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The effect of mindfulness meditation on sleep quality: a systematic review and meta-analysis of randomized controlled trials

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Abstract

There is a growing interest in the effectiveness of mindfulness meditation for sleep disturbed populations. Our study sought to evaluate the effect of mindfulness meditation interventions on sleep quality. To assess To assess for relative efficacy, comparator groups were restricted to specific active controls (such as evidenced-based sleep treatments) and nonspecific active controls (such as time/attention-matched interventions to control for placebo effects), which were analyzed separately. From 3303 total records, 18 trials with 1654 participants were included. We determined the strength of evidence using four domains (risk of bias, directness of outcome measures, consistency of results, and precision of results). At post-treatment and follow-up, there was low strength of evidence that mindfulness meditation interventions had no effect on sleep quality compared with specific active controls (ES 0.03 [95% CI -0.43-0.49]) and (ES -0.14 [95% CI -0.62-0.34]) respectively. Additionally, there was moderate strength of evidence that mindfulness meditation interventions significantly improved sleep quality compared with nonspecific active controls at post-intervention (ES 0.33 [95% CI 0.17–0.48]) and at follow-up (ES 0.54 [95% CI 0.24–0.84]). These preliminary findings suggest that mindfulness meditation may be effective in treating some aspects of sleep disturbance. Further research is warranted.

Graphical abstract:

There is a growing interest in the effectiveness of mindfulness meditation for sleep disturbed populations. Our study sought to evaluate the effect of mindfulness meditation interventions on sleep quality. To assess for relative efficacy, comparator groups were restricted to specific active controls, such as evidenced-based sleep treatments and nonspecific active controls, such as time/attention-matched interventions to control for placebo effects, which were analyzed separately.

Introduction

Sleep disturbance is a common health complaint affecting an estimated 10–25% of the general population.¹ Accumulated sleep deficiency can increase the risk for mood and anxiety disorders,^{2–4} cognitive impairment,⁵ and a variety of medical conditions, including cardiovascular disease⁶ and obesity.⁷ Pharmaceutical sleep aids remain the first-line treatment for insomnia. While effective, they have the potential for abuse, cross-reactivity with other medications, and side effects including memory loss, abnormal thoughts, behavioral changes, and headaches.^{8,9} Alternatively, behavioral treatments, such as cognitive behavioral therapy for insomnia (CBT-I), can be expensive and inaccessible.¹⁰ While the risks are attenuated with CBT-I, some of the therapeutic components, such as intensive sleep restriction, may exacerbate comorbid psychiatric symptoms and thus compromise adherence.^{11–13} Taken together, there is a need for complementary health interventions, which increase patient choice and may be offered as a second-line treatment option when first-line treatments are not viable or are intolerable.

In recent years, mindfulness meditation has gained interest as an alternative treatment for sleep disturbance. Mindfulness means paying attention in a particular way: on purpose, in the present moment, and non-judgmentally—this attention is curious and kind.¹⁴ Cultivating present moment awareness, in lieu of reinforcing past or future reactivity, may function to transform engrained cognitive patterns and subsequent maladaptive behaviors.¹⁵ Mindfulness meditation is hypothesized to target multiple cognitive and emotional processes that contribute to poor sleep quality. It has been shown to decrease ruminative thoughts,¹⁶ diminish emotional reactivity,^{17,18} and promote impartial reappraisal of salient experiences, which together may facilitate sleep.¹⁹

The effect of mindfulness meditation on sleep quality has also been the topic of recent metaanalyses. However, findings were inconsistent and ranged from no effect to a moderate positive effect in favor of mindfulness meditation. Two of the four meta-analyses were not restricted to randomized control trials (RCTs).^{20,21} A third meta-analysis, restricted its investigation to RCTs;²² however, due to the small number of included trials investigators were unable to analyze the active control and waitlist control trials separately. This made it difficult to parse nonspecific effects (e.g., attention and expectancy bias) from the effect of the intervention. A fourth meta-analysis compared the effect of mindfulness meditation to active controls independently;²³ however, the small number of included trials limited its generalizability. The objective of this meta-analysis is to build on prior meta-analyses by only including RCTs that employed a mindfulness meditation intervention in populations with clinically significant sleep disturbance. Furthermore, To assess for relative efficacy, comparator groups were restricted to specific active controls (such as evidenced-based sleep treatments) and nonspecific active controls (such as time/attention-matched interventions to control for placebo effects), which were analyzed separately. We aim to examine the following three questions: (1) Does mindfulness meditation improve sleep quality when compared with specific active controls or nonspecific active controls; (2) Does the effect persist long-term; and (3) Is there a dose-response effect.

