BMJ Open

Effects of mindfulness-based stress reduction on adults with sleep disturbance: an updated systematic review and meta-analysis

Seong Min Kim ,[1] Jeong Min Park,[2] Hyun-Ju Seo ,[3] Jinhee Kim ,[4] Jin-Won Noh ,[5] Hyun Lye Kim[4]

To cite: Kim SM, Park JM, Seo H-J, *et al*. Effects of mindfulness-based stress reduction on adults with sleep disturbance: an updated systematic review and meta-analysis. *BMJ Open* 2022;**12**:e058032. doi:10.1136/bmjopen-2021-058032

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2021-058032).

SMK and JMP contributed equally.

Received 08 October 2021
Accepted 16 October 2022

For numbered affiliations see end of article.

Correspondence to
Professor Hyun-Ju Seo;
shj5th@korea.ac.kr

ABSTRACT

Objective Mindfulness-based stress reduction (MBSR) is a meditation-based therapy originally recommended for stress management. However, it is currently used to alleviate sleep disturbances. Therefore, this contemporary systematic review aimed to elucidate the clinical effects of MBSR on sleep quality and sleep-related daytime impairment in adults with sleep disturbances, including chronic insomnia disorders.

Design Systematic review and meta-analysis of randomised controlled trials (RCTs).

Methods A comprehensive search was conducted using the following databases: Ovid MEDLINE, AMED, Ovidembase, PsycINFO, Cochrane Library, CINAHL, and four domestic databases: KoreaMed, KISS, KMbase and NDSL. The final search update was performed in June 2022. Two researchers independently selected relevant studies, assessed the risk of bias and extracted the data.

Results Of the 7516 records searched, 20 RCTs and 21 reports were included. In the subgroup analysis, MBSR did not improve objective or subjective sleep quality in chronic insomnia and cancers. However, MBSR versus waitlist control might have been effective in improving subjective sleep quality, but with substantial heterogeneity (standardised mean difference=−0.32; 95% CI: −0.56 to −0.08; I^2=71%). In addition, MBSR compared with active control did not improve the sleep-related daytime impairments including depression, anxiety, stress, fatigue and quality of life. The overall risk of bias included in this review was a concern because of performance and detection bias.

Conclusions MBSR might be ineffective for improving sleep quality in patients with chronic insomnia and cancers. In addition, more than half of the RCTs included in this review had small sample sizes and were vulnerable to performance and detection biases. Therefore, well-designed RCTs with larger sample sizes are required to confirm the clinical effects of MBSR in adults with sleep disturbances.

PROSPERO registration number CRD42015027963.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The present study is a contemporary systematic review and meta-analysis of the effectiveness of mindfulness-based stress reduction interventions for improving sleep quality and sleep-related daytime impairments in people with sleep disturbance.
⇒ This systematic review and meta-analysis included subgroup analyses and comparisons according to the various types of participants in an effort to provide concrete evidence on the effectiveness of interventions.
⇒ Objective assessment of sleep quality including subjective sleep quality measures was a key feature of the analysis.
⇒ The overall risk of bias among the studies included in the present systematic review raises concerns, making definitive conclusions difficult.

INTRODUCTION

Sleep disturbances are a common health problem affecting approximately 20%–30% of adults,[1] and include difficulties in falling asleep, maintaining normal sleep or sleeping for sufficient duration.[2] Individuals are diagnosed with sleep disturbances if the symptoms seriously affect their social and professional performance.[3] According to American guidelines on chronic insomnia treatment published in 2017,[4] pharmacotherapy and non-pharmacological therapy are the two major treatment modalities for sleep disturbances. Although pharmacotherapy is more effective than non-pharmacological therapy, it can have various side effects such as substance abuse induced by physical/psychological tolerance, withdrawal, drug–drug interactions, abnormal thoughts, behavioural changes and headaches.[5 6] Recently, patients with sleep disturbances have shown a preference for non-pharmacological therapy.[7]

Mindfulness-based stress reduction (MBSR) is a key non-pharmacological type of mindfulness-based intervention (MBI) that effectively relieves insomnia by decentring.[8] The MBSR method developed by Jon Kabat-Zinn in 1979 is a modern adaptation of

mindfulness meditation practised in ancient Buddhism.[9] Mindfulness refers to the way of life or state of mind, in which individuals are aware of their thoughts, emotions and experiences at a given moment.[9] It focuses on regulating the levels of physical and psychological stresses, including those caused by cancer, chronic pain and sleep disturbance.[9] Physiological changes during meditation activate the parasympathetic-limbic pathway, which reduces the heart rate, systolic blood pressure, respiratory rate, and consequently, stress.[10] Stress is the primary cause of sleep disturbances.[11] Thus, stress reduction may improve sleep quality or duration.

Although several systematic reviews and meta-analyses have investigated the effects of MBSR on sleep disturbances, non-comparative and comparative studies were simultaneously included in previous reviews,[12 13] and some failed to examine the effectiveness of MBSR due to co-interventions.[14–16] Moreover, several reviews only included patients with insomnia and not those with sleep disturbances.[16 17] The 2021 American Academy of Sleep Medicine clinical practice guidelines[18] contain no recommendation for mindfulness therapies for chronic insomnia disorder. Therefore, this contemporary systematic review aimed to elucidate the clinical effects of MBSR on sleep quality and sleep-related daytime impairment in individuals with sleep disturbances, including chronic insomnia disorders.

METHODS

Search strategy and eligibility criteria

The following databases were searched for relevant studies: Ovid MEDLINE, AMED, Ovidembase, PsycINFO, the Cochrane Library, CINAHL, KoreaMed, Korean Studies Information Service System, Korean Medical Database and National Digital Science Library. Additional searches were performed by reviewing the references provided in the relevant studies.

Search terms were established by combining “sleep disturbance” and “mindfulness”. In international databases where Medical Subject Headings were available, terms related to sleep disturbance and mindfulness (using exp Sleep disturbances/AND exp Meditation/) were used with keywords. In other databases where controlled vocabulary were unavailable, keywords or text words were used. Proximity operators, Boolean operators and truncation searches were used to comprehensively search the literature (online supplemental appendix 1). A literature search was conducted in October 2018, and the final search update was performed in June 2022.

Inclusion and exclusion criteria

The main study question and inclusion criteria were as follows:

Population

Adults aged ≥18 years who experienced sleep problems or disturbances including insomnia.

Intervention

Participants performed simple and formal meditation such as body-scan meditation (including stretching and postural adjustment), seated meditation, walking meditation and Hatha yoga. The studies included in this analysis examined the administration of a structured mindfulness-based programme to participants with sleep disturbance for a minimum of 6 weeks.

Comparison

Passive control including waitlist, and active control groups, such as those receiving usual care, cognitive–behavioural therapy and sleep-hygiene education.

Outcomes

The primary outcomes were: objective sleep quality measured with wrist actigraphy, and subjective sleep quality assessed using self-reported questionnaires. The secondary outcomes were changes in sleep-related daytime impairments such as depressive symptoms, anxiety, stress, fatigue and reduced quality of life.

Study design: randomised controlled trial

Studies were excluded if: (1) participants worked in shifts or were jet-lagged after a trip; (2) it was not possible to determine the effect size of MBSR alone due to complex interventions; and (3) they were published as abstracts, dissertations or reports.

Two researchers independently selected studies based on the inclusion and exclusion criteria. The titles and abstracts were reviewed during the first screening, and the full texts were reviewed during the second screening. In cases of disagreement between the two researchers on the final selection of studies, consensus was reached by involving a third researcher.

Assessment of the risk of bias

The Cochrane risk of bias tool was used by two researchers who independently assessed the risk of bias in the included studies.[19] The researchers rated the risk of bias for each domain as ‘low’, ‘high’ or ‘unclear’. In cases of disagreement between the two researchers, a consensus was reached by involving a third reviewer.

Data extraction

The study characteristics, intervention information and outcome measures for the assessment of clinical effects were extracted from the selected studies using a predefined data extraction form. Two researchers independently collated the data, and all discrepancies were resolved through a consensus with a third researcher. If insufficient data were reported, a request for additional data was sent to the corresponding author via email.

Statistical analysis

A meta-analysis was performed using a random-effects model considering the heterogeneity of the included studies. Review Manager software (RevMan V.5.3.5, Copenhagen, Denmark, 2011) was used for data analyses.

For studies measuring outcomes at multiple follow-ups, the final value measured at the end of the follow-up was chosen. Continuous outcome data were pooled using a weighted mean difference if the same measurement tools were used, and a standardised mean difference (SMD) if different measurement tools were used.

Because the health conditions of adults with sleep disturbance and existing treatments were expected to be diverse, a subgroup analysis was performed according to type of participants and controls.[20] Heterogeneity was assessed using I^2 and Q statistics. An I^2 >50% indicated significant heterogeneity.[21] Publication bias was examined using a funnel plot if a meta-analysis included more than 10 studies.[22] If a study reported incomplete outcome data and the authors could not manage the missing data using the formulas presented by Hozo *et al*,[23] a narrative description was used to summarise the results.

Patient and public involvement

There was no direct patient or public involvement in this review.

RESULTS

Study selection and study characteristics

In total, 7516 records were retrieved from multiple databases. After removing duplicates with EndNote, 6534 records were screened. Of these, 86 reports were selected by two independent researchers after the first screening. In the second round, the full texts of these articles were reviewed. Consequently, 65 reports were excluded based on the exclusion criteria (figure 1 and online supplemental appendix 2). Ultimately, 20 studies from 21 reports were included in this review.

The general characteristics of the included studies are shown in table 1. Eleven waitlist control groups were included, all of which were waitlisted controls. The remainder were active control groups comprising those receiving usual care, positive adult development, behavioural therapy for insomnia and so on.

