (DSM-IV,1995)<sup>28</sup> as Axis 1 conditions. Axis 1 describes various categories of clinical disorders that cause significant impairment such as childhood developmental and adjustment abnormalities, adult anxiety, mood, sleep and sexual disorders. MBCT has produced positive results in patients with previous major depressive disorders.<sup>29–32</sup> Although many current studies have significant flaws<sup>4,18,33</sup> and generalisability is limited, meta-analysis suggests that mindfulness interventions may have potential, particularly for chronic disease, pain and stress.<sup>34</sup>

The objective of this review was to systematically evaluate the literature related to the application of mindfulness-based interventions in healthcare and to draw conclusions based on the evidence from the highest quality randomised controlled trials. This study evaluates recent research not included in the review of mindfulness as a clinical intervention by Baer in 2003<sup>18</sup> or analysed in the extensive meta-analysis of MBSR conducted by Grossman et al. in 2004.<sup>34</sup> In addition explicit methodological quality criteria were applied to provide new information on the quality of the current primary research literature on mindfulness.

## 2. Methods

The review protocol for this systematic review was formulated in accordance with the current guidelines for methodological best practice.<sup>35–41</sup>

### 2.1. Inclusion and exclusion criteria

Inclusion was restricted to randomised controlled trials reported in English language peer-reviewed literature. Unpublished dissertations and conference papers were excluded, as were interventions involving non-mindfulness based techniques such as Transcendental Meditation. Strategies focussed on changing the content of cognition rather than on non-judgmental awareness such as Attentional Control Training (ACT) were excluded. Multi-component MBSR and MBCT interventions were included as well as those that used mindfulness meditation alone, or as part of a modified psychological programme.

To encompass the diverse and rapidly growing research interest in mindfulness, the study populations of the reviewed trials included patients diagnosed with medical or psychological conditions and those in non-clinical populations. Studies using outcome measures such as practitioner administered questionnaires, psychological self-report inventories, patient diaries of subjective well-being, quality of life, and physical functioning, as well as physiological measures were included.

### 2.2. Data extraction

To minimise reviewer bias in accordance with current recommendations the included articles were manually blinded for author, publication, date, sponsor and institution.<sup>37</sup> The trials were evaluated in a random order through the use of an individual study number derived from a computerised random number generator.<sup>44</sup> To enhance the efficiency and uniformity of information retrieval, in accordance with the guidelines proposed by the Centre for Reviews and Dissemination,<sup>40</sup> a customised data extraction form was created based on standardised methodological quality criteria.<sup>41</sup> The applicability of the data extraction template was tested in a pilot carried out on three studies<sup>45–47</sup> that were not part of the main review.

### 2.3. Methodological quality

The initial methodological quality assessment was conducted by one reviewer (TM). The standardised methodological quality assessment criteria<sup>41</sup> used in the pilot review are shown in Table 1. The pilot revealed significant reporting and methodological deficiencies. In an effort to achieve a more comprehensive evaluation of the reviewed trials four additional criteria were included (see Table 2).<sup>48</sup>

#### 2.3.1. Methodological evaluation

The trials included in this review were evaluated using 21 criteria. The reviewer (TM) rated each criterion as positive, negative or unknown based on the information reported in the study. Criteria that were unreported or unknown after re-evaluation were marked as negative. Each study was given a total methodological quality score, which was the sum of all the positive ratings.

Four weeks after the initial review a random sample of five studies (23%) was re-evaluated to determine an acceptable level of intra-rater consistency. An independent and experienced analyst reviewed a further five randomly chosen studies to validate inter-rater reliability. Re-evaluation of all studies was undertaken and consensus was reached in the light of inter or intra-rater anomalies.

Table 1  
Methodological quality assessment criteria.<sup>41</sup>

<i>Methodological assessment criteria used in pilot</i>	
Patient selection	
A.	Were the eligibility criteria specified?
B. Treatment allocation	
1)	Was a method of randomization performed?
2)	Was the treatment allocation concealed?
C.	Were the groups similar at baseline regarding the most important prognostic indicators?
Interventions	
D.	Were the index and control interventions explicitly described?
E. <sup>a</sup>	Was the care provider blinded to the intervention?
F.	Were co-interventions avoided or comparable?
G.	Was the compliance acceptable in all groups?
H. <sup>a</sup>	Was the patient blinded to the intervention?
Outcome measurement	
I.	Was the outcome assessor blinded to the intervention?
J.	Were the outcome measures relevant?
K.	Were adverse effects described?
L.	Was the withdrawal/drop out rate described and acceptable?
M. Timing and follow up measurements	
1)	Was a short term follow up measurement performed?
2)	Was a long term follow up measurement performed?
N.	Was the timing of the outcome assessment in both groups comparable?
Statistics	
O.	Was the sample size for each group described?
P.	Did the analysis include an intention to treat analysis?
Q.	Were point estimates and measures of variability presented for the primary outcome measures?

<sup>a</sup> Criteria E. and H. were excluded as inappropriate for the assessment of studies using a psychological intervention.

### 3. Results

Computerised literature searches using the terms meditation, mindfulness and randomised controlled trial were conducted across 13 databases from the date of their inception to July 2006 (see Table 3).

#### 3.1. Study selection process

Stage 1; the database searches yielded two hundred and twenty six studies for potential review. Eligibility for inclusion was determined initially by inspection of the relevant abstracts by one reviewer (TM). One hundred and eighty seven studies were rejected because they involved non-mindfulness based interventions such as Transcendental Meditation, Yoga, Attention Control Therapy or concerned socio psychological definitions of mindfulness.

Stage II; fifteen studies were rejected because they were not randomised controlled trials.

Stage III; twenty-four trials met the inclusion criteria. However two trials were excluded from the methodological review, a study of mindfulness and relationship enhancement<sup>42</sup> was not considered sufficiently relevant to health care, and in a trial concerning the diet of women with breast cancer<sup>43</sup> mindfulness was a control and not the primary intervention.