Methods

Systematic search

This review was conducted in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) statement.²⁴ PubMed, EBSCO, Embase, and The Cochrane Library databases were searched for articles through May 2018, with no start date restriction. For search terms, two main subject-heading domains were combined with the AND operator: one to designate the intervention (meditation, mindfulness, mindfulness-based stress reduction (MBSR), mindfulness-based cognitive therapy (MBCT), or Vipassanā), and the second to designate the outcome (sleep or insomnia). No language restrictions were placed on the search. The bibliography of identified trials and germane review articles were manually searched for additional references.

Inclusion and exclusion criteria

We included published reports of RCTs in populations with clinically significant sleep disturbance that employed a mindfulness meditation intervention with multiple treatment sessions and assessment of baseline and post-intervention sleep quality. Validated sleep measures included both objective and subjective measurements, for example, actigraphy, self-reported sleep quality questionnaires, and diary-reported sleep quality. Evidence-based sleep treatments were determined by an American Academy of Sleep Medicine 2006 report²⁵ and updated with a recent meta-analysis of 19 trials reporting medium to large effects of physical activity on subjective measures of sleep.²⁶ Trials were excluded that compared mindfulness meditation to an experimental sleep treatment (e.g., transcendental meditation,

tai chi, and yoga), or compared novice meditators to experienced meditators. All other populations with clinically significant sleep disturbance, excluding children and adolescents, were eligible. <u>Table 1</u> includes a detailed summary of the inclusion and exclusion criteria.

Table 1.

Detailed inclusion and exclusion summary.

	Inclusion	Exclusion
Population	Adult populations with clinically significant sleep disturbance (i.e., ICD insomnia diagnosis or met symptom severity threshold defined by sleep quality questionnaires)	Children, adolescents, and experienced meditators
Intervention	In-person, structured mindfulness meditation (e.g., mindfulness-based stress reduction and Vipassanā)	Mantra-based meditation and movement- based therapies like, tai chi and yoga, internet administration
Comparator	Specific active controls: evidence-based sleep treatments	Waitlist or usual care controls
	Nonspecific active controls: time/attention-matched interventions	
Outcome	Assessment of a pre-intervention and post- intervention validated subjective or objective measure of sleep	No validated measure of sleep or only a baseline measurement
Study Design	Randomized controlled trials	Nonrandomized controlled trials
Other	All languages and dates through May 2018	Abstracts, reviews, and nonpublished trials, as well as duplicate participant samples

Data extraction

Two investigators independently screened the title and abstract of each record to assess eligibility. The full-text article was obtained for all potentially eligible trials and screened for inclusion. Of the included trials, three investigators independently extracted data relating to author, publication year, population type, sample size, mindfulness meditation intervention, control intervention, control type, intervention weeks, in-class meditation hours, retreat meditation hours, at-home meditation hours, criteria for sleep disturbance, sleep quality outcome measure, assessment time-points, assessment data, and risk of bias criteria. Discrepancies in the eligibility and data extraction were resolved through further contact with corresponding authors, discussion, and consensus.