Of the 20 studies included, 8 (40%) involved patients with cancer and 3 (15%) involved patients with chronic mental disorders (chronic insomnia). MBSR was provided for 8 weeks in 14 (70%) studies. In nine studies (45%), interventions were performed for 2 hours per week. The time spent by individuals performing home exercises ranged from 15 to 45 min in 16 (80%) studies. Most studies did not report whether participants were prescribed sleep medications.

Risk of bias assessment

A summary of the risk of bias in the included studies is presented in figure 2. Under the domain of generating a random allocation sequence, 18 (90%) studies were rated as having a low risk of bias as they specifically described the appropriate random sequence generation methods. Eight studies (40%) were rated as having an unclear risk of bias, because they did not mention the allocation concealment process. Regarding the blinding of participants and personnel, three (15%) studies in which investigators or participants were blinded and did not affect the outcomes were evaluated as having a low risk of bias. Three (15%) studies were rated as having a low risk of detection bias because the outcome assessors were blinded. The risk of bias associated with reporting incomplete outcomes was deemed to be low in 11 (55%) studies, because an intention-to-treat analysis was performed and the dropout rate was similar between groups. Four (20%)

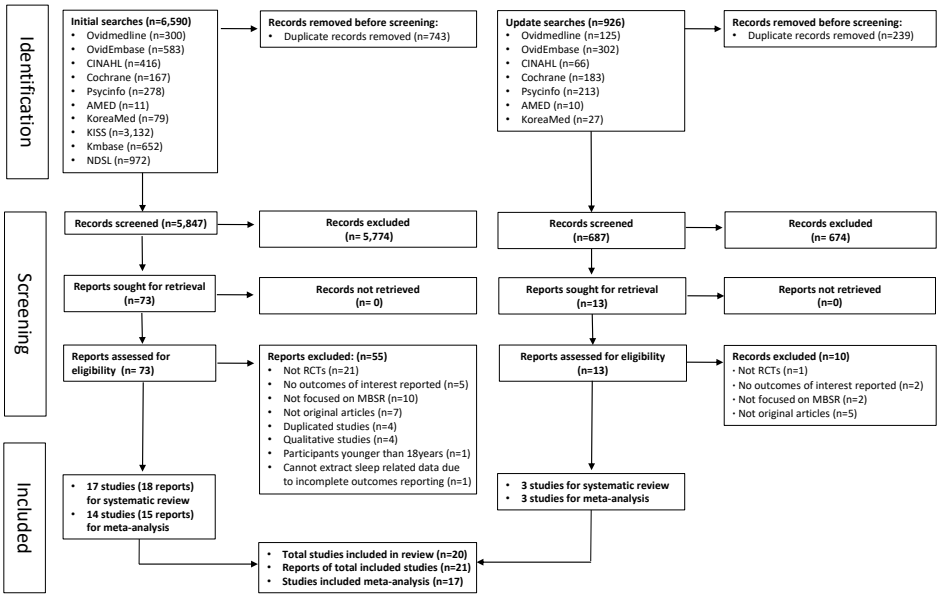


Figure 1 Study selection process.

Table 1 Characteristics of included studies

Study (year)	Country	No of participants (E/C)	Participants	Age (mean)		Intervention						Type of comparison (active vs passive)	Outcome	Sleep medication use
				E	C	Time (hours)	Duration (weeks)	Follow-up (weeks)	Home practice (minutes)	Day-long retreat	Provider			
Andersen *et al* (2013)[40]	Denmark	168/168	Patients with breast cancer	53.9	54.4	2.0	8	48	45	O	Instructor	Active: treatment as usual	Primary outcome: patient-reported sleep quality (MOSSS)	No
Barrett *et al* (2020)[29]	USA	138/275	Healthy adults	49.2	49.9	2.5	8	28	20~45	O	Instructor	Active: EX training Passive: waitlist control	Primary outcome: patient-reported sleep quality (PSQI)	No
Carmody *et al* (2011)[30]	USA	57/53	Late menopausal transition and early postmenopause	52.5	53.8	2.5	9	20	45	O	Instructor	Passive: waitlist control	Primary outcome: patient-reported sleep quality (WHIIRS) Secondary outcomes: anxiety (HADS-A), overall QOL (MENQOL), stress (PSS)	No
Cash *et al* (2015)[31]	USA	51/40	Fibromyalgia symptoms in women over 18	NR	NR	2.5	8	16	45	O	Instructor	Passive: waitlist control	Primary outcome: patient-reported sleep quality (SSQ) Secondary outcomes: stress (PSS), fatigue (FSI)	No
Dykens *et al* (2014)[41]	USA	116/127	Mothers of children with autism and other disabilities	NR	NR	1.5	6	30.8	NR	X	Instructor	Active: positive adult development	Primary outcome: patient-reported sleep quality (ISI) Secondary outcomes: depression (BDI), anxiety (BAI), stress (PSI)	No
Esmer *et al* (2010)[42]	USA	19/21	Failed back surgery syndrome	55.2	54.9	1.5~2.5	8	40	45	O	Instructor	Passive: waitlist control	Primary outcome: patient-reported sleep quality (abridged PSQI)	No
Gallegos *et al* (2018)[32]	USA	228	Facility-residing older adults	72	73	2.0	8	24	30	O	Instructor	Passive: waitlist control	Primary outcome: patient-reported sleep quality (PSQI)	No

Continued

Table 1 Continued

Study (year)	Country	No of participants (E/C)	Participants	Age (mean)		Intervention						Type of comparison (active vs passive)	Outcome	Sleep medication use
				E	C	Time (hours)	Duration (weeks)	Follow-up (weeks)	Home practice (minutes)	Day-long retreat	Provider			
Garland *et al* (2014)[25]	Canada	64/47	Insomnia comorbid with cancer	60.3	58.7	1.5	8	20	NR	O	Instructor	Active: cognitive–behavioural therapy for insomnia	Primary outcomes: patient-reported sleep quality (PSQI), objective sleep quality (actigraphy, SE) Secondary outcome: stress (C-SOSI)	No
Gordon*et al* (2021)[33]	Canada	52/52	Menopause transition women	48.7	48.7	2.5	8	24	45	O	Instructor	Passive: waitlist control	Primary outcome: patient-reported sleep quality (PSQI) Secondary outcomes: depression (CES-D), anxiety (STAI), stress (PSS)	No
Gross *et al* (2010)[34]	USA	72/66	Solid organ transplant recipients	55	52	2.5	8	48	29	O	Instructor	Active: health education	Primary outcome: patient-reported sleep quality (PSQI) Secondary outcomes: depression (CES-D), anxiety (STAI), QOL (QOL VAS)	NR
Gross *et al* (2011)[26]	USA	20/10	Primary chronic insomnia	47	53.5	2.5	8	12	45	O	Instructor	Active: pharmacotherapy	Primary outcomes: patient-reported sleep quality (PSQI), objective sleep quality (actigraphy, SE) Secondary outcomes: depression (CES-D), anxiety (STAI)	Eszopiclone

Continued

Table 1 Continued

Study (year)	Country	No of participants (E/C)	Participants	Age (mean)		Intervention						Type of comparison (active vs passive)	Outcome	Sleep medication use
				E	C	Time (hours)	Duration (weeks)	Follow-up (weeks)	Home practice (minutes)	Day-long retreat	Provider			
Johns *et al* (2015)[36]	USA	18/17	Persistently fatigued cancer survivors	58.8	55.7	2.0	7	24	20	X	Instructor	Passive: waitlist control	Primary outcome: patient-reported sleep quality (ISI) Secondary outcomes: depression (PHQ-8), fatigue (FSI), anxiety (GAD-7)	No
Johns *et al* (2016)[44]	USA	35/36	Breast and colorectal cancer survivors	56.9	56.4	2.0	8	24	20	X	Instructor	Active: psychoeducation/ support groups	Primary outcome: patient-reported sleep quality (ISI) Secondary outcomes: fatigue (FSI), depression (PHQ-8), anxiety (GAD-7)	No
Lengacher *et al* (2012)[37]	USA	41/43	Breast cancer	NR	NR	2.0	6	6	NR	X	Instructor	Passive: waitlist control	Primary outcome: patient-reported sleep quality (MDASI) Secondary outcomes: fatigue (MDASI), stress (MDASI)	No
Lengacher *et al* (2015)[27]	USA	38/41	Breast cancer	56.1	58.0	2.0	6	12	15~45	X	NR	Passive: waitlist control	Primary outcomes: patient-reported sleep quality (PSQI), objective sleep quality (actigraphy, SE)	No
Ong *et al* (2014)[28]	USA	19/38	Chronic insomnia	42.4	41.3	2.5	8	24	30~45	O	Instructor	Active: mindfulness-based therapy for insomnia, sleep diary self-monitoring followed by behaviour therapy	Primary outcomes: patient-reported sleep quality, objective sleep quality (actigraphy, SE)	No
Ong *et al* (2018)[45]				41.9	42.4	2.0	8	8					Secondary outcomes: depression (BDI-II), anxiety (STSI-T), fatigue (FSS)	No