Table 2  
Additional methodological quality assessment criteria.

<i>Additional post pilot descriptive methodological assessment criteria.</i>	
R.	Does the introduction state the clinical objectives/prospectively defined hypothesis?
S.	Is internal/external validity discussed?
T.	Was the randomization protocol reported?
U.	Were details of the programme delivery team reported?

Table 3  
Database search results.

Search criteria	Meditation and Randomised Controlled Trial	Mindfulness and Randomised Controlled Trial
Database	Hits	Hits
AMED	5	3
ASSIA	4	1
BNI	0	0
CENTRAL <sup>a</sup>	1	14
CINAHL	7	4
CCTR <sup>b</sup>	4	0
DARE <sup>c</sup>	20	0
INGENTA	0	0
CONNECT		
NHSTAP <sup>d</sup>	4	0
PSYCHINFO	15	6
PUBMED	104	- <sup>e</sup>
SCIENCE DIRECT	0	0
SCOPUS	25	9

<sup>a</sup> CENTRAL = Cochrane Central Register of Controlled Trials.

<sup>b</sup> CCTR = Cochrane Controlled Trials Register.

<sup>c</sup> DARE = Database of Abstracts and Reviews.

<sup>d</sup> NHSTAP = National Health Service Technology Assessment Database Programme.

<sup>e</sup> Mindfulness is not a [MESH] term.

Stage IV; Twenty-two studies were selected for final review (see Fig. 1).

#### 3.2. Study categorisation

The twenty-two trials included in the analysis were categorised into three population groups; Axis 1 conditions, diagnosed medical conditions and non-clinical patients (see Table 4).

#### 3.3. Descriptive overview of reviewed trials

##### 3.3.1. Axis 1 disorders

Five trials studied Axis 1 disorders. In two studies of populations with 3 or more episodes of major remitted depressive disorder MBCT intervention resulted in significantly lower relapse rates ( $p < 0.005$ ,  $n = 99$ , 44% risk reduction)<sup>29</sup> ( $p < 0.001$ ,  $n = 55$ , 54% risk reduction).<sup>31</sup> However, the authors noted that because MBCT is a multicomponent intervention beneficial effects could not be attributed to specific elements of the programme. The absence of a group comparison control also means that the effects of non-specific factors such as therapeutic alliance could not be assessed.<sup>29,31</sup> MBCT resulted in significant effects on over-generalised autobiographical memory ( $p = 0.03$ ,  $n = 41$ ),<sup>32</sup> a potential factor in depressive relapse, although the strength of the findings was limited by the absence of a placebo control.<sup>32</sup> One trial suggested that depressive relapse may be reduced by the increased availability of decentred meta-cognitive sets produced by MBCT however this result is weakened by a lack of prior evidence for the validity of the outcome measures.<sup>30</sup> In a trial on substance abuse patients mindfulness meditation did not significantly enhance treatment outcomes.<sup>49</sup>

##### 3.3.2. Diagnosed medical disorders

Ten trials studied diagnosed medical disorders. In a large heterogeneous study of a multi-component Mindfulness Based Art Therapy intervention, it was found that the intervention group reported statistically significant decreases of distress (GSI<sup>99</sup>  $p < 0.001$ ,  $n = 111$ )<sup>53</sup> and improvements in social functioning, vitality and health related quality of life measures.<sup>53</sup>