The strength of the body of evidence

The methods for determining the strength of the body of evidence were replicated from our prior meta-analysis.²⁷ Briefly, three investigators graded the strength of evidence for each outcome, independently and then by consensus, using the grading scheme recommended by the Methods Guide for Conducting Comparative Effectiveness Reviews.²⁸ In assigning evidence grades, we considered four domains: risk of bias, directness of outcome measures, consistency of results, and precision of results. Evidence was classified into the following four categories: (1) high (indicating high confidence that the estimate of effect lies close to the true effect for this outcome, and further studies would not change the conclusion); (2) moderate (indicating moderate confidence that the estimate of effect lies close to the true effect for this outcome, and findings are likely to be stable, but some doubt remains); (3) low (indicating limited confidence that the estimate of effect lies close to the true effect for this outcome that the estimate of effect lies close to the indicating limited confidence that the estimate of effect lies close to the true effect for this outcome, and findings are likely to be stable, but some doubt remains); (3) low (indicating limited confidence that the estimate of effect lies close to the true effect for this outcome that the estimate of effect lies close to the true effect for this outcome and findings are likely to be stable, but some doubt remains); (3) low (indicating limited confidence that the estimate of effect lies close to the true effect for this outcome and findings are likely to be stable, but some doubt remains); (3) low (indicating limited confidence that the estimate of effect lies close to the true effect for this outcome, and that additional evidence is needed); and (4) insufficient (indicating no evidence or inability to estimate an effect for this outcome).²⁸

Risk of bias scoring was used to evaluate the methodological quality of the included trials. Four major and four minor criteria were determined based on a system implemented in a prior comprehensive U.S. Agency for Healthcare Research and Quality review of meditative practices.²³ Two points were given for meeting each major criterion and one point was given for meeting each minor criterion. A low risk of bias was assigned to trials with a score between 9 and 12 points. A medium risk of bias was assigned to trials with a score between 6 and 8 points. Any trial with five or fewer points was assigned a high risk of bias (<u>Table 2</u>). In assessing the directness of measures, both objective and subjective sleep measures were considered direct if they were validated to assess a sleep quality dimension. The consistency of results was based on the CI range from the meta-analysis. If the CI range was wide due to a large heterogeneity (which was attributed to the inconsistency of results) the evidence was not scored as imprecise as well.²⁸

Table 2.

Major and minor criteria in assessing risk of bias

Vas the randomization procedure described? Vas allocation concealed?
as allocation concealed?
as an intent-to-treat analysis used?
l evaluate the credibility, and if so parable?

Outcome measures

Objective measures of sleep quality included the actigraphy. Subjective measures with established validity included the insomnia sleep index (ISI), the medical outcomes study-sleep scale (MOS-SS), and the Pittsburgh sleep quality index (PSQI). Due to the high overlap in content validity between the three sleep quality scales, they were pooled in the meta-analysis.

Data synthesis and analysis

Quantitative data were analyzed with the Cochrane Collaborative Review Manager Software (RevMan 5.3).²⁹ All essential data that were not reported in the original papers were requested and received from the trial authors. Since sleep quality measures differed between trials (e.g., ISI, MOS-SS, and PSQI), the between-group standardized mean difference was used as the summary effect estimate of sleep quality and was calculated as Hedges' g. Two trials used multiple sleep quality measures (ISI and PSQI).^{30,31} In this instance, the PSQI score was included in the meta-analysis since it was the most common measure used across all trials. Outcomes were analyzed on change from baseline to post-intervention to evaluate between-group percent change and the consistency of results across trials. A meta-analysis was used to estimate long-term effects of trials with a follow-up assessment between 5 to 12 months from baseline. To test for relative efficacy, all analyses were stratified by control type (i.e., specific active control or nonspecific active control). Spearman's correlation was used to examine a dose-response between in-class meditation hours and standardized sleep quality change scores. Heterogeneity was evaluated using the I² statistic, whereby an I² \leq 25% was

considered low, an $I^2 = 50\%$ was considered moderate, and an $I^2 \ge 75\%$ was considered high.³² Effect sizes were interpreted based on Cohen's recommendation.³³ *P*-values of <0.05 were considered significant.

Results

Search results

A total of 3303 records were initially identified for inclusion in the review. After adjusting for duplicates (n = 1312), another 1912 records were further excluded based on title and abstract. A full-text review of the remaining 79 articles was conducted and 18 trials with 1654 participants were included in the final analysis (see CONSORT flow diagram in Fig. 1).