Continued

Table 1 Continued

Study (year)	Country	No of participants (E/C)	Participants	Age (mean)		Intervention						Type of comparison (active vs passive)	Outcome	Sleep medication use
				E	C	Time (hours)	Duration (weeks)	Follow-up (weeks)	Home practice (minutes)	Day-long retreat	Provider			
Reich *et al* (2017)[38]	USA	167/155	Breast cancer survivors	56.5	57.6	2.0	6	12	15~45	X	Instructor	Passive: waitlist control	Primary outcome: patient-reported sleep quality (PSQI) Secondary outcomes: depression (CES-D), anxiety (STAI), stress (PSS), fatigue (FSI), QOL (SF-36)	No
Schmidt *et al* (2011)[35]	Germany	59/115	Fibromyalgia	53.4	51.9	2.5	8	8	45~60	O	Instructor	Active: social support and topical educational discussions	Primary outcome: patient-reported sleep quality (PSQI) Secondary outcomes: depression (CES-D), anxiety (STAI), QOL (HRQOL)	NR
Witek *et al* (2019)[43]	USA	84/80	Breast cancer	55.0	55.2	2.5	8	32	NR	O	Instructor	Active: active control condition	Primary outcome: patient-reported sleep quality (PSQI) Secondary outcomes: stress (PSS), depression (CES-D), fatigue (MFSI-SF)	NR
Zhang *et al* (2015)[39]	China	30/30	Chronic insomnia	78.6	77.6	2.0	8	8	45	O	Instructor	Passive: waitlist control	Primary outcome: patient-reported sleep quality (PSQI) Secondary outcomes: depression (GDS), anxiety (SAS)	NR

*The MBSR group was regarded as the intervention group, and Mindfulness-Based Therapy for Insomnia arm and sleep diary self-monitoring followed by behavior therapy arm were combined as a control group, based on the formula of Cochrane Handbook (2011).
BAI, Beck Anxiety Inventory; BDI, Beck Depression Inventory; BDI-II, Beck Depression Inventory II; C, control group; CES-D, Center for Epidemiological Studies-Depression Scale; C-SOSI, Calgary Symptoms of Stress Inventory; E, experimental group; EX training, intensity aerobic exercise training; FSI, Fatigue Symptom Inventory; FSS, Fatigue Severity Scale; GAD-7, seven-item Patient Health Questionnaire Generalized Anxiety Disorder Scale; GDS, Geriatric Depression Scale; HADS-A, Hospital Anxiety and Depression Scale-Anxiety; HRQOL, health-related quality of life; ISI, Insomnia Severity Index; MDASI, M D Andersen Symptom Inventory; MENQOL, Menopause-Related Quality of Life; MFSI-SF, Multidimensional Fatigue Scale Inventory-Short Form; MOSSS, Medical Outcome Study Sleep Scale; NO, no description; NR, not reported; PHQ-8, Patient Health Questionnaire eight-item depression scale; PSI, Parenting Stress Index-Short Form; PSQI, Pittsburgh Sleep Quality Index; PSS, Perceived Stress Scale; SAS, Self-rating Anxiety Sale; SE, sleep efficiency; SF-36, Short-Form General Health Survey; SSQ, Stanford Sleep Questionnaire; STAI, State-Trait Anxiety Inventory-State Version; STSI-T, State-Trait Anxiety Inventory-Trait; QOL VAS, quality of life Visual Analogue Scale; WHIIRS, Women's Health Initiative Insomnia Rating Scale.

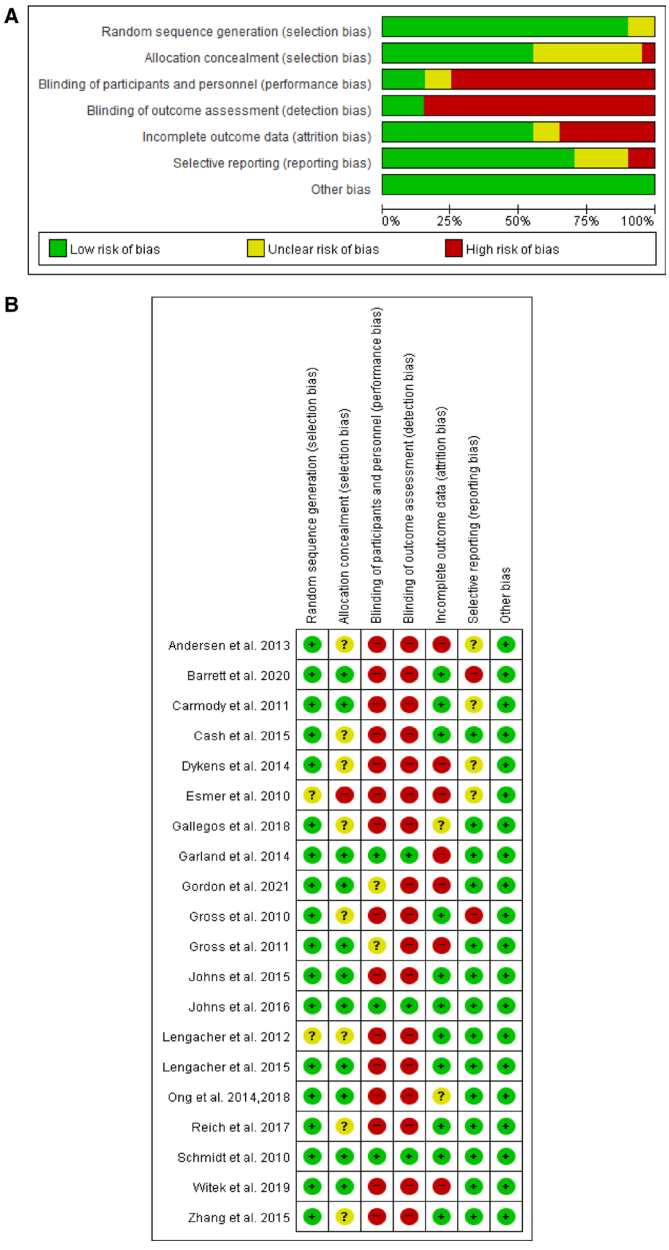


Figure 2 Risk of bias assessment. (A) Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies. (B) Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

studies were evaluated as having an unclear risk of bias for selective outcome reporting, as they only reported on the value of change. Therefore, the overall risk of bias across studies was a concern, although blinding of participants and personnel was difficult during the intervention trial.

Effects of MBSR

Primary outcomes: sleep quality

Objective sleep quality

Four studies reporting objective sleep quality by using sleep efficiency (SE) with wrist actigraphy were included in the meta-analysis. SE is considered the standard for evaluating the efficacy of insomnia interventions,[24] with a high SE score indicating long sleep duration. When compared with the controls, MBSR did not improve SE (MD=−1.17; 95% CI: −4.26 to 1.92).[25–28] Due to significant heterogeneity (I^2=68%), we performed MBSR subgroup analyses according to the types of participants and type of controls. The analyses revealed that when compared with the control group, MBSR did not increase SE (table 2 and online supplemental appendix 3).

Patient-reported sleep quality

In 17 studies, 2127 participants were included to examine the pooling effects of sleep quality by using patient-reported questionnaires. The SMD of MBSR versus controls was −0.17 (95% CI: −0.35 to 0.01; I^2=74%). As the heterogeneity of the pooled estimate was substantial, subgroup analyses were conducted. Among the participants, groups including other conditions (solid organ transplant, patients with fibromyalgia, menopausal-transition women, etc) showed an improvement in sleep quality (SMD=−0.21; 95% CI: −0.36 to −0.06; I^2=36%).[29–35] Moreover, MBSR might have demonstrated significantly improved sleep quality versus the waitlist control group. However, it should be noted that the heterogeneity was significant (SMD=−0.32; 95% CI: −0.56 to −0.08; I^2=71%) (table 2 and online supplemental appendix 4).[27 30–33 36–39] No obvious publication bias was detected using the funnel plot (figure 3).

Similar to the results of meta-analyses, the results of three studies not included in the meta-analysis were as follows: MBSR compared with active control did not improve sleep quality in patients with breast cancer (between group p=not significant),[40] and in mothers of children with autism and other disabilities (Effect size=0.03, SE=0.02, p=not significant).[41] MBSR versus waitlist control improved sleep quality in failed back surgery syndrome in long-term follow-up (MD=1.9, SD=3.3, p<0.047).[42]

Secondary outcomes: sleep-related daytime impairments

Depressive symptoms

Ten studies including 499 participants who received MBSR and 560 controls were included in the meta-analysis. MBSR reduced depressive symptoms, compared with the controls but with considerable heterogeneity (SMD=−0.35; 95% CI: −0.68 to −0.02; I^2=83%). Therefore, we conducted subgroup analyses to explore the causes of heterogeneity. In the subgroup analysis according to the type of participants, MBSR did not improve depressive symptoms (table 3). However, MBSR versus active control slightly improved depression level in mothers of children with autism spectrum disorder and other disabilities (ES=0.04, SE=0.02, p<0.05).[41]

Anxiety

The effect of MBSR on anxiety was investigated in nine studies, including 935 participants. The results showed that MBSR reduced anxiety levels compared with that in the controls, but with substantial heterogeneity

Table 2 Subgroup analysis of MBSR versus controls in sleep quality for people with sleep disturbance

Category	Objective sleep quality (sleep efficiency, %)				Patient-reported sleep quality			
	Studies, n	Participants, n	Random effects, MD (95% CI)	I^2, %	Studies, n	Participants, n	Random effects, SMD (95% CI)	I^2, %
Overall pooled estimates	4	252	−1.17 (−4.26 to 1.92)	68	17	2127	−0.17 (−0.35 to 0.01)	74
Participants' type								
Chronic insomnia	2	62	−3.21 (−7.64 to 1.21)	45	3	122	−0.25 (−1.14 to 0.65)	81
Cancers	2	190	0.35 (−4.45 to 5.15)	81	7	797	−0.08 (−0.44 to 0.28)	82
Others					7	1208	−0.21 (−0.36 to −0.06)	36
Control group								
Active	3	173	−2.48 (−4.68 to −0.28)	28	8	1071	−0.01 (−0.27 to 0.29)	71
Passive	1	79	3.10 (−0.67 to 6.87)	NA	9	1056	−0.32 (−0.56 to −0.08)	71

MBSR, mindfulness-based stress reduction; NA, not applicable; SMD, standardised mean difference.