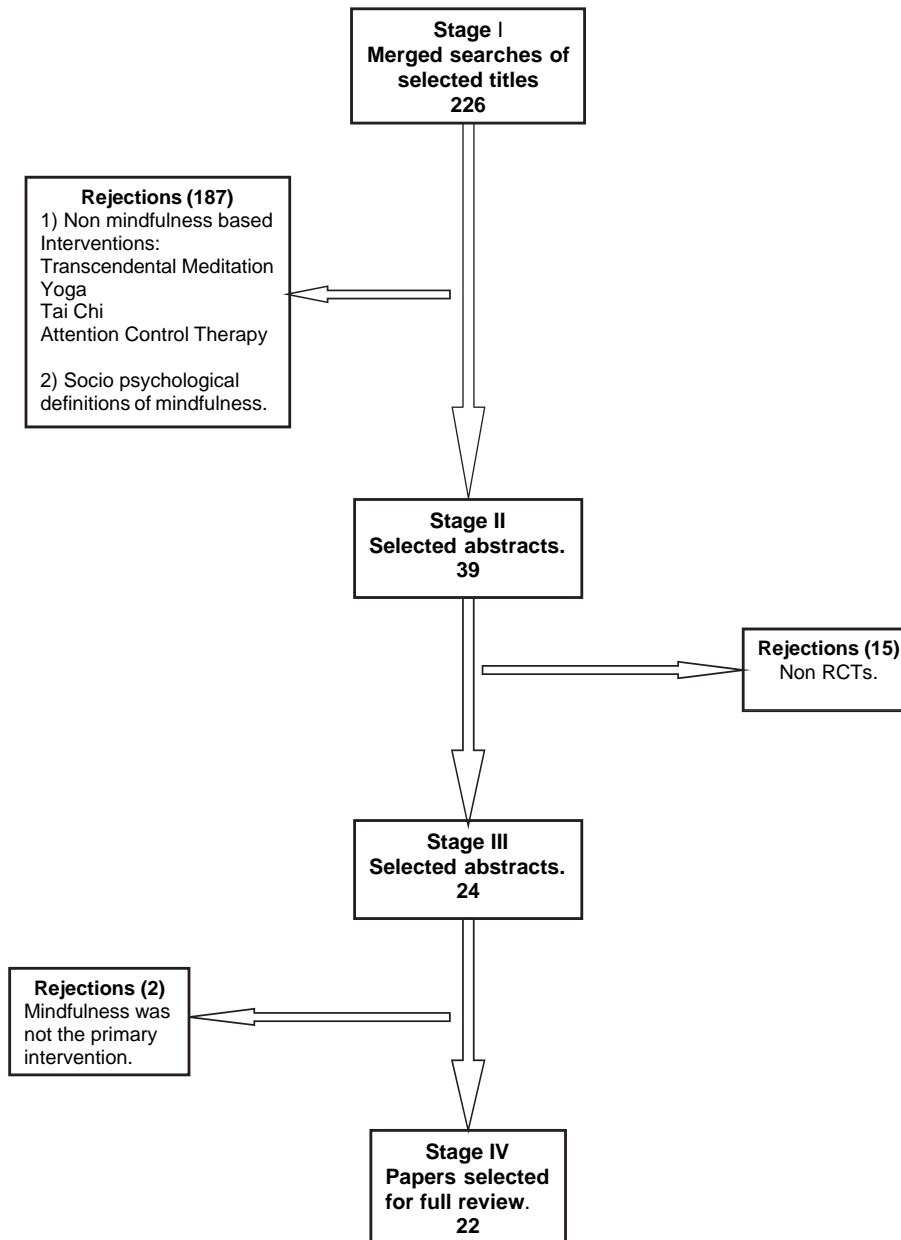


Fig. 1. Study selection flow chart.

In a study of patients with fibromyalgia it was found that an MBSR programme produced significant improvement in sense of life coherence measures (SOC<sup>100</sup>  $p < 0.001$ ,  $n = 91$ ).<sup>59</sup> Another study found that both intervention and control groups registered improvements in myalgic score (TMS<sup>102</sup>  $p < 0.004$ ,  $n = 128$ ),<sup>50</sup> pain and depression (BDI<sup>71</sup>  $p < 0.001$ ,  $n = 128$ )<sup>50</sup> although the trial was significantly weakened by a high attrition rate.

Two small studies have investigated female patients with heart disease. Modified MBSR interventions produced significant benefits in breathing frequency and ventilation rates ( $p < 0.01$ ,  $n = 18$ ),<sup>54</sup> reduced anxiety scores ( $p < 0.01$ ,  $n = 18$ ),<sup>58</sup> decreased inability to express negative emotion (CECS<sup>83</sup>  $p < 0.02$ ,  $n = 18$ )<sup>58</sup> and increased measures of reactive coping style (PF-SOC<sup>93</sup>  $p < 0.01$ ,  $n = 18$ ).<sup>58</sup>

Psoriasis patients who listened to mindfulness audiotapes and music during individual light therapy sessions showed significantly faster skin clearing compared to those who received light therapy alone ( $p = 0.033$ ,  $n = 37$ ).<sup>51</sup> However, the authors point out that

further studies that control more effectively for potential positive expectancy effects and use placebo light wavelengths are necessary.<sup>51</sup>

The generalisability of the positive results found in chronic fatigue and progressive multiple sclerosis patients are limited by small sample sizes and the difficulties of measuring improvement in the fluctuating symptoms of these conditions.<sup>52,57</sup>

### 3.3.3. Non-clinical populations

Seven trials studied non-clinical populations. Three studies included health workers. In a study of health professionals that used a modified MBSR intervention, measures of self-compassion (SCS<sup>110</sup>  $p = 0.004$ ,  $n = 38$ )<sup>67</sup> and perceived stress (PSS<sup>96</sup>  $p = 0.04$ ,  $n = 38$ )<sup>67</sup> were improved, however changes in psychological distress, burnout, stress and life satisfaction did not reach statistical significance.<sup>67</sup> In a study of nurses that recorded both quantitative and qualitative data and used the Mindfulness Awareness Scale

Table 4  
Included randomised controlled trials of mindfulness-based interventions grouped by patient population.

Study	Population classification	N	Type of Participant	Age range	Mean age	% Male	Treatment group	Control	Follow up	Outcome Measures
Alterman et al. (2004) <sup>49</sup>	Axis 1	31	Alcohol and drug users	-	37	45	TAU	TAU	5 months	ASI LAP-R LOT PANAS SF-36 SAS
Ma & Teasedale (2004) <sup>31</sup>	Axis 1	75	Remitted MDD after Medication	18-65	-	-	MBCT and TAU	TAU	1-year quarterly	BDI MOPS SCI SCID HAM-D
Teasedale et al. (2000) <sup>29</sup>	Axis 1	132	Remitted MDD after Medication	18-65	44	24	MBCT	TAU	1-year bi-monthly	SCID
Teasedale et al. (2002) <sup>a,30</sup>	Axis 1	100	Remitted MDD after Medication.	18-65	-	-	MBCT	TAU	1 year	MACAM
Williams et al. (2002) <sup>32</sup>	Axis 1	41	Remitted MDD after Medication	-	44	27	MBCT and TAU	TAU	6 months	AMT HRS-D
Astin et al. (2003) <sup>50</sup>	Diagnosed medical	128	Patients with Fibromyalgia	18-60	39	1.6	Modified MBSR	Active wait list	6 months	TMS FIQ BDI Timed six minute walk. MOSSF-36
Kabat-Zinn et al. (1998) <sup>51</sup>	Diagnosed medical	37	Psoriasis patients receiving light ttt therapy.	28-55	43	46	Mindfulness tapes in ttt	TAU	Open ended: To skin clearingpoint.	Days to psoriasis Clearing. STAI SCL-90-R
Mills & Allen (2000) <sup>b,52</sup>	Diagnosed medical	24	Patients with Multiple Sclerosis	-	47.9	-	Mindfulness of movement	TAU and self help	3 months	Single Leg Standing. SADLMS
Monti et al. (2006) <sup>53</sup>	Diagnosed medical	111	Cancer patients	26-82	54	0	MBAT	Wait list	2 months	SF-36 SCL-90-R
Robert-McComb et al. (2004) <sup>54</sup>	Diagnosed medical	18	Patients with heart disease	54-66	61	0	Modified MBSR	Wait list	Pre-post	Resting Cortisol. Exercise response. PCSM
Shapiro et al. (2003) <sup>55</sup>	Diagnosed medical	63	Patients with breast cancer	38-77	58	0	Modified MBSR	Active wait list	3 months 9 months	Sleep quality Sleep efficiency
Specia et al. (2000) <sup>56</sup>	Diagnosed medical	90	Cancer Outpatients	27-75	51	19	Modified MBSR	Wait list	Pre-post	POMS SOSI
Surawy et al. (2005) <sup>57</sup>	Diagnosed medical	18	Chronic fatigue awaiting CBT	18-65	-	36	Modified MBSR/MBCT	Active wait list	3 months	SF-36 CFS HADS FIS
Tacon et al. (2003) <sup>58</sup>	Diagnosed medical	18	Patients with heart disease	48-74	60	0	Modified MBSR	Wait list	Pre-post	STAI CECS PF-SOC MHLC
Weissbecker et al. (2002) <sup>59</sup>	Diagnosed medical	91	Patients with Fibromyalgia	23-74	49	0	MBSR	Wait list	2 months	SOC
Astin (1997) <sup>60</sup>	Non-clinical	28	College students	-	-	5	Modified MBSR	Wait list	Pre-post	SCL-90-R GSI SC I INSPIRIT
Cohen-Katz et al. (2005) <sup>61-63</sup>	Non-clinical	27	Hospital nurses	32-60	46	0	MBSR	Wait list	3 months	MBI BSI MAAS GSI Qualitative data
Davidson et al. (2003) <sup>64</sup>	Non-clinical	41	Right handed healthy employees	23-56	40	29	MBSR	Wait list	4 months	EEG PANAS STAI Influenza antibody titres
Mackenzie et al. (2006) <sup>65</sup>	Non-clinical	30	Working Nurses and Nurse Aides	-	-	3.33	Modified MBSR	Wait list	Pre-post	MBI SRDI JSS SWLS
Shapiro et al. (1998) <sup>66</sup>	Non-clinical	73	Premedical and Medical students	-	-	44	Modified MBSR	Wait list	Pre-post	SCL-90-R STAI ECRS INSPIRIT
Shapiro et al. (2005) <sup>67</sup>	Non-clinical	38	Health care professionals	18-65	42	-	Modified MBSR	Wait list	Pre-post	BSI MBI PSS SWLS SCS
Williams et al. (2001) <sup>68</sup>	Non-clinical	75	Stressed volunteers	-	43	28	Modified MBSR	Active wait list	3 months	DSI SCL-90-R GSI MSCL