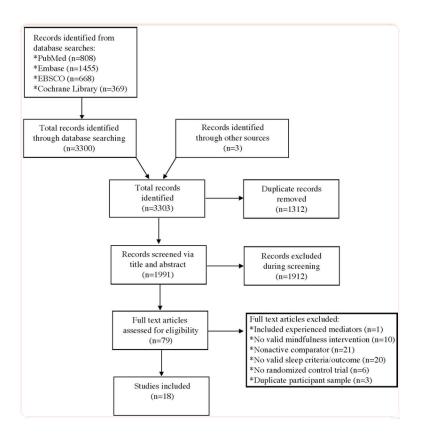


Figure 1.

Flow diagram from record identification to a final study inclusion.

Characteristics of included trials

Publication dates ranged from 2010 to 2018. MBSR was the most prevalent intervention (9/18), followed by MBCT (3/18), and mind-body bridging (MBB) (3/18). Weekly in-class meditation sessions ranged from 1 to 2.5 h for 2 to 16 weeks. At-home meditation practice was encouraged in all 18 trials; however, 12 trials recommended a specific daily practice time, which ranged from 15 to 60 minutes. Seven trials included a one-day meditation retreat, and one trial offered an in-class booster session at 2 months post-intervention. All 18 trials included at least one subjective measure of sleep quality and two trials used an objective measure (e.g., actigraphy). Detailed characteristics of the 18 included trials are presented in Table 3.

Table 3.

Study characteristics.

Author ^{ref}	Control type	Population	Subject, n	Control, n	Meditation intervention	Comparison intervention	Medita duratio weeks
Adler, <i>et</i> $al.\frac{34}{2}$	SAC	Obesity	100	94	MBSR	Progressive muscle relaxation	16
Garland, et $al \cdot \frac{30}{2}$	SAC	Cancer with insomnia	64	47	MBSR	CBT-I	8
Gross, <i>et</i> al. ³¹	SAC	Insomnia	20	10	MBSR	Drug	8
Schmidt, <i>et</i> $al \cdot \frac{35}{2}$	SAC	Fibromyalgia syndrome	53	56	MBSR	Progressive muscle relaxation	8
van der Zwan, <i>et</i> al· ³⁶	SAC	High stress	27	23	MM	Exercise	5
Vanhuffel, <i>et</i> <i>al</i> . ^{<u>37</u>}	SAC	Insomnia	16	13	MBCT	CBT-I	8
Wong, <i>et</i> <i>al</i> . ^{<u>38</u>}	SAC	Insomnia	101	95	MBCT-I	Sleep psycho- education with exercise	8
Black,et	NSAC	Older adults	24	25	MAPs	Sleep hygiene	6

^aMeditation hours were reported as expected in-class hours per intervention, including the retreat.

^bThe v0 sleep scale mean (e.g., baseline weighted average) was used to determine that the study cohort had clinically relevant sleep disturbance based on established cutoff scores.

^cDirection of effect is based on the relative difference in change analysis.

^dFollow-up findings were reported for studies with a follow-up assessment between 5 and 12 months. ^eInability to obtain the Dykens, *et al.*,⁴⁰ follow-up data precluded inclusion in the meta-analysis. CBT-I, cognitive behavioral therapy-insomnia; ISI, insomnia severity index; MAPs, meditation awareness practices; MAT, meditation awareness training; MBB, mind-body bridging; MBCT, mindfulness-based cognitive therapy; MBCT-I, mindfulness-based cognitive therapy for insomnia; MBSR, mindfulness-based stress reduction; MM, mindfulness meditation; MOS-SS, medical outcomes study-sleep scale; NR, mediation was encouraged, but no specific time was reported; NSAC, nonspecific active control; PSQI, Pittsburgh sleep quality index; RCTS, randomized controlled trials; SAC, specific active control; **h**, high risk of bias; **m**, medium risk of bias; **l**, low risk of bias; +, favors meditation (>5%) and is statistically significant; -, favors control (<-5%) and is not statistically significant; **ø**, no effect (within -5% to 5%).