(SMD=−0.41; 95% CI: −0.72 to −0.09; I^2=79%). Therefore, we performed subgroup analyses to address the heterogeneity (p<0.0001). In the subgroup analysis according to type of controls, MBSR compared with waitlist control might be effective in reducing anxiety, but with significant heterogeneity (SMD=−0.75; 95% CI: −1.44 to −0.07, I^2=90%, p<0.00001) (table 3).[33 36 38 39] However, MBSR versus active control did not decrease anxiety level in mothers of children with autism spectrum disorder and other disabilities (ES=0.01, SE=0.02, p=not significant).[41]

Stress

Six studies (n=824) were included in this meta-analysis.[25 31 33 37 38 43] When compared with the controls, MBSR had no effect on stress (SMD=−0.32; 95% CI: −0.70 to 0.06; I^2=85%). We then performed subgroup analyses to address the considerable heterogeneity and found that according to the type of participants, MBSR did not improve stress levels when compared with the control group (table 3). Consistently, MBSR versus active control did not decrease parental distress level in mothers of children with autism spectrum disorder and other disabilities ((ES=0.00, SE=0.02, p=not significant).[41]

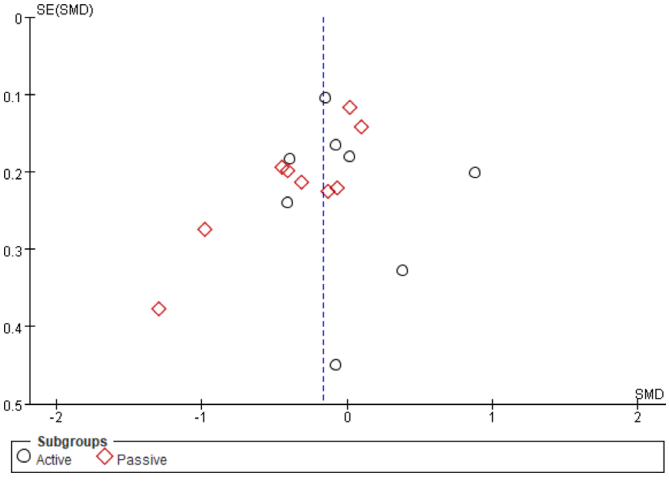


Figure 3 Funnel plot of MBSR versus controls; outcome measure: patient-reported sleep quality. MBSR, mindfulness-based stress reduction; SMD, standardised mean difference.

Fatigue

Seven studies, including 372 participants who underwent MBSR, and 378 controls were included in the meta-analysis.[31 36–38 43–45] MBSR did not decrease fatigue level, compared with controls (SMD=−0.23; 95% CI: −0.51 to 0.04; I^2=66%). To address the substantial heterogeneity, subgroup analyses according to the type of participants and type of controls were performed. Consistently, MBSR did not improve stress, when compared with the controls (table 3).

Quality of life

Three studies including 589 participants were included to determine the combined effect of MBSR.[34 35 38] Results showed that MBSR compared with controls had no effect on quality of life improvement (SMD=0.05; 95% CI: −0.12 to 0.23; I^2=11%) (table 3).

DISCUSSION

This systematic review and meta-analysis revealed that MBSR had no effect on the improvement of sleep quality in chronic insomnia and patients with cancer. However, when compared with waitlist controls, MBSR might be an effective treatment for improving subjective sleep quality as measured by self-report questionnaires. However, we observed considerable heterogeneity in the subgroup analysis. This discrepant result can be explained by the placebo effect in the open-label trial investigating the effect of MBSR compared with waitlist controls.[46] Furthermore, the most studies included in this meta-analysis raised concerns regarding the detection bias, despite

Table 3 Subgroup analysis of MBSR versus controls in sleep-related daytime impairments

Category	Depression				Anxiety				Stress				Fatigue				Quality of life			
	Studies, N	Participants, N	Random effects, SMD (95% CI)	I^2, %	Studies, N	Participants, N	Random effects, SMD (95% CI)	I^2, %	Studies, N	Participants, N	Random effects, SMD (95% CI)	I^2, %	Studies, N	Participants, N	Random effects, SMD (95% CI)	I^2, %	Studies, N	Participants, N	Random effects, SMD (95% CI)	I^2, %
Overall pooled estimates																				
	10	1059	−0.35 (−0.68 to −0.02)	83	9	935	−0.41 (−0.72 to −0.09)	79	6	824	−0.32 (−0.70 to 0.06)	85	7	750	−0.23 (−0.51 to 0.04)	66	3	589	0.05 (−0.12 to 0.23)	11
Participants' type																				
Chronic insomnia	3	132	0.11 (−0.26 to 0.47)	0	3	132	−0.14 (−0.67 to 0.38)	47					1	48	−0.22 (−0.86 to 0.42)	NA				
Cancers	4	533	−0.50 (−1.07 to 0.07)	87	3	409	−0.42 (−0.93 to 0.08)	74	4	629	−0.14 (−0.43 to 0.15)	66	5	611	−0.25 (−0.63 to 0.12)	77				
Others	3	394	−0.57 (−1.22 to 0.08)	89	3	394	−0.60 (−1.29 to 0.10)	91	2	195	−0.67 (−1.79 to 0.46)	93	1	91	−0.27 (−0.68 to 0.15)	NA				
Control group																				
Active	6	557	−0.13 (−0.31 to 0.05)	6	5	433	−0.19 (−0.39 to 0.01)	0	2	235	−0.06 (−0.57 to 0.45)	74	3	243	−0.05 (−0.31 to 0.21)	0				
Passive	4	502	−0.84 (−1.68 to 0.00)	93	4	502	−0.75 (−1.44 to −0.07)	90	4	589	−0.46 (−1.01 to 0.10)	89	4	507	−0.42 (−0.89 to 0.06)	81				

MBSR, mindfulness-based stress reduction; NA, not applicable; SMD, standardised mean difference.

accounting for the difficulty of blinding in behavioural intervention trials.

In a meta-analysis and subgroup analysis, MBSR measured using wrist actigraphy did not improve objective sleep quality versus the controls. These findings were consistent with those of a study that used an activity tracker as an objective outcome measure to examine the effect of MBIs on sleep disturbances.[13] Furthermore, Wang *et al*[16] reported that MBSR did not improve sleep duration when measured by wrist actigraphy. In a study by Gong *et al*,[14] MBIs improved self-reported sleep quality, but had little effect on sleep duration. Similarly, whereas MBIs effectively reduced self-reported insomnia, they had little effect on objective sleep data obtained using polysomnography and wrist actigraphy.[47]

In this review, exposure to MBSR interventions in participants categorised by other conditions (solid organ transplant, patients with fibromyalgia, menopausal-transition women, etc) improved the self-reported sleep quality with a small effect size. However, caution is required because of the clinical heterogeneity of the studies included in this subgroup. Therefore, the results should be carefully interpreted until further trials confirm or refute them, especially since the results of this study in favour of intervention might be associated with raised expectations in intervention groups with unblinded or inadequate blinding.[48]

In a previous systematic review, MBI of healthy adults with insomnia[49] or sleep disorders, and patients diagnosed with insomnia[16] reported improved subjective sleep quality as measured by a self-reported questionnaire. However, in this review, the MBSR programme did not improve subjective sleep quality when measured using a self-reported questionnaire for chronic insomnia and cancer. In fact, no recommendations exist for mindfulness therapies for chronic insomnia in recently published clinical practice, which may support the findings of this study.[18] However, in the case of patients with cancer with sleep disturbance, additional evidence is required as the data are insufficient to evaluate the effect.[18]

In the overall meta-analysis, MBSR effectively reduced depressive symptoms and anxiety when compared with the control group. However, the results should be interpreted with caution because of the substantial heterogeneity. The results may be explained by the inclusion of participants with clinical conditions in the meta-analysis. In the subsequent subgroup analysis, MBSR did not improve depressive symptoms and anxiety levels when compared with controls. Similarly, in a meta-analysis by Haller *et al*, MBSR did not decrease anxiety levels in patients with breast cancer at long-term follow-up (anxiety k=2, SMD=−0.22, 95% CI: −0.48 to 0.05).[50] Moreover, a systematic review of mindfulness-based and acceptance-based interventions in patients with fibromyalgia[51] found no difference between groups in the anxiety levels and depression symptoms measured at follow-up. However, these results were inconsistent with those of a 2019 study by Haugmark *et al*[51] showing that mindfulness and acceptance-based interventions effectively reduced depression in patients with fibromyalgia. An explanation for this finding may be that Haugmark *et al*[51] examined the effects of mindfulness meditation plus Qigong movement therapy, acceptance and commitment therapy, and mindfulness-based cognitive therapies, in addition to MBSR.

The subgroup analyses reported in this study revealed that MBSR did not improve stress, fatigue and quality of life in people with sleep disturbances. In a systematic review of the stress-reducing effect of MBI in patients with breast cancer, MBSR compared with usual care did not effectively reduce stress and fatigue in the medium term (SMD=−0.25, 95% CI: −0.68 to 0.19 for stress level; SMD=0.19; 95% CI: −0.50 to 0.88 for fatigue level).[50] These results were consistent with those of meta-analyses that used outcome measures assessed at the end of follow-up.