A legend of the outcome measures cited in this review is shown in Appendix 1.

<sup>a</sup> An extension study of Teasedale et al. (2000),<sup>19</sup> using a subset of participants.

<sup>b</sup> An extension study of Mills et al. (2000)<sup>58</sup>

(MAAS),<sup>15</sup> emotional exhaustion was the most significantly impacted outcome measure (MBI<sup>108</sup>  $p = 0.05$ ,  $n = 27$ ).<sup>61-63</sup> However, the most robust finding was a significant between-group post intervention difference in MAAS scores (MAAS<sup>15</sup>  $p = 0.001$ ,  $n = 27$ ).<sup>61-63</sup> The authors of these trials noted that the benefits of mindfulness are not easily captured by traditional psychological self-report inventories. A brief 4-week MBSR programme produced significant positive changes to levels of burnout (MBI<sup>108</sup>  $p < 0.05$ ,  $n = 30$ ),<sup>65</sup> relaxation (SRDI<sup>111</sup>  $p < 0.05$ ,  $n = 30$ )<sup>65</sup> and life satisfaction (SWLS<sup>112</sup>  $p < 0.01$ ,  $n = 30$ )<sup>65</sup> in nurses and nurse aides.

Two studies used a modified MBSR intervention to investigate responses in medical students and both found that the intervention group scored significantly higher on spirituality measures (INSPIRIT<sup>106</sup>  $p < 0.002$ ,  $n = 73$ )<sup>66</sup>(INSPIRIT<sup>106</sup>  $p < 0.03$ ,  $n = 28$ ),<sup>60</sup> and lower on psychological symptoms (GSI<sup>99</sup>  $p < 0.01$ ,  $n = 73$ )<sup>66</sup> (GSI<sup>99</sup>  $p < 0.002$ ,  $n = 28$ ).<sup>60</sup>

A study of stressed community volunteers that used a modified MBSR programme reported significant improvements in medical

symptoms (MSCL<sup>109</sup>  $p < 0.001$ ,  $n = 75$ ).<sup>68</sup> daily stress (DSI<sup>105</sup>  $p = 0.01$ ,  $n = 75$ )<sup>68</sup> and psychological distress (GSI<sup>99</sup>  $p = 0.04$ ,  $n = 75$ )<sup>68</sup> that were maintained at 3 month follow up.<sup>68</sup> In a study of healthy employees a MBSR intervention produced increases in left-sided anterior cortical activation, a pattern previously associated with positive affect, and significant increase in influenza antibody titres.<sup>64</sup>

### 3.4. Methodological quality

Eleven of the 22 reviewed studies scored higher than the mean methodological quality score of 15.5 (SD 2.8) see Table 5. The internal validity of all the trials studied was compromised by a failure to report allocation concealment (criterion B2-3/22). The internal validity of the studies that scored below the mean was significantly weakened by failures in outcome assessor blinding (criterion I-0/11), deficiencies in the reporting of the randomisation protocol (criterion T-1/11) and a failure to undertake an intention-to-treat analysis (criterion P-1/11). Details of the programme

delivery team were rarely reported (criterion U-2/11), the reporting of withdrawal/drop out rates was poor (criterion L-3/11) and less than half of these studies had a long-term follow up (criterion M2-4/11).

### 3.5. Outcome measures

The 22 studies in this review used 44 psychological self-report inventories and 10 physiological and physical tests as outcome measures. Only one study utilised a measure specifically designed to measure mindfulness.<sup>61-63</sup> The outcome measures that reached statistical significance in single trials scoring above the mean methodological quality score (11/22) are shown in Table 6. The outcome measures that reached statistical significance in more than one high quality trial are shown in Table 7.