Quality of included trials

All or most trials included a description of withdrawals and dropouts (18/18), described the randomization procedure (17/18), matched the control group for time and attention to the meditation group (16/18), and reported attrition rates less than 20% at post-intervention (13/18). Quality limitations included a failure to evaluate the intervention credibility (3 did/18), conceal allocation (8/18), blind evaluators to participant allocation (9/18), and include an intent-to-treat analysis (10/18). The majority of trials had a moderate risk of bias (10/18), seven had a low risk of bias, and one had a high risk of bias. There were no significant differences in risk bias scores between the specific active control and nonspecific active control groups. Certified meditation instructors were included in 16 trials, trait mindfulness was assessed in 11 trials, and prior meditation was explicitly excluded in 10 trials.

Specific active controls

Seven of the included trials used specific active control groups, $\frac{30,31,34-38}{30,31,34-38}$ with a total of 716 participants. There was low strength of evidence that mindfulness meditation interventions had no effect on sleep quality compared with specific active controls (i.e., evidence-based sleep treatments) at post-intervention (ES -0.03 [95% CI -0.49-0.43]) and at a 5- to 12-month follow-up (ES -0.14 [95% CI -0.62-0.34]). This grading was based on an overall

medium risk of bias, directness of measure, inconsistency of results (due to high heterogeneity at post-intervention $[I^2 = 88\%]$ and a follow-up $[I^2 = 84\%]$), and precision of results (see Fig. 2A and Figs. 3 and 4).

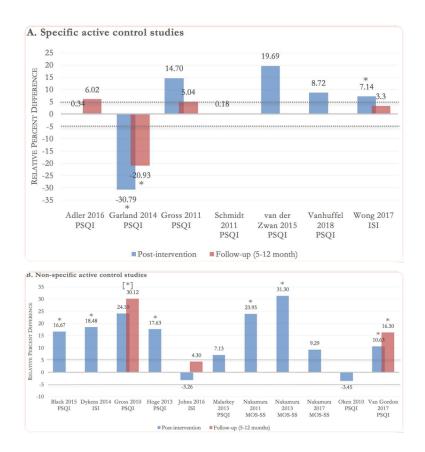


Figure 2.

A-B Between-group relative percent difference in change score. Author, year, and sleep scale are noted at the bottom of each cluster bar. Follow-up scores are reported for trials with a follow-up assessment between 5 and 12 months from baseline. Percent change in sleep score was calculated using the formula: $\{[(\text{postintervention mean^control} - \text{baseline mean^control}) - (\text{postintervention mean^meditation} - \text{baseline mean^meditation})\} \times 100$. Positive scores should be interpreted as relative percent change in favor of meditation. For example, a change score of 20% indicates the meditation group had a 20% higher improvement in sleep quality score compared with the control group. Dotted lines at -5% and 5% demarcate the effect threshold and do not indicate statistical significance. *The result is statistically significant per manuscript. [*] overall group effect is statistically significant; the effect for individual time points was not reported.

