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

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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; I² = 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.

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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 decen-
mindfulness meditation practised in ancient Buddhism. 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. It focuses on regulating the levels of physical and psychological stresses, including those caused by cancer, chronic pain and sleep disturbance. Physiological changes during meditation activate the parasympathetic-limbic pathway, which reduces the heart rate, systolic blood pressure, respiratory rate, and consequently, stress. Stress is the primary cause of sleep disturbances. 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, and some failed to examine the effectiveness of MBSR due to co-interventions. Moreover, several reviews only included patients with insomnia and not those with sleep disturbances. The 2021 American Academy of Sleep Medicine clinical practice guidelines 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 reviewer.

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. 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. Heterogeneity was assessed using $I^2$ and $Q$ statistics. An $I^2 >50\%$ indicated significant heterogeneity. Publication bias was examined using a funnel plot if a meta-analysis included more than 10 studies. If a study reported incomplete outcome data and the authors could not manage the missing data using the formulas presented by Hozo et al., 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%)
### 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 |
|--------------|---------|--------------------------|--------------|------------|--------------|---------------------------------------|---------|---------------------|
| Andersen et al (2013) | Denmark | 168/168 | Patients with breast cancer | 53.9 54.4 | Time (hours) 2.0 8 | Duration (weeks) 48 | Follow-up (week(s)) 45 | O | Instructor | Active: treatment as usual | Primary outcome: patient-reported sleep quality (MOSSS) | No |
| Barrett et al (2020) | USA | 138/275 | Healthy adults | 49.2 49.9 | Time (hours) 2.5 8 | Duration (weeks) 28 | Follow-up (week(s)) 20–45 | O | Instructor | Active: EX training Passive: waitlist control | Primary outcome: patient-reported sleep quality (PSQI) | No |
| Carmody et al (2011) | USA | 57/53 | Late menopausal transition and early postmenopause | 52.5 53.8 | Time (hours) 2.5 9 | Duration (weeks) 20 | Follow-up (week(s)) 45 | O | Instructor | Passive: waitlist control | Primary outcome: patient-reported sleep quality (WHIRS) Secondary outcomes: anxiety (HADS-A), overall QOL (MENQOL), stress (PSS) | No |
| Cash et al (2015) | USA | 51/40 | Fibromyalgia symptoms in women over 18 | NR NR | Time (hours) 2.5 8 | Duration (weeks) 16 | Follow-up (week(s)) 45 | O | Instructor | Passive: waitlist control | Primary outcome: patient-reported sleep quality (SSQ) Secondary outcomes: stress (PSS), fatigue (FSI) | No |
| Dykens et al (2014) | USA | 116/127 | Mothers of children with autism and other disabilities | NR NR | Time (hours) 1.5 6 | Duration (weeks) 30.8 | Follow-up (week(s)) NR X | Instructor | Active: positive adult development | Primary outcome: patient-reported sleep quality (SSI) Secondary outcomes: depression (BDI), anxiety (BAI), stress (PSI) | No |
| Esmer et al (2010) | USA | 19/21 | Failed back surgery syndrome | 55.2 54.9 | Time (hours) 1.5–2.5 8 | Duration (weeks) 40 | Follow-up (week(s)) 45 | O | Instructor | Passive: waitlist control | Primary outcome: patient-reported sleep quality (abridged PSQI) | No |
| Gallegos et al (2018) | USA | 228 | Facility-residing older adults | 72 73 | Time (hours) 2.0 8 | Duration (weeks) 24 | Follow-up (week(s)) 30 | O | Instructor | Passive: waitlist control | Primary outcome: patient-reported sleep quality (PSQI) | No |