Where possible for studies that used outcome measures with multiple subscales the statistical significance of the results are shown by subscale. For example the Addiction Severity Index (ASI<sup>70</sup>) has six subscales and in the study of substance abusers by Alterman et al.<sup>49</sup> the results of five subscales failed to achieve statistical significance, one achieved a *p* value >0.01 therefore the results are shown as (0)(0)(0)(0)(0)(\*\*) (see Table 6).

## 4. Discussion

The 22 randomised controlled trials analysed in this review used a wide range of outcome measures to study a diverse range of patient populations, including Axis 1 conditions, diagnosed medical disorders and non-clinical populations. The methodologically strongest studies (11/22) demonstrated statistically significant changes following the application of mindfulness based interventions, as measured by 19 outcome variables. Improvements in psychological distress, spirituality, depressive relapse and recurrence, and positive health variables were observed although few authors considered the potential clinical significance of their findings. However, these results may be considered to be the clearest currently available indicators of the potential of mindfulness to impact on health as evidenced by conventional measures.

There are a number of important conceptual and methodological issues that make a meaningful interpretation of these results difficult. The precise measurement of mindfulness is a major issue.<sup>15</sup> There is currently limited understanding and consensus regarding the inherent components of the mindfulness experience. In addition there is debate concerning the implied psychological processes contained within mindfulness, the specific attitudinal, emotional and behavioural changes that may occur, and how these components should be evaluated.<sup>2-6,10,11,18</sup> These issues are intimately related to the difficulties of incorporating the specific historical and cultural heritage of mindfulness into a contemporary scientific paradigm and the problems inherent in the objective scientific study of consciousness.<sup>12,16,17</sup>

There is an unresolved methodological problem in differentiating between mindfulness as a definable construct, a psychological process, and as a set of measurable outcomes. Many authors question the ability of traditional psychological self-report measures to capture the changes ascribed to mindfulness and this may in part be responsible for the ambiguity in some of the findings. Only one trial in this review (Cohen-Katz et al.)<sup>61-63</sup> employed a measure, the 15 item Mindful Attention Awareness Scale (MAAS)<sup>15</sup> specifically designed to evaluate mindfulness as a process.

It has been argued that all future studies of meditation must fully integrate quantitative and qualitative data.<sup>12</sup> The exclusive use of self-report inventories exposes trials to significant response bias.<sup>26</sup> This is potentially of great consequence in group interventions such as MBSR when a generally positive student-teacher relationship is established and is compounded by a lack of outcome assessor blinding found in the reviewed studies.

Half of the reviewed studies used a wait list control. However, the use of inactive wait list controls is considered inadequate to control for the group effects seen in both MBSR and MBCT, and as yet there is little or no data on the specific active elements of these multi-component interventions.<sup>4</sup> The optimisation of adequate placebo controls would be central to this analysis<sup>113</sup> however, the use of placebo controls in psychological interventions is complicated by methodological and ethical problems.<sup>30,60</sup> Issues of

**Table 5**  
The reviewed trials scored and ranked according to the methodological assessment criteria.

Criteria Study/Year	A	B1	B2	C	D	F	G	I	J	K	L	M1	M2	N	O	P	Q	R	S	T	U	Total/21	%	Rank
Ma and Teasedale (2004) <sup>31</sup>	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21	100	1
Teasedale et al. (2002) <sup>30</sup>	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21	100	1
Teasedale et al. (2000) <sup>29</sup>	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21	100	1
Astin et al. (2003) <sup>50</sup>	+	+	-	+	+	+	+	+	-	-	+	+	+	+	-	+	+	+	+	+	+	17	81	2
Alterman et al. (2004) <sup>49</sup>	+	+	-	+	+	+	+	-	+	-	+	+	+	+	-	+	+	+	+	+	+	16	76	3
Astin et al. (1997) <sup>60</sup>	+	+	-	+	+	+	+	-	+	-	+	+	+	+	-	+	+	+	+	+	+	16	76	3
Cohen-Katz et al. (2005) <sup>61-63</sup>	+	+	-	+	+	+	+	-	+	-	+	+	+	+	-	+	+	+	+	-	+	16	76	3
Kabat-Zinn et al. (1998) <sup>51</sup>	+	+	-	+	+	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	16	76	3
Monti et al. (2006) <sup>53</sup>	+	+	-	+	+	+	+	+	-	+	-	+	+	+	+	+	+	+	+	-	+	16	76	3
Shapiro et al. (1998) <sup>66</sup>	+	+	+	+	+	+	+	+	+	-	+	+	+	-	+	+	-	+	+	+	-	16	76	3
Specia et al. (2000) <sup>56</sup>	+	+	-	+	+	+	+	-	+	-	+	-	+	+	+	+	+	+	+	+	+	16	76	3
Davidson et al. (2003) <sup>64</sup>	+	+	-	+	+	+	+	-	+	-	+	+	+	+	+	-	+	+	+	-	+	15	71	4
Robert-McComb et al. (2004) <sup>54</sup>	+	+	-	+	+	+	+	-	+	-	+	-	+	+	+	-	+	+	+	+	-	15	71	4
Williams et al. (2000) <sup>32</sup>	+	+	-	+	+	+	+	-	+	-	+	+	+	+	-	+	+	+	+	+	-	15	71	4
Williams et al. (2001) <sup>68</sup>	+	+	-	+	+	+	+	-	+	-	+	+	+	+	+	+	+	+	+	-	-	15	71	4
Shapiro et al. (2003) <sup>55</sup>	+	+	-	-	+	+	+	-	+	-	+	+	+	+	+	-	+	+	+	-	-	14	67	5
Tacon et al. (2003) <sup>58</sup>	+	+	-	+	+	+	+	-	+	-	+	-	+	+	-	+	+	+	+	+	-	14	67	5
Shapiro et al. (2005) <sup>67</sup>	+	+	-	+	+	+	+	-	+	-	-	+	-	+	+	-	+	+	+	-	+	13	62	6
Weissbecker et al. (2002) <sup>59</sup>	+	+	-	+	+	+	+	-	+	-	-	+	-	+	+	-	+	+	+	-	-	13	62	6
Mills and Allen (2000) <sup>52</sup>	+	+	-	+	+	+	-	-	+	-	-	+	-	+	+	-	+	+	+	-	-	12	57	7
Mackenzie et al. (2006) <sup>65</sup>	+	+	-	+	+	+	-	-	+	-	+	-	+	+	-	+	+	+	+	-	-	11	52	8
Surawy et al. (2005) <sup>57</sup>	+	+	-	+	+	+	-	-	+	-	-	+	-	+	+	-	+	+	+	-	-	11	52	8
Total/22	22	22	4	18	21	22	18	6	22	4	12	22	12	22	22	7	22	22	22	7	10			
%	100	100	18	82	95	100	82	27	100	18	55	100	55	100	100	32	100	100	100	32	45			