	Favor	s [Cont	rol]	C	ontrol			Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
2.1.1 Specific active	control								
Adler 2016	4.64	4.3	94	4.33	2.58	100	16.2%	0.09 [-0.19, 0.37]	
Garland 2014	7.19	2.19	47	10.93	2.88	64	15.1%	-1.42 [-1.84, -1.00]	
Gross 2011	9.11	2.09	9	7.25	3.02	18	11.1%	0.65 [-0.17, 1.48]	
Schmidt 2011	10.12	4.21	56	10.04	3.76	53	15.5%	0.02 [-0.36, 0.40]	_ _
Van der Zwan 2015	5.48	3.04	23	4.64	2.12	27	13.8%	0.32 [-0.24, 0.88]	
Vanhuffel 2018	9	4.62	13	8.38	3.52	16	12.0%	0.15 [-0.58, 0.88]	
Wong 2017	14.9	4.7	95	14.1	4	101	16.2%	0.18 [-0.10, 0.46]	+
Subtotal (95% CI)			337			379	100.0%	-0.03 [-0.49, 0.43]	-
Heterogeneity: Tau ² =	= 0.32; 0	$hi^2 = 4$	9.12, d	f = 6 (P	< 0.00	001); I ²	= 88%		
Test for overall effect	: Z = 0.1	4 (P = 0)	0.89)						
2.1.2 Nonspecific ac	tive con	trol							
Black 2015	9.1	2	25	7.4	1.9	24	5.9%	0.86 [0.27, 1.44]	
Dykens 2014	10.77	6.79	91	9.49	6.4	65	14.6%	0.19 [-0.13, 0.51]	+
Gross 2010	6.9	3.84	59	6	3.57	63	12.7%	0.24 [-0.11, 0.60]	+
Hoge 2013	6.78	3.72	32	6.24	2.94	29	7.6%	0.16 [-0.35, 0.66]	
Johns 2016	12.31	5.04	36	10.82	5.74	35	8.6%	0.27 [-0.19, 0.74]	
Malarkey 2013	7.81	2.82	83	7.49	3.02	79	15.2%	0.11 [-0.20, 0.42]	
Nakamura 2011	41.6	24.7	25	32.93	16.72	33	7.1%	0.42 [-0.11, 0.94]	
Nakamura 2013	47.22	16.21	18	32.13	14.81	19	4.5%	0.95 [0.27, 1.64]	
Nakamura 2017	50.2	15.1	26	45.1	18.14	29	7.0%	0.30 [-0.23, 0.83]	
Oken 2010	8	4.1	11	9	2.7	8	2.7%	-0.27 [-1.18, 0.65]	
Van Gordon 2017	13.39	2.53	74	11.91	2.71	74	14.1%	0.56 [0.23, 0.89]	
Subtotal (95% CI)			480				100.0%	0.33 [0.17, 0.48]	•
Heterogeneity: Tau ² =	= 0.02; 0	$hi^2 = 1$	3.31, d	f = 10(P = 0.2	1); I ² =	25%		
Test for overall effect	: Z = 4.1	3 (P < 0	0.0001)						
									-2 -1 0 1
									Favors [Control] Favors [Meditation]

Figure 3.

Random effects meta-analysis of the effect of mindfulness meditation on sleep quality at postintervention, stratified by control type. The standardized mean difference was used as the summary effect estimate and was calculated as Hedges' *g*. Abbreviations: CI, confidence interval; IV, inverse variance; SD, standard deviation; Total, number of participants.

	Mee	ditatio	n	C	ontrol		:	Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
3.1.1 Specific active	control								
Adler 2016	5.47	5.1	94	4.83	1.57	100	28.8%	0.17 [-0.11, 0.45]	
Garland 2014	7.19	2.47	47	9.7	3.2	64	26.3%	-0.86 [-1.25, -0.46]	← -
Gross 2011	7.75	2.43	8	7	4.56	18	16.2%	0.18 [-0.66, 1.01]	
Wong 2017 Subtotal (95% CI)	12.9	4.9	95 244	12.8	4.9	101 283	28.8% 100.0%	0.02 [-0.26, 0.30] -0.14 [-0.62, 0.34]	
Test for overall effect 3.1.2 Nonspecific ac			0.56)						
Gross 2010	7.8		59	6.4	3.57	63	35.8%	0.36 [-0.00, 0.72]	
Johns 2016	12.1	6.84	36	9.45	6.01	35	26.0%	0.41 [-0.06, 0.88]	
Van Gordon 2017 Subtotal (95% CI)	13.64	2.55	74 169	11.36	3.09	74 172	38.2% 100.0%	0.80 [0.47, 1.14] 0.54 [0.24, 0.84]	
Heterogeneity: Tau ² =	= 0.03; 0	Chi ² =	3.61, d	f = 2 (P	= 0.1	6); I ² =	45%		
Test for overall effect	: Z = 3.5	57 (P =	0.000	4)					
									-1 -0.5 0 0.5 1
									Favors [Control] Favors [Meditation]

Figure 4.

Random effects meta-analysis of the effect of mindfulness meditation on sleep quality at a 5- to 12month follow-up, stratified by control type. The standardized mean difference was used as the summary effect estimate and was calculated as Hedges' *g*. Abbreviations: CI, confidence interval; IV, inverse variance; SD, standard deviation; Total, number of participants.