In this review, both randomised controlled trials (RCTs) evaluating the effect of MBSR on menopausal women and patients with solid organ transplants reported no effective improvement in quality of life.[30 34] These results were consistent with those of the systematic review on mindfulness-based and acceptance-based interventions in patients with fibromyalgia,[51] which reported no significant differences between intervention and control groups in health-related quality of life measured post-intervention and at follow-up (SMD=−0.74, 95% CI: −2.02 to 0.54; and SMD=−0.61, 95% CI: −1.48 to 0.26, respectively). Additionally, a meta-analysis of the effects of MBSR in patients with breast cancer reported no improvement in quality of life at short-term and long-term follow-ups (SMD=0.20; 95% CI: −0.05 to 0.45; and SMD=0.15; 95% CI: −0.11 to 0.41, respectively).[50]

Limitations

This study had some limitations that should be considered when interpreting its results. First, the people with sleep disturbances included in this review were adults with diverse health conditions including chronic insomnia, cancer and other conditions. Additionally, a variety of controls, including active and passive controls, were included. Therefore, statistical heterogeneity was identified in the meta-analysis assessing the effects of MBSR on reported sleep quality, depression, anxiety, stress and fatigue levels. However, although subgroup analyses were performed using a random-effects model, an unexplained heterogeneity remained. Second, most studies included in this review were deemed vulnerable to performance bias and detection bias in risk of bias assessment. Moreover, since a small number of studies were included in some subgroup analyses, further well-designed RCTs should be conducted. Finally, despite an extensive literature search, the risk of publication bias might have remained because only studies published in English and Korean were included.

Implications

This systematic review and meta-analysis showed that MBSR might be ineffective in improving objective and

subjective sleep quality in patients with chronic insomnia and cancer. Moreover, most RCTs included in this review were small studies with a potential risk of bias due to deviations from the intended interventions and missing outcome data. Further well-designed large RCTs, with a low risk of bias, are required to determine whether MBSR, as a non-pharmacological intervention, helps improve sleep quality and mitigate sleep-related daytime impairments in adults with sleep disturbances.

Author affiliations
[1]Department of Nursing, Donggang University, Gwangju, Korea
[2]Department of Nursing, Nambu University, Gwangju, Korea
[3]College of Nursing, Chungnam National University, Daejeon, Korea
[4]Department of Nursing, College of Medicine, Chosun University, Gwangju, Korea
[5]Division of Health Administration, College of Software and Digital Healthcare Convergence, Yonsei University-Mirae Campus, Wonju-si, Gangwon-do, Korea

Contributors SMK and HJS conceptualised the study. SMK and JMP analysed the data. JK, JWN and HLK interpreted the data. SMK and JMP wrote the first drafts. HJS administrated the study and revised the manuscript. HJS takes responsibility for the decision to publish this study. All authors have read and approved the manuscript. HJS is guarantor of the study, contribution in study design, preparation of the manuscript, provided revisions to the scientific content of the manuscript.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not required.

Ethics approval Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Our study uses published data only. The original contributions presented in the study are included in the article and online supplemental material, further inquiries can be directed to the corresponding author.

ORCID iDs
Seong Min Kim http://orcid.org/0000-0002-9505-5762
Hyun-Ju Seo http://orcid.org/0000-0001-9019-1135
Jinhee Kim http://orcid.org/0000-0002-8037-9174
Jin-Won Noh http://orcid.org/0000-0001-5172-4023

REFERENCES

1 Morin CM, Jarrin DC. Epidemiology of insomnia: prevalence, course, risk factors, and public health burden. *Sleep Med Clin* 2022;17:173–91.
2 Marcks BA, Weisberg RB, Edelen MO, *et al*. The relationship between sleep disturbance and the course of anxiety disorders in primary care patients. *Psychiatry Res* 2010;178:487–92.
3 Cormier RE. Sleep disturbances. In: Walker HK, Hall WD, Hurst JW, eds. *Clinical methods: the history, physical, and laboratory examinations*. 3rd edn. Boston: Butter worths, 1990.
4 Sateia MJ, Buysse DJ, Krystal AD, *et al*. Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: an American Academy of sleep medicine clinical practice guideline. *J Clin Sleep Med* 2017;13:307–49.
5 National Institutes of Health. National Institutes of health state of the science conference statement on manifestations and management of chronic insomnia in adults, June 13-15, 2005. *Sleep* 2005;28:1049–57.
6 Buscemi N, Vandermeer B, Friesen C, *et al*. The efficacy and safety of drug treatments for chronic insomnia in adults: a meta-analysis of RCTs. *J Gen Intern Med* 2007;22:1335–50.
7 Espie CA, Barrie LM, Forgan GS. Comparative investigation of the psychophysiologic and idiopathic insomnia disorder phenotypes: psychologic characteristics, patients' perspectives, and implications for clinical management. *Sleep* 2012;35:385–93.
8 Teasdale JD, Segal ZV, Williams JM, *et al*. Prevention of relapse/recurrence in major depression by mindfulness-based cognitive therapy. *J Consult Clin Psychol* 2000;68:615–23.
9 Segal ZV, Williams MG, Teasdale JD. *Mindfulness-based cognitive therapy for depression: a new approach to prevention relapse*. New York: Guilford Press, 2002: 315.
10 Cahn BR, Polich J. Meditation states and traits: EEG, Erp, and neuroimaging studies. *Psychol Bull* 2006;132:180–211.
11 American Academy of Sleep Medicine. *The International classification of sleep disorders, revised: diagnostic and coding manual*. Westchester, 2005: 3.
12 Winbush NY, Gross CR, Kreitzer MJ. The effects of mindfulness-based stress reduction on sleep disturbance: a systematic review. *Explore* 2007;3:585–91.
13 Kanen J, Nazir R, Sedky K, *et al*. The effects of mindfulness-based interventions on sleep disturbance: a meta-analysis. *Adolesc Psychiatry* 2015;5:105–15.
14 Gong H, Ni C-X, Liu Y-Z, *et al*. Mindfulness meditation for insomnia: a meta-analysis of randomized controlled trials. *J Psychosom Res* 2016;89:1–6.
15 Rash JA, Kavanagh VAJ, Garland SN. A meta-analysis of mindfulness-based therapies for insomnia and sleep disturbance: moving towards processes of change. *Sleep Med Clin* 2019;14:209–33.
16 Wang Y-Y, Wang F, Zheng W, *et al*. Mindfulness-based interventions for insomnia: a meta-analysis of randomized controlled trials. *Behav Sleep Med* 2020;18:1–9.
17 Ong JC, Moore C. What do we really know about mindfulness and sleep health? *Curr Opin Psychol* 2020;34:18–22.
18 Edinger JD, Arnedt JT, Bertisch SM, *et al*. Behavioral and psychological treatments for chronic insomnia disorder in adults: an American Academy of sleep medicine clinical practice guideline. *J Clin Sleep Med* 2021;17:255–62.
19 Higgins JPT, Green S. *Cochrane Handbook for systematic reviews of interventions version 5.1.0*. The Cochrane Collaboration, 2011. www.handbook.cochrane.org
20 Levack WM, Martin RA, Graham FP, *et al*. Compared to what? An analysis of the management of control groups in Cochrane reviews in neurorehabilitation. *Eur J Phys Rehabil Med* 2019;55:353–63.
21 Schroll JB, Moustgaard R, Gøtzsche PC. Dealing with substantial heterogeneity in Cochrane reviews. cross-sectional study. *BMC Med Res Methodol* 2011;11:22.
22 Shea BJ, Grimshaw JM, Wells GA, *et al*. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. *BMC Med Res Methodol* 2007;7:10.
23 Hozo SP, Djulbegovic B, Hozo I. Estimating the mean and variance from the median, range, and the size of a sample. *BMC Med Res Methodol* 2005;5:13.
24 Reed DL, Sacco WP. Measuring sleep efficiency: what should the denominator be? *J Clin Sleep Med* 2016;12:263–6.
25 Garland SN, Carlson LE, Stephens AJ, *et al*. Mindfulness-based stress reduction compared with cognitive behavioral therapy for the treatment of insomnia comorbid with cancer: a randomized, partially blinded, noninferiority trial. *J Clin Oncol* 2014;32:449–57.
26 Gross CR, Kreitzer MJ, Reilly-Spong M, *et al*. Mindfulness-based stress reduction versus pharmacotherapy for chronic primary insomnia: a randomized controlled clinical trial. *Explore* 2011;7:76–87.
27 Lengacher CA, Reich RR, Paterson CL, *et al*. The effects of mindfulness-based stress reduction on objective and subjective sleep parameters in women with breast cancer: a randomized controlled trial. *Psychooncology* 2015;24:424–32.