Mean study score = 15.5. (SD 2.8) Mean study percentage = 73.3.  
See Tables 1 and 2 for methodological assessment criteria.

**Table 6**

Outcome measures that achieved statistical significance in single trials that scored above the methodological mean grouped by methodological rank.

Outcome measure	Study	Population classification	Rank	Post intervention	Follow up
MOPS (Parenting Style) <sup>77</sup>	Ma and Teasedale (2004) <sup>31</sup>	Axis 1	1		(0)(***)(***)
MACAM (Autobiographical Memory) <sup>76</sup>	Teasedale et al. (2002) <sup>30</sup>	Axis 1	1		(*)
BDI (Depression) <sup>71</sup>	Astin et al. (2003) <sup>50</sup>	Diagnosed medical	2	(*)	(*)
FIQ (Fibromyalgia) <sup>86</sup>	Astin et al. (2003) <sup>50</sup>	Diagnosed medical	2	(**)	(**)
Timed six minute walk.	Astin et al. (2003) <sup>50</sup>	Diagnosed medical	2	(*)	
TMS (Myalgia) <sup>102</sup>	Astin et al. (2003) <sup>50</sup>	Diagnosed medical	2	(**)	(**)
ASI (Addiction) <sup>70</sup>	Alterman et al. (2004) <sup>49</sup>	Axis 1	3		00000(**)
SCI (Control) <sup>80</sup>	Astin et al. (1997) <sup>60</sup>	Non-clinical	3	(*)(**)(**)	
MBI (Burnout) <sup>109</sup>	Cohen-Katz et al. (2005) <sup>61-63</sup>	Non-clinical	3	0(*)(*)	
MAAS (Mindful Awareness) <sup>15</sup>	Cohen-Katz et al. (2005) <sup>61-63</sup>	Non-clinical	3	(**)	(**)
Days to skin clearing.	Kabat-Zinn et al. (1998) <sup>51</sup>	Diagnosed medical	3		(**)(**)(**)(**)
ECRS (Empathy) <sup>105</sup>	Shapiro et al. (1998) <sup>66</sup>	Non-clinical	3	(***)	
STAI (Anxiety) <sup>90</sup>	Shapiro et al. (1998) <sup>66</sup>	Non-clinical	3	(***)	
POMS (Mood States) <sup>95</sup>	Specia et al. (2000) <sup>56</sup>	Diagnosed medical	3	(***)	
SOSI (Stress Response) <sup>101</sup>	Specia et al. (2000) <sup>56</sup>	Diagnosed medical	3	(**)	

(\*\*\*)  $p < 0.001$ , (\*\*)  $p < 0.01$ , (\*)  $p < 0.05$ , (0) no statistical significance.

All outcome measure acronyms are shown in Appendix 1.

intervention consistency are exacerbated by the use of modified MBSR interventions in many trials, particularly in non-clinical populations. The “dose-response” relationship of mindfulness is unclear and the relationship between formal and informal practice is unresolved.<sup>49,55,61-63</sup>

Methodological criteria concerning patient and care provider blinding were removed from this analysis, as they were considered inappropriate for use with psychological interventions. However, the absence of patient blinding and the use of volunteer subjects has a potentially distorting effect on the intervention results.<sup>55,60,113</sup> Similarly, intervention effects may be exaggerated by the common absence of an intention-to-treat analysis and a failure to achieve allocation concealment.<sup>113,114</sup>

Despite methodological difficulties, the results of the reviewed trials indicate that mindfulness may have the potential to impact spirituality, positive health measures and a wide range of symptomatology, including psychological distress and depressive recurrence. In addition the findings of enhanced immune function<sup>64</sup> and accelerated skin healing<sup>51</sup> suggest that mindfulness meditation may have an impact on physiological function.

#### 4.1. Limitations of this study

Systematic reviews are vulnerable to many potential sources of bias.<sup>115</sup> In this review the EMBASE database was not searched and there was no attempt to search for ‘grey literature’. The review was limited to English studies in peer-reviewed journals that are subject to positive publication bias,<sup>114</sup> and there was no consideration of the considerable eastern literature.<sup>10</sup> The use of cumulative methodological scores is questionable<sup>116</sup> and the methodological findings might have been made more robust by the use of multiple

scoring scales.<sup>37</sup> The ascription of statistical significance on the basis of  $p$ -values may be considered mechanistic<sup>117</sup> and any implicit assumption that statistical significance equates to clinical significance is simplistic and misleading.<sup>118</sup> The emphasis on replicated statistical significance as an indicator of the potential of mindfulness to impact health may be considered arbitrary, as these results are in part a function of the frequency with which each outcome measure was tested. Replicated significance also fails to account for the number of studies where the same outcome measure failed to achieve statistical significance or the resultant effect sizes.