Nonspecific active controls

Eleven of the included trials used nonspecific active control groups, $\frac{39-49}{2}$ with a total of 939 participants. There was moderate strength of evidence that mindfulness meditation interventions significantly improved sleep quality compared with nonspecific active controls

(i.e., time/attention matched controls) at post-intervention (ES 0.33 [95% CI 0.17–0.48]) and at a 5- to 12-month follow-up (ES 0.54 [95% CI 0.24–0.84]). This grading was based on an overall medium risk of bias, directness of measure, consistency of results (due to low heterogeneity at post-intervention [I² = 0%] and follow-up [I² = 45%]), and precision of results (see Fig. 2B and Figs. <u>3–4</u>).

Dose-response effect

Seventeen trials reported on total in-class meditation hours for the intervention, which ranged from 3 to 42 h (15.6 M, 9.8 SD), including the one-day retreat. No significant correlation was found between in-class meditation hours and standardized sleep quality change scores ($r_s = 0.1, P = 0.704$). Six trials assessed a dose-response relationship between at-home practice minutes and sleep quality improvements from baseline to post-intervention. Three trials identified no relationship, $\frac{31,38,41}{31,38,41}$ while another three trials identified a significant positive correlation. $\frac{34,36,49}{34}$ One trial investigated a long-term dose–response effect and found a significant positive correlation between continued at-home practice minutes and additional sleep quality improvements at 18-month follow-up. $\frac{34}{34}$

Sensitivity analysis

We conducted a sensitivity analysis to confirm that our conclusions were not dependent on the updated evidenced-based sleep treatment determination. The specific active control group (minus the two exercise control trials $\frac{36,38}{10}$) had similar results at post-intervention (ES -0.14) [95% CI - 0.80 - 0.53]) $[I^2 = 91\%]$ and at a 5- to 12-month follow-up (ES -0.19 [95% CI -0.96-0.58]) [I² = 89%]). The nonspecific active control group (plus the two exercise control trials) also had similar and significant results at post-intervention (ES 0.30 [95% CI 0.17– (0.43]) [I² = 14%] and did not report additional 5- to 12-month follow-up data. A second sensitivity analysis was conducted by including trials with a PSQI score greater than 10, and an ISI score greater than 14, which are indicative of severe sleep disturbance. $\frac{50,51}{10}$ The specific active controls had a similar effect size at post-intervention (ES -0.12 [95% CI -0.80-0.57]) [I² = 91%]) and a decreased effect size at a 5 - to 12-month follow-up (ES -0.26 [95% CI -0.93-0.42]) [I² = 85%]), which remained nonsignificant. Meanwhile, the nonspecific active controls had an increased effect size at post-intervention (ES 0.52 [95% CI (0.32-0.72) [I² = 0%]) and a similar effect size at a 5- to 12-month follow-up (ES 0.64 [95%) CI 0.26–1.02]) $[I^2 = 44\%]$), which remained significant. Lastly, a leave-one-out sensitivity analysis determined that the significant heterogeneity in the specific active control metaanalysis was the result of a single CBT-I trial. $\frac{30}{10}$ The heterogeneity was reduced from 88% and 84% to 0% at post-intervention and at a 5- to 12-month follow-up. Results were similar at post-intervention (ES 0.15 [95% CI -0.01-0.31]) and at a 5- to 12-month follow-up (ES 0.10) [95% CI - 0.09 - 0.29]), with a change in direction of effect.

Discussion

The evidence suggests that mindfulness meditation can improve sleep quality in a variety of clinical populations with sleep disturbance. While our results indicated no effect of mindfulness meditation on sleep quality when compared with evidenced-based sleep treatments, the strength of evidence was low and further studies are needed to elucidate these findings. Results also indicated that mindfulness meditation significantly improved sleep quality compared with nonspecific active controls. This meta-analysis only included RCTs with an active comparator group, so there is greater confidence that the reported benefits are not attributed to placebo effects commonly observed in usual care and waitlist control trials.