28 Ong JC, Manber R, Segal Z, *et al*. A randomized controlled trial of mindfulness meditation for chronic insomnia. *Sleep* 2014;37:1553–63.
29 Barrett B, Harden CM, Brown RL, *et al*. Mindfulness meditation and exercise both improve sleep quality: secondary analysis of a randomized controlled trial of community dwelling adults. *Sleep Health* 2020;6:804–13.
30 Carmody JF, Crawford S, Salmoirago-Blotcher E, *et al*. Mindfulness training for coping with hot flashes: results of a randomized trial. *Menopause* 2011;18:611–20.
31 Cash E, Salmon P, Weissbecker I, *et al*. Mindfulness meditation alleviates fibromyalgia symptoms in women: results of a randomized clinical trial. *Ann Behav Med* 2015;49:319–30.
32 Gallegos AM, Moynihan J, Pigeon WR. A secondary analysis of sleep quality changes in older adults from a randomized trial of an MBSR program. *J Appl Gerontol* 2018;37:1327–43.
33 Gordon JL, Halleran M, Beshai S, *et al*. Endocrine and psychosocial moderators of mindfulness-based stress reduction for the prevention of perimenopausal depressive symptoms: a randomized controlled trial. *Psychoneuroendocrinology* 2021;130:105277.
34 Gross CR, Kreitzer MJ, Thomas W, *et al*. Mindfulness-based stress reduction for solid organ transplant recipients: a randomized controlled trial. *Altern Ther Health Med* 2010;16:30–8.
35 Schmidt S, Grossman P, Schwarzer B, *et al*. Treating fibromyalgia with mindfulness-based stress reduction: results from a 3-armed randomized controlled trial. *Pain* 2011;152:361–9.
36 Johns SA, Brown LF, Beck-Coon K, *et al*. Randomized controlled pilot study of mindfulness-based stress reduction for persistently fatigued cancer survivors. *Psychooncology* 2015;24:885–93.
37 Lengacher CA, Reich RR, Post-White J, *et al*. Mindfulness based stress reduction in post-treatment breast cancer patients: an examination of symptoms and symptom clusters. *J Behav Med* 2012;35:86–94.
38 Reich RR, Lengacher CA, Alinat CB, *et al*. Mindfulness-based stress reduction in post-treatment breast cancer patients: immediate and sustained effects across multiple symptom clusters. *J Pain Symptom Manage* 2017;53:85–95.
39 Zhang J-X, Liu X-H, Xie X-H, *et al*. Mindfulness-based stress reduction for chronic insomnia in adults older than 75 years: a randomized, controlled, single-blind clinical trial. *Explore* 2015;11:180–5.
40 Andersen SR, Würtzen H, Steding-Jessen M, *et al*. Effect of mindfulness-based stress reduction on sleep quality: results of a randomized trial among Danish breast cancer patients. *Acta Oncol* 2013;52:336–44.
41 Dykens EM, Fisher MH, Taylor JL, *et al*. Reducing distress in mothers of children with autism and other disabilities: a randomized trial. *Pediatrics* 2014;134:e454–63.
42 Esmer G, Blum J, Rulf J, *et al*. Mindfulness-based stress reduction for failed back surgery syndrome: a randomized controlled trial. *J Am Osteopath Assoc* 2010;110:646–52.
43 Witek Janusek L, Tell D, Mathews HL. Mindfulness based stress reduction provides psychological benefit and restores immune function of women newly diagnosed with breast cancer: a randomized trial with active control. *Brain Behav Immun* 2019;80:358–73.
44 Johns SA, Brown LF, Beck-Coon K, *et al*. Randomized controlled pilot trial of mindfulness-based stress reduction compared to psychoeducational support for persistently fatigued breast and colorectal cancer survivors. *Support Care Cancer* 2016;24:4085–96.
45 Ong JC, Xia Y, Smith-Mason CE, *et al*. A randomized controlled trial of mindfulness meditation for chronic insomnia: effects on daytime symptoms and cognitive-emotional arousal. *Mindfulness* 2018;9:1702–12.
46 von Wernsdorff M, Loef M, Tuschen-Caffier B, *et al*. Effects of open-label placebos in clinical trials: a systematic review and meta-analysis. *Sci Rep* 2021;11:3855.
47 Ong JC, Smith CE. Using mindfulness for the treatment of insomnia. *Curr Sleep Med Rep* 2017;3:57–65.
48 Feys F, Bekkering GE, Singh K, *et al*. Do randomized clinical trials with inadequate blinding report enhanced placebo effects for intervention groups and nocebo effects for placebo groups? A protocol for a meta-epidemiological study of PDE-5 inhibitors. *Syst Rev* 2012;1:54.
49 Rusch HL, Rosario M, Levison LM, *et al*. The effect of mindfulness meditation on sleep quality: a systematic review and meta-analysis of randomized controlled trials. *Ann N Y Acad Sci* 2019;1445:5–16.
50 Haller H, Winkler MM, Klose P, *et al*. Mindfulness-based interventions for women with breast cancer: an updated systematic review and meta-analysis. *Acta Oncol* 2017;56:1665–76.
51 Haugmark T, Hagen KB, Smedslund G, *et al*. Mindfulness- and acceptance-based interventions for patients with fibromyalgia – a systematic review and meta-analyses. *PLoS One* 2019;14:e022189.

Appendix 1. Search strategy

1. Ovid MEDLINE

1	exp Meditation/
2	meditat*.ti.
3	meditat*.ab.
4	mindful*.ti.
5	mindful*.ab.
6	mindfulness-based stress reduction.ti.
7	mindfulness-based stress reduction.ab.
8	MBSR.ti.
9	MBSR.ab.
10	exp Mindfulness/
11	(mind body adj3 rela*).mp.
12	exp Sleep Disorders/
13	exp "Sleep Initiation and Maintenance Disorders"/
14	insomnia.ti.
15	insomnia.ab.
16	sleep disturbance.ti.
17	sleep disturbance.ab.
18	sleep.tw.
19	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11
20	12 or 13 or 14 or 15 or 16 or 17 or 18
21	19 and 20
22	limit 21 to yr="2020 -Current"
23	randomized controlled trial.pt.
24	controlled clinical trial.pt.
25	randomized.ab.
26	placebo.ab.
27	drug therapy.fs.
28	randomly.ab.
29	trial.ab.
30	groups.ab.
31	23 or 24 or 25 or 26 or 27 or 28 or 29 or 30
32	exp animals/ not humans/
33	31 not 32
34	22 and 33

2. AMED (Allied and Complementary Medicine)

1	mindfulness.mp.
2	exp Meditation/
3	mindfulness-based stress reduction.mp.
4	(mind-body adj3 rela*).mp. [mp=abstract, heading words, title]
5	exp Sleep disorders/
6	sleep disturbance.mp.
7	MBSR*.mp.
8	1 or 2 or 3 or 4 or 7
9	sleep*.mp.
10	exp Insomnia/
11	5 or 6 or 9 or 10
12	8 and 11
13	meditat*.mp.
14	mindful*.mp.
15	insomnia*.mp.
16	1 or 2 or 3 or 4 or 7 or 13 or 14
17	5 or 6 or 9 or 10 or 15
18	16 and 17

3. Embase

1	exp mindfulness/
2	exp meditation/
3	mindfulness-based stress reduction.mp.
4	MBSR*.mp.
5	(mind-body adj3 rela*).mp.
6	exp sleep disorder/
7	sleep disturbance.mp.
8	exp sleep/
9	exp insomnia/
10	meditat*.tw.
11	mindful*.tw.
12	insomnia*.tw.
13	1 or 2 or 3 or 4 or 5 or 10 or 11
14	6 or 7 or 8 or 9 or 12
15	13 and 14
16	Randomized controlled trial/
17	Controlled clinical study/
18	random$.ti,ab.
19	randomization/
20	intermethod comparison/
21	placebo.ti,ab.
22	(compare or compared or comparison).ti.
23	((evaluated or evaluate or evaluating or assessed or assess) and (compare or compared or comparing or comparison)).ab.
24	(open adj label).ti,ab.
25	((double or single or doubly or singly) adj (blind or blinded or blindly)).ti,ab.
26	double blind procedure/
27	parallel group$1.ti,ab.
28	(crossover or cross over).ti,ab.
29	((assign$ or match or matched or allocation) adj5 (alternate or group$1 or intervention$1 or patient$1 or subject$1 or participant$1)).ti,ab.
30	(assigned or allocated).ti,ab.
31	(controlled adj7 (study or design or trial)).ti,ab.
32	(volunteer or volunteers).ti,ab.
33	human experiment/
34	trial.ti.
35	or/16-34
36	Animal experiment/ not (human experiment/ or human/)
37	35 not 36
38	15 and 37

4. CINAHL Plus with Full Text

1	(MH randomized controlled trials OR MH double-blind studies OR MH single-blind studies OR MH random assignment OR MH pretest-posttest design OR MH cluster sample OR TI (randomised OR randomized) OR AB (random*) OR TI (trial) OR (MH (sample size) AND AB (assigned OR allocated OR control)) OR MH (placebos) OR PT (randomized controlled trial) OR AB (CONTROL W5 GROUP) OR MH (CROSSOVER DESIGN) OR MH (COMPARATIVE STUDIES) OR AB (CLUSTER W3 RCT)) NOT ((MH ANIMALS+ NOT MH HUMAN) OR (MH (ANIMAL STUDIES) NOT MH (HUMAN)) OR (TI (ANIMAL MODEL) NOT MH (HUMAN)))
2	(MH "Mindfulness") OR "Mindfulness"
3	(MH "Meditation") OR "Meditation"
4	TI MBSR OR AB MBSR
5	TI mindfulness based stress reduction OR AB mindfulness based stress reduction
6	TI mind-body N3 rela* OR AB mind-body N3 rela*
7	(MH "Sleep Disorders+")
8	TI Sleep Disturbance OR AB Sleep Disturbance
9	sleep*
10	insomnia*
11	(MH "Sleep+")
12	S2 OR S3 OR S4 OR S5 OR S6
13	S7 OR S8 OR S9 OR S10 OR S11
14	S12 and S13

5. COCHRANE Library

1	MeSH descriptor: [Meditation] explode all trees
2	MeSH descriptor: [Mindfulness] explode all trees
3	(mind-body near/3 rela*):ti,ab,kw (Word variations have been searched)
4	(mindful* near/3 stress):ti,ab,kw (Word variations have been searched)
5	(MBSR):ti,ab,kw (Word variations have been searched)
6	(meditat*):ti (Word variations have been searched)
7	(meditat*):ab
8	(mindful*):ti
9	(mindful*):ab
10	MeSH descriptor: [Sleep] explode all trees
11	MeSH descriptor: [Sleep Wake Disorders] explode all trees
12	MeSH descriptor: [Sleep Initiation and Maintenance Disorders] explode all trees
13	(sleep disturbance):ti,ab,kw
14	("sleep disorder"):ti,ab,kw
15	(insomnia):ti,ab,kw
16	#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9
17	#10 or #11 or #12 or #13 or #14 or #15
18	#16 and #17