#### 4.2. Mindfulness as a clinical intervention

Mindfulness presents difficulties when considered as a clinical intervention.<sup>18</sup> If researchers are insensitive to the cultural and spiritual roots of mindfulness they may, in their attempts to secularise the construct miss elements vital to its effectiveness as a healthcare intervention.<sup>33,119</sup> However the relationship of mindful experience and the practice of specific meditation techniques is unclear. A one pointed, non-judgmental and total absorption into the present moment, a central element of mindfulness, may be achieved without the use of meditative practices at all. Sportspeople who are “in the zone” or those engrossed at work or totally absorbed in a hobby to the extent that time “stands still” may be in exactly the same state of present minded awareness as the ardent mindfulness practitioner.

Mindfulness is practiced in the seemingly paradoxical attitude of non-striving,<sup>14</sup> therefore patients would necessarily be instructed *not* to seek for relief from the ailments for which they had sought treatment. Moreover, it is unclear what conditions may be amenable to treatment by mindfulness training, as it may have both

**Table 7**

Outcome measures that achieved statistical significance in more than one trial that scored above the methodological mean grouped by methodological rank.

Outcome measure.	Study	Population classification	Rank	Post intervention	Follow up
SCID (Depressive Recurrence) <sup>81</sup>	Ma and Teasedale (2004) <sup>21</sup>	Axis 1	1		(0)(**)
SCID (Depressive Recurrence) <sup>81</sup>	Teasedale et al. (2000) <sup>19</sup>	Axis 1	1		(0)(**)
SF-36 (Pain subscale) <sup>82</sup>	Astin et al. (2003) <sup>53</sup>	Diagnosed medical	2	(*)	(*)
SF-36 (Positive Health) <sup>82</sup>	Monti et al. (2006) <sup>51</sup>	Diagnosed medical	3	(0)(**)(**)(**)(**)	(0)(*)(**)(**)(**)(**)
GSI (Distress) <sup>99</sup>	Astin et al. (1997) <sup>65</sup>	Non-clinical	3	(**)	
GSI (Distress) <sup>99</sup>	Monti et al. (2006) <sup>51</sup>	Diagnosed medical	3	(***)	(***)
GSI (Distress) <sup>99</sup>	Shapiro et al. (1998) <sup>64</sup>	Non-clinical	3	(*)	
INSPIRIT (Spirituality) <sup>106</sup>	Astin et al. (1997) <sup>65</sup>	Non-clinical	3	(*)	
INSPIRIT (Spirituality) <sup>106</sup>	Shapiro et al. (1998) <sup>64</sup>	Non-clinical	3	(**)	

(\*\*\*)  $p < 0.001$ , (\*\*)  $p < 0.01$ , (\*)  $p < 0.05$ , (0) no statistical significance.

All outcome measure acronyms are shown in Appendix 1.



stabilising and destabilising effects.<sup>120-122</sup> For example patients with epilepsy have experienced negative effects from mindfulness meditation.<sup>123</sup> The cultural heritage of mindfulness may also limit the patient populations who will participate.<sup>6,124</sup>

The current literature reveals both the potential and the difficulties of deploying mindfulness based techniques in a clinical context. However all therapeutic interventions require comparable practitioner vigilance to ensure the maximisation of benefit and the minimisation of potential harms to each individual patient. Moreover clinician informed research into the practical application of mindfulness may result in the development of new self-management strategies that could benefit those suffering from conditions causing considerable morbidity such as chronic pain that have proved to be particularly resistant to conventional interventions.

#### 4.3. Mindfulness as an intervention in osteopathy and manual therapy

The construct of mindfulness and its utilisation as a healthcare intervention is problematic. Practitioner training, the apparent necessity of practitioner mindfulness and the time necessary for mindfulness practice are major issues.<sup>6</sup> However in appropriate populations, despite difficulties and paradoxes, the individual experience of mindfulness may be related to the direct and indirect cultivation of the innate healing resources of the mind and body and as such is completely consistent with both contemporary definitions of osteopathy<sup>125</sup> and those of A. T. Still.<sup>126</sup>

The cultivation of compassion is intimately related to the development of mindfulness and may be seen as a source of healing intentionality,<sup>127</sup> which can also be transmitted through touch.<sup>128</sup> Mindfulness practice has been linked to enhanced palpation.<sup>129</sup> There is a burgeoning literature on mindfulness as a therapeutic strategy that focuses on the positive influence of practitioner mindfulness on the therapeutic relationship, clinical decision-making, practitioner wellness and enhanced patient outcomes<sup>130-133</sup> Mindfulness as a therapeutic strategy may enhance individual self-awareness and self-care and provide a vehicle for the osteopathic practitioner to develop the essential personal attributes that underpin the concept of professional capability.<sup>134</sup>

Manual therapists frequently treat the somatic manifestations of stress and patients in chronic pain and mindfulness has been found to be a potentially effective intervention in these difficult areas.<sup>18,26,27</sup> For example recent investigations on the impact of loving kindness meditation, an essential component of mindfulness, on those with chronic low back pain have produced positive results.<sup>135,136</sup> The "Back Sense" programme<sup>137</sup> utilises mindfulness to recover lost daily activities in patients with back pain by preventing the somatization of symptoms and thereby maintaining patient "agency".<sup>138</sup>

#### 4.4. Implications for further research

The evident inadequacy of psychological self-report inventories necessitates the increased use of scales specifically developed to measure mindfulness, such as the Mindfulness and Attention Awareness Scale<sup>15</sup> and the Freiburg Mindfulness Inventory.<sup>139</sup> The development of objective mindfulness measures may produce significant advances. The increased use of active controls would enhance the assessment of non-specific factors<sup>4</sup> and the deployment of standardised mindfulness interventions would minimise problems of intervention comparison.