At a 5- to 12-month follow-up, mindfulness meditation did not differ in effect from evidencebased sleep treatments and significantly improved sleep quality compared with nonspecific active controls. These findings provide preliminary evidence for a long-term effect. The maintenance of intervention effects may be attributed to learned techniques that reduce sleepinterfering cognitive processes, $\frac{20}{20}$ changes in sleep architecture, $\frac{52}{2}$ as well as morphometric and connectivity alterations in sleep-related brain regions. $\frac{53,54}{20}$ Despite these advances, additional evidence is needed to clarify the conditions and mechanisms that drive the maintenance of intervention effects.

The evidence did not support a dose-response relationship between in-class meditation hours and sleep quality scores. This finding is consistent with a meta-analysis of 20 trials that assessed the relationship between in-class meditation hours and psychological distress.⁵⁵ The link between at-home practice minutes and sleep quality scores was inconclusive due to the limited number of trials that assessed this relationship. Dose–response relationships are arguably one of the most challenging measures in meditation research. It's difficult to accurately assess how mindful (versus mind wandering) an individual is during meditation practice.⁵⁶ Studies with tailored curriculums, expert instructors, and different patient populations may result in larger effects with shorter course durations. Moreover, the nonlinear trajectory of mediation progress is often misunderstood.⁵⁷ Traditionally, success is defined by increased awareness and equanimity, whereby positive states are a byproduct. When symptom change over a short period is utilized as a benchmark of success, meditation progress and its potential effect on well-being may be veiled.

Of the 10 trials that reported on adverse events, there was no evidence of increased risk of harm. Two trials reported a worsening of sleep quality in 3% and 7% of the meditation groups, compared with 24% and 12% in the comparator groups.^{45,47} Another trial reported one case of muscle soreness in the meditation group and one case of sleep disruption in the control group.⁴² It's not uncommon for symptoms to worsen, particularly in the early weeks of the intervention.⁵⁸ Feelings of anger, sadness, or fear, may appear stronger as practice

develops since present moment awareness can highlight emotions.⁵⁹ A history of trauma, mental instability, addiction, or major life changes, may heighten emotional reactivity and require additional clinical monitoring.⁶⁰

Limitations

There are several limitations that reduced our ability to draw robust conclusions from these results. At the meta-analysis level, a leave-one-out sensitivity analysis indicated substantial heterogeneity due to the inclusion of a single CBT-I trial.³⁰ This may be attributed to the large positive effects CBT-I is estimated to have on sleep quality when compared to other evidenced-based sleep treatments. $\frac{61}{11}$ It might also be due to the 50% attrition rate in the MBSR group (verses 14% in the CBT-I group). Participants who withdrew typically did so within the first three weeks and had higher levels of baseline insomnia severity, which may have attenuated effects. $\frac{30}{10}$ Additional heterogeneity might have been introduced by combining scores from the ISI, MOS-SS, and PSQI to create a single global sleep quality score. At the study level, the most common drawbacks were a failure to evaluate the intervention credibility and conceal allocation, which may lead to expectation bias. The lack of comprehensive reporting of treatment adherence and adverse events limited our ability to rigorously examine the effect of a dose-response and assess for safety. Moreover, only two trials included an objective measure of total sleep time via actigraphy. One trial identified a statistically significant between-group effect in favor of MBSR at a 5-month follow-up, but not at post-intervention.³⁰ The other trial did not report between-group effects.³¹

Future directions

These findings support continued research exploring the clinical application of mindfulness meditation and provide a foundation for healthcare providers to consider these interventions in sleep-disturbed populations. Future research in mindfulness meditation would benefit from addressing the outstanding methodological limitations, as well as incorporating adherence measures, such as mobile applications, so participants can easily record at-home practice time. Future research should include systematic reporting of adverse events, which can help identify factors of increased risk. Researchers should use a combination of objective and subjective sleep outcomes to better understand if improved sleep quality is due to reduced sleep onset latency, improved total sleep time, or some other factor. The effectiveness of web-and app-based mindfulness meditation interventions should be investigated to increase accessibility, especially for low-income minorities with poor health and barriers to access.

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Footnotes

Competing interests

The authors declare no competing interests.

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