Koreamed

1	mindfulness 국내, 인간 제한 (gugnae, ingan jehan)
2	meditation 국내, 인간 제한 (gugnae, ingan jehan)
3	MBSR 국내, 인간 제한 (gugnae, ingan jehan)
6	Or/1-3

Kmbase

1	mindfulness ti, ab, kw 국내 제한 (gugnae jehan)
2	meditation ti, ab, kw 국내 제한 (gugnae jehan)
3	MBSR ti, ab, kw 국내 제한 (gugnae jehan)
4	마음챙김(ma-eumchaeng-gim) ti, ab, kw 국내 제한 (gugnae jehan)
5	Or/1-4

KISS

1	mindfulness ti 제한 (jehan)
2	meditation ti 제한 (jehan)
3	MBSR ti 제한 (jehan)
4	마음챙김 (ma-eumchaeng-gim) ti 제한 (jehan)
5	Or/1-4

NDSL

1	mindfulness ti, ab, kw, 국내 제한 (gugnae jehan)
2	meditation ti, ab, kw, 국내 제한 (gugnae jehan)
3	MBSR ti, ab, kw, 국내 제한 (gugnae jehan)
4	마음챙김 (ma-eumchaeng-gim) ti, ab, kw, 국내 제한 (gugnae jehan)
5	Or/1-4

Appendix 2. The 65 excluded studies from full-text review

	Reason for exclusion	Reference
1	not RCTs	Bootzin RR, Stevens SJ. Adolescents, substance abuse, and the treatment of insomnia and daytime sleepiness. *Clinical psychology review* 2005;25:629–644.
2	not RCTs	Brand S, Holsboer-Trachsler E, Naranjo JR *et al.* Influence of mindfulness practice on cortisol and sleep in long-term and short-term meditators. *Neuropsychobiology* 2012;65:109–118.
3	not RCTs	Carlson LE, Garland SN. Impact of mindfulness-based stress reduction (MBSR) on sleep, mood, stress and fatigue symptoms in cancer outpatients. *International journal of behavioral medicine* 2005;12:278–285.
4	not RCTs	Carlson LE, Speca M, Patel KD, *et al.* Mindfulness-based stress reduction in relation to quality of life, mood, symptoms of stress, and immune parameters in breast and prostate cancer outpatients. *Psychosomatic medicine* 2003;65:571–581.
5	not RCTs	Cincotta AL, Gehrman PR, Gooneratne NS, *et al.* The effects of a mindfulness-based stress reduction programme on pre-sleep cognitive arousal and insomnia symptoms: a pilot study. *Stress &Health: Journal of the International Society for the investigation of stress* 2011;27:e299-305.
6	not RCTs	Flugel Colle KF, Vincent A, Cha SS, *et al.* Measurement of quality of life and participant experience with the mindfulness-based stress reduction program. *Complementary therapies in clinical practic*. 2010;16:36–40.
7	not RCTs	Gross CR, Kreitzer MJ, Russas V, *et al.* Mindfulness meditation to reduce symptoms after organ transplant: a pilot study. *Adv Mind Body Med* 2004;20:20-29.
8	not RCTs	Kreitzer MJ, Gross CR, Ye X, *et al.* Longitudinal impact of mindfulness meditation on illness burden in solid-organ transplant recipients. *Prog Transplant* 2005;15:166-172.
9	not RCTs	Melnyk BM, Fineout-Overholt E, Stetler C, *et al.* Outcomes and implementation strategies from the first U.S. Evidence-Based Practice Leadership Summit. *Worldviews Evid Based Nurs* 2005;2:113-121.
10	not RCTs	Roth B, Robbins D. Mindfulness-based stress reduction and health-related quality of life: findings from a bilingual inner-city patient population. *Psychosom Med* 2004;66:113-123.
11	not RCTs	Wall RB. Tai Chi and mindfulness-based stress reduction in a Boston Public Middle School. *J Pediatr Health Care* 2005;19:230-237.
12	not RCTs	Foulk MA, Ingersoll-Dayton B, Kavanagh J, *et al.* Mindfulness-based cognitive therapy with older adults: an exploratory study. *J GerontolSoc Work* 2014;57:498-520.
13	not RCTs	Larouche M, Côté G, Bélisle D, *et al.* Kind attention and non-judgment in mindfulness-based cognitive therapy applied to the treatment of insomnia: state of knowledge. *PatholBiol (Paris)* 2014;62:284-291.
14	not RCTs	Yook K, Lee SH, Ryu M, *et al.* Usefulness of mindfulness-based cognitive therapy for treating insomnia in patients with anxiety disorders: a pilot study. *J Nerv Ment Dis* 2008;196:501-503.
15	not RCTs	Ong JC, Shapiro SL, Manber R. Combining mindfulness meditation with cognitive-behavior therapy for insomnia: a treatment-development study. *Behav Ther* 2008;39:171-182.

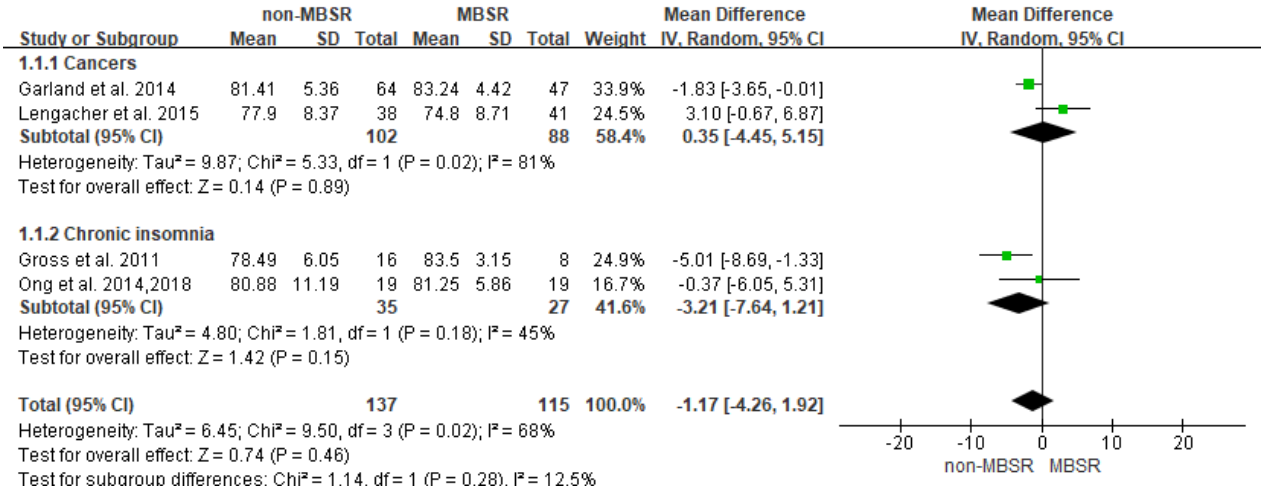
16	not RCTs	Ong JC, Shapiro SL, Manber R. Mindfulness meditation and cognitive behavioral therapy for insomnia: a naturalistic 12-month follow-up. *Explore (NY)* 2009;5:30-36.
17	not RCTs	Garland SN, Rouleau CR, Campbell T, *et al.* The Comparative Impact of Mindfulness-Based Cancer Recovery (MBCR) and Cognitive Behavior Therapy for Insomnia (CBT-I) on Sleep and Mindfulness in Cancer Patients. *Explore (NY)* 2015;11:445-454.
18	not RCTs	Lawson K. Demystifying mindfulness. *Minn Med* 2011;94:37-39.
19	not RCTs	Purohit MP, Wells RE, Zafonte R, *et al.* Neuropsychiatric symptoms and the use of mind-body therapies. *J Clin Psychiatry* 2013;74:e520-526.
20	not RCTs	Roberts KC, Danoff-Burg S. Mindfulness and health behaviors: is paying attention good for you?. *J Am Coll Health* 2010;59:165-173.
21	not RCTs	Conesa J. Isolated sleep paralysis and lucid dreaming: Ten-year longitudinal case study and related dream frequencies, types, and categories. *Sleep and Hypnosis* 2002;4:132-142.
22	not RCTs	Xiao C, Chen Y, Wu Y, *et al.* Mindfulness-based stress reduction therapy as a preclinical intervention for peri-menopausal depressive moods - An observational study. *European journal of integrative medicine* 2020;39.
23	No information of primary sleep outcome	Lengacher CA, Johnson-Mallard V, Post-White J, *et al.* Randomized controlled trial of mindfulness-based stress reduction (MBSR) for survivors of breast cancer. *Psychooncology* 2009;18:1261-1272.
24	No information of primary sleep outcome	Ahani A, Wahbeh H, Nezamfar H, *et al.* Quantitative change of EEG and respiration signals during mindfulness meditation. *J Neuroeng Rehabil* 2014;11:87.
25	No information of primary sleep outcome	Van der Lee ML, Garssen B. Mindfulness-based cognitive therapy reduces chronic cancer-related fatigue: a treatment study. *Psychooncology* 2012;21:264-272.
26	No information of primary sleep outcome	Skovbjerg S, Hauge CR, Rasmussen A, *et al.* Mindfulness-based cognitive therapy to treat multiple chemical sensitivities: a randomized pilot trial. *Scand J Psychol* 2012;53:233-238.
27	No information of primary sleep outcome	Bower JE, Crosswell AD, Stanton AL, *et al.* Mindfulness meditation for younger breast cancer survivors: a randomized controlled trial. *Cancer* 2015;121:1231-1240.
28	No information of primary sleep outcome	Chinh K, Mosher CE, Brown LF, *et al.* Psychological processes and symptom outcomes in mindfulness-based stress reduction for cancer survivors: A pilot study. *Mindfulness* 2020;11: 905-916.
29	No information of primary sleep outcome	Janssen M, Heerkens Y, van der Heijden B *et al.* Effects of mindfulness-based stress reduction and an organizational health intervention on Dutch teachers' mental health. *Health promotion international*. 2022;4.1-15
30	Not focused on MBSR	Klatt MD, Buckworth J, Malarkey WB. Effects of low-dose mindfulness-based stress reduction (MBSR-ld) on working adults. *Health Educ Behav* 2009;36:601-614.
31	Not focused on MBSR	Adler E, Dhruva A, Moran PJ, *et al.* Impact of a Mindfulness-Based Weight-Loss Intervention on Sleep Quality Among Adults with Obesity: Data from the SHINE Randomized Controlled Trial. *J Altern Complement Med* 2017;23:188-195.
32	Not focused on MBSR	Black DS, O'Reilly GA, Olmstead R, *et al.* Mindfulness meditation and improvement in sleep quality and daytime impairment among older adults with sleep disturbances: a randomized clinical trial. *JAMA Intern Med* 2015;175:494-501.
33	Not focused on MBSR	Beddoe AE, Lee KA, Weiss SJ, *et al.* Effects of mindful yoga on sleep in pregnant women: a pilot study. *Biol Res Nurs* 2010;11:363-370.
34	Not focused on MBSR	Van Gordon W, Shonin E, Dunn TJ, *et al.* Meditation awareness training for the treatment of fibromyalgia syndrome: A randomized controlled trial. *Br J Health Psychol* 2017;22:186-206.