The patient populations in the reviewed studies were predominantly female, white Caucasian, middle class, educated and employed. Further studies of other socio-economic and ethnic groups with larger study populations would enhance external

validity.<sup>49</sup> Longitudinal and additional follow up studies are necessary to investigate the seemingly powerful impact of mindfulness on experienced meditators.<sup>15,56,60,140</sup> Further investigations into potential adverse effects, increased concentration on clinical issues and the deconstruction of multi-component interventions may enhance practical applicability.<sup>4,18,119</sup> There is an emerging literature on the under-researched role of mindfulness as an agent in the alteration of damaging health behaviours that awaits further development.<sup>33,120,141</sup>

## 5. Conclusions

Mindfulness may have potential as a positive healthcare intervention. The randomised controlled trials reviewed in this study have produced statistically significant results across a wide range of patient populations, including those with Axis 1 conditions, diagnosed medical conditions and non-clinical populations. The clearest indicators of the impact of mindfulness on health are those replicated in methodologically sound trials. The higher quality studies have shown statistically significant results in mitigating psychological stress, depressive recurrence and pain. These studies have also demonstrated statistically significant increases in spirituality and positive health measures. The on-going empirical evaluation of mindfulness can be enhanced by the use of methodological improvements in future randomised controlled trials. Traditional psychological measures may be inadequate to capture the impact of mindfulness. The use of specific mindfulness instruments in trials with long-term follow up is recommended. Further research using validated measures on the impact of mindfulness on health behaviours, the use of mindfulness as a clinical intervention, and as a therapeutic strategy is necessary.

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## Appendix 1

Legend: outcome measures cited in this review grouped by patient population.

### Axis 1

AMT = Autobiographical Memory Test<sup>69</sup>; ASI = Addiction Severity Index<sup>70</sup>; BDI ¼ Beck Depression Inventory<sup>71</sup>; HAM-D/HRS-D = Hamilton Rating Scale for Depression<sup>72,73</sup>; LAP-R = Life Attitude Profile Related-Revised<sup>74</sup>; LOT = Life Orientation Test<sup>75</sup>; MACAM = Measure of Awareness and Coping in Autobiographical Memory<sup>76</sup>; MBCT = Mindfulness-Based Cognitive Therapy<sup>9</sup>; MDD = Major Depressive Disorder; MOPS = Measure of Parenting Scale<sup>77</sup>; PANAS = Positive and Negative affect Scale<sup>78</sup>; SAS = Spirituality Assessment Scale<sup>79</sup>; SCI = Shapiro Control Inventory<sup>80</sup>; SCID = Structured Clinical Interview for DSM-3-R<sup>81</sup>; SF-36 = Short-Form Health Survey<sup>82</sup>; TAU = Treatment As Usual.

## Diagnosed medical

**BDI** = Beck Depression Inventory<sup>71</sup>; **CBT** = Cognitive Behavioural Therapy; **CECS** = Courtauld Emotional Control Scale<sup>83</sup>; **CFS** = Chalder Fatigue Scale<sup>84</sup>; **FACT-B** = Functional Assessment of Cancer Treatment-Breast<sup>85</sup>; **FIQ** = Fibromyalgia Impact Questionnaire<sup>86</sup>; **FIS** = Fatigue Impact Scale<sup>87</sup>; **HADS** = Hospital Anxiety and Depression Scale<sup>88</sup>; **MBAT** = Mindfulness-Based Art Therapy; **MBSR** = Mindfulness-Based Stress Reduction<sup>6</sup>; **MHLC** = Multidimensional Health Locus of Control<sup>89</sup>; **MOSSF-36/SF-36** = Short-Form Health Survey<sup>82</sup>; **STAI** = State-trait Anxiety Inventory<sup>90</sup>; **OLQ** = Orientation to Life Questionnaire<sup>91</sup>; **PENN** = Penn State Worry Questionnaire<sup>92</sup>; **PF-SOC** = Problem-Focused Styles of Coping<sup>93</sup>; **PCSM** = Physical Component Summary Measure<sup>94</sup>; **POMS** = Profile of Mood States<sup>95</sup>; **PSS** = Perceived Stress Scale<sup>96</sup>; **SADLMS** = Symptoms of Daily Living in Multiple Sclerosis<sup>97,98</sup>; **SCI** = Shapiro Control Inventory<sup>80</sup>; **SCL-90-R** = Symptom Check List 90 Revised<sup>99</sup>; **SOC** = Sense of Coherence<sup>100</sup>; **SOSI** = Symptoms of Stress Inventory<sup>101</sup>; **TAU** = Treatment As Usual; **TTT** = Treatment. **TMS** = Total Myalgic Score; Obtained by summing the tenderness score for each of the 18 tender points as defined by the American College of Rheumatology criteria for Fibromyalgia.<sup>102</sup>

## Non-clinical

**BDI** = Beck Depression Inventory<sup>71</sup>; **BSI** = Brief Symptom Inventory<sup>103</sup>; **DSI** = Daily Stress Inventory<sup>104</sup>; **ECRS** = Empathy Construct Rating<sup>105</sup>; **EEG** = Electro-Encephalogram; **GSI** = Global Severity Index<sup>99</sup>; (Derived from the SCL-90-R as an indicator of overall psychological stress), **INSPIRIT** = Index of Core Spiritual Experiences<sup>106</sup>; **JSS** = Job Satisfaction Scale<sup>107</sup>; **MAAS** = Mindfulness Awareness Attention Scale<sup>15</sup>; **MBI** = Maslach Burnout Inventory<sup>108</sup>; **MBSR** = Mindfulness-Based Stress Reduction; **MSCL** = Medical Symptom Checklist<sup>109</sup>; **OLQ** = Orientation to Life Questionnaire<sup>91</sup>; **PANAS** = Positive and Negative affect Scale<sup>78</sup>; **PSS** = Perceived Stress Scale<sup>96</sup>; **SCI** = Shapiro Control Inventory<sup>80</sup>; **SCL-90-R** = Symptom Check List 90 Revised<sup>99</sup>; **SCS** = Self-Compassion Scale<sup>110</sup>; **SRDI** = Smith Relaxation Dispositions Inventory<sup>111</sup>; **STAI** = State-Trait Anxiety Inventory<sup>90</sup>; **SWLS** = Satisfaction with Life Scale.<sup>112</sup>

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