35	Not focused on MBSR	Wong MY, Ree MJ, Lee CW. Enhancing CBT for Chronic Insomnia: A Randomised Clinical Trial of Additive Components of Mindfulness or Cognitive Therapy. *Clin Psychol Psychother* 2016;23:377-385.
36	Not focused on MBSR	Ong JC, Manber R, Segal Z, *et al.* A randomized controlled trial of mindfulness meditation for chronic insomnia. *Sleep* 2014;37:1553-1563.
37	Not focused on MBSR	Britton WB, Haynes PL, Fridel KW, *et al.* Polysomnographic and subjective profiles of sleep continuity before and after mindfulness-based cognitive therapy in partially remitted depression. *Psychosom Med* 2010;72:539-548.
38	Not focused on MBSR	Britton WB, Haynes PL, Fridel KW, *et al.* Mindfulness-based cognitive therapy improves polysomnographic and subjective sleep profiles in antidepressant users with sleep complaints. *Psychother Psychosom* 2012;81:296-304.
39	Not focused on MBSR	Malboeuf-Hurtubise C, Achille M, Sultan S, *et al.* Mindfulness-based intervention for teenagers with cancer: study protocol for a randomized controlled trial. *Trials* 2013;14:135.
40	Not focused on MBSR	Burns JW, Jensen MP, Thorn B*, et al.* Cognitive therapy, mindfulness-based stress reduction, and behavior therapy for the treatment of chronic pain: randomized controlled trial. *Pain* 2020;163(2): 376-389.
41	Not focused on MBSR	Liang H, Liu L, Hu H, *et al.* The effects of mindfulness-based stress reduction on the mental states, sleep quality, and medication compliance of patients with acute myocardial infarction after percutaneous coronary intervention. *International Journal of Clinical and Experimental Medicine* 2019;12(12): 13514-13523.
42	Not original article	Hong SC, Kim TW, Kim SY. The effectiveness of mindfulness with cognigive behavioral therapy in patiients with chronic insomnia*. Journal of sleep research 23*, 2014;132.
43	Not original article	Heidenreich T, Tuin I, Pflug B, *et al.* Mindfulness-based cognitive therapy for persistent insomnia: a pilot study. *Psychother Psychosom* 2006;75:188-189.
44	Not original article	Kozasa EH, Hachul H, Monson C, *et al.* Mind-body interventions for the treatment of insomnia: a review. *Braz J Psychiatry* 2010;32:437-443.
45	Not original article	Hülsheger UR, Lang JW, Depenbrock F, *et al.* The power of presence: the role of mindfulness at work for daily levels and change trajectories of psychological detachment and sleep quality. *J Appl Psychol* 2014;99:1113-1128.
46	Not original article	Dempsey C, Chesney M, Lao L *et al.* Acupuncture and mindfulness-based stress reduction among female child abuse survivors: A randomized waitlist-controlled pilot study. *The Journal of alternative and complementary medicine (NewYork, N.Y.)* 2014;20:A87.
47	Not original article	Gross CR, Kreitzer MJ, Reilly-Spong M, *et al.* Mindfulness meditation training to reduce symptom distress in transplant patients: rationale, design, and experience with a recycled waitlist. *Clin Trials* 2009;6:76-89.
48	Not original article	Gallegos AM, Hoerger M, Talbot NL, *et al.* Emotional benefits of mindfulness-based stress reduction in older adults: the moderating roles of age and depressive symptom severity. *Aging Ment Health* 2013;17:823-829.
49	Not original article	Janusek LW, Tell D, Mathews HL, *et al.* Mindfulness Predicts Psycho-behavioral Improvement after Breast Cancer Diagnosis: influence of Childhood Adversity. *Western journal of nursing research* 2021;43(3): 239-249.
50	Not original article	Cavalcante V, Mesquita E, Cavalcante AC *et al.* A Stress Reduction, Meditation and Mindfulness Program in Stable Patients with Chronic Heart Failure. *Journal of the American College of Cardiology* 2020;75(11 Supplement 1): 992.
51	Not original article	Drks. Effects of mindfulness Meditation (MBSR) on daytime sleepiness for excessive daytime sleepiness: A randomized controlled pilotstudy. 2021. https://trialsearch.who.int/Trial2.aspx?TrialID=DRKS00026812.

52	Not original article	Tong LQ. Effects of eight weeks of simple mindfulness stress reduction training on anxiety, depression, and sleep quality in elderly patients with functional dyspepsia. *World Chinese Journal of Digestology* 2020;28(7): 265-269.
53	Not original article	Victorson D, Phillips S, Murphy K*, et al.* Mindfulness mediates the relationship between negative mind-body experiences and engagement in physical activity in a sample of young adult cancer survivors. *Global Advances in Health and Medicine* 2020;9: 4-5.
54	Duplicates	Garland SN, Carlson LE, Antle MC, *et al.* I-CAN SLEEP: rationale and design of a non-inferiority RCT of Mindfulness-based Stress Reduction and Cognitive Behavioral Therapy for the treatment of Insomnia in CANcer survivors. *Contemp Clin Trials* 2011;32:747-754.
55	Duplicates	Johns SA, Brown LF, Beck-Coon K, *et al*. Randomized controlled pilot trial of mindfulness-based stress reduction compared to psychoeducational support for persistently fatigued breast and colorectal cancer survivors. *Support Care Cancer* 2016;24:4085-4096.
56	Duplicates	Cash E, Salmon P, Weissbecker I*, et al*. Mindfulness meditation alleviates fibromyalgia symptoms in women: results of a randomized clinical trial. *Ann Behav Med* 2015;49:319-330.
57	Duplicates	Ong JC, Manber R, Segal Z, *et al.* A randomized controlled trial of mindfulness meditation for chronic insomnia. *Sleep* 2014;37:1553-1563.
58	Duplicates	Gross CR, Kreitzer MJ, Thomas W, *et al.* Mindfulness-based stress reduction for solid organ transplant recipients: a randomized controlled trial. *Altern Ther Health Med* 2010;16:30-38.
59	Duplicates	Gross CR, Kreitzer MJ, Reilly-Spong M, *et al*. Mindfulness-based stress reduction versus pharmacotherapy for chronic primary insomnia: a randomized controlled clinical trial. *Explore (NY)* 2011;7:76-87.
60	Qualitative study	Kvillemo P, Bränström R. Experiences of a mindfulness-based stress-reduction intervention among patients with cancer. *Cancer Nurs* 2011;34:24-31.
61	Qualitative study	Ong J, Sholtes D. A mindfulness-based approach to the treatment of insomnia. *J Clin Psychol* 2010;66:1175-1184.
62	Qualitative study	Lehto RH, Wyatt G. Perceptions about using mindfulness therapy: a lung cancer focus group study. *Cancer Nurs* 2013;36:E51-60.
63	Qualitative study	Morone NE, Lynch CS, Greco CM, *et al.* "I felt like a new person." the effects of mindfulness meditation on older adults with chronic pain: qualitative narrative analysis of diary entries. *J Pain* 2008;9:841-848.
64	Participants: not adult	Biegel GM, Brown KW, Shapiro SL, *et al.* Mindfulness-based stress reduction for the treatment of adolescent psychiatric outpatients: A randomized clinical trial. *J Consult Clin Psychol* 2009;77:855-866.
65	Cannot extract sleep data due to imcomplete outcome reporting	Shapiro SL, Bootzin RR, Figueredo AJ, *et al.* The efficacy of mindfulness-based stress reduction in the treatment of sleep disturbance in women with breast cancer: an exploratory study. *J Psychosom Res* 2003;54:85-91.

Appendix 3

Figure 1. Forest plot-effectiveness of MBSR compared with controls to improve objective sleep quality



Appendix 4

Figure 2 Forest plot-effectiveness of MBSR compared with controls to improve patient-reported sleep quality