Continued
| Study (year) | Country | No of participants (E/C) | Participants | Age (mean) | Intervention | Home practice (minutes) | Day-long retreat | Provider | Type of comparison (active vs passive) | Outcome | Sleep medication use |
|-------------|---------|--------------------------|--------------|------------|--------------|-------------------------|------------------|----------|--------------------------------------|----------|---------------------|
| Garland et al (2014) | Canada | 64/47 | Insomnia comorbid with cancer | 60.3 58.7 | 1.5 8 20 | NR O | Instructor | Active: cognitive–behavioural therapy for insomnia | No patient-reported sleep quality (PSQI), objective sleep quality (actigraphy, SE) Secondary outcome: stress (C-SOSI) |
| Gordon et al (2021) | Canada | 52/52 | Menopause transition women | 48.7 48.7 | 2.5 8 24 | 45 O | Instructor | Passive: waitlist control | No patient-reported sleep quality (PSQI) Secondary outcomes: depression (CES-D), anxiety (STAI), stress (PSS) |
| Gross et al (2010) | USA | 72/66 | Solid organ transplant recipients | 55 52 | 2.5 8 48 | 29 O | Instructor | Active: health education | No patient-reported sleep quality (PSQI) Secondary outcomes: depression (CES-D), anxiety (STAI), QOL (QOL VAS) |
| Gross et al (2011) | USA | 20/10 | Primary chronic insomnia | 47 53.5 | 2.5 8 12 | 45 O | Instructor | Active: pharmacotherapy | Eszopiclone patient-reported sleep quality (PSQI), objective sleep quality (actigraphy, SE) Secondary outcomes: depression (CES-D), anxiety (STAI) |
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 |
|--------------------|---------|--------------------------|-----------------------------|------------|-----------------------------------------------------------------------------|----------------------------------------|------------------------------------------------------------------------|---------------------|
| Johns et al (2015) | USA     | 18/17                    | Persistently fatigued cancer survivors | 58.8 55.7  | Time (hours) 2.0 Duration (weeks) 7 Follow-up (weeks) 24 Home practice (minutes) 20 Day-long retreat X Provider 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) | USA     | 35/36                    | Breast and colorectal cancer survivors | 56.9 56.4  | Time (hours) 2.0 Duration (weeks) 8 Follow-up (weeks) 24 Home practice (minutes) 20 Day-long retreat X Provider 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) | USA    | 41/43                    | Breast cancer NR NR | 56.1 58.0  | Time (hours) 2.0 Duration (weeks) 6 Follow-up (weeks) 6 Home practice (minutes) NR Day-long retreat X Provider Instructor | Passive: waitlist control               | Primary outcome: patient-reported sleep quality (MDASI) Secondary outcomes: fatigue (MDASI), stress (MDASI) | No                  |
| Lengacher et al (2015) | USA    | 38/41                    | Breast cancer | 56.1 58.0  | Time (hours) 2.0 Duration (weeks) 6 Follow-up (weeks) 12 Home practice (minutes) 15-45 Day-long retreat X Provider Instructor | Passive: waitlist control               | Primary outcomes: No patient-reported sleep quality (PSQI), objective sleep quality (actigraphy, SE) | No                  |
| Ong et al (2014)    | USA     | 19/38                    | Chronic insomnia | 42.4 41.3  | Time (hours) 2.5 Duration (weeks) 8 Follow-up (weeks) 24 Home practice (minutes) 30-45 Day-long retreat O Provider Instructor | Active: mindfulness-based therapy for insomnia, sleep diary self-monitoring followed by behaviour therapy | Primary outcomes: No patient-reported sleep quality, objective sleep quality (actigraphy, SE) | No                  |
| Ong et al (2018)    | USA     | 41.9 42.4 2.0 8 8        |                             |            |                                                                            | Secondary outcomes: depression (BDI-II), anxiety (STSI-T), fatigue (FSS) | No                  |
| Study (year) | Country | No of participants (E/C) | Participants | Age (mean) | Intervention | Time (hours) | Duration (weeks) | Follow-up (week(s)) | Home practice (minutes) | Day-long retreat | Provider | Type of comparison (active vs passive) | Outcome | Sleep medication use |
|-------------|---------|--------------------------|--------------|------------|-------------|--------------|-----------------|-------------------|----------------------|----------------|----------|----------------------------------+---------|-----------------|
| Reich et al (2017) | 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) | 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) | 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) | 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).*
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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, 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). Due to significant heterogeneity (I²=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; I²=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; I²=36%). 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; I²=71%) (table 2 and online supplemental appendix 4).

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), and in mothers of children with autism and other disabilities (Effect size=0.03, SE=0.02, p=not significant). 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).

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; I²=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).

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.
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, I²=90%, p<0.00001) (table 3). 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).

**Stress**

Six studies (n=824) were included in this meta-analysis. When compared with the controls, MBSR had no effect on stress (SMD=−0.32; 95% CI: −0.70 to 0.06; I²=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).

**Fatigue**

Seven studies, including 372 participants who underwent MBSR, and 378 controls were included in the meta-analysis. MBSR did not decrease fatigue level, compared with controls (SMD=−0.23; 95% CI: −0.51 to 0.04; I²=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. 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; I²=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. Furthermore, the most studies included in this meta-analysis raised concerns regarding the detection bias, despite

| Category                          | Objective sleep quality (sleep efficiency, %) | Patient-reported sleep quality |
|-----------------------------------|-----------------------------------------------|--------------------------------|
|                                   | Studies, n Participants, n | Random effects, MD (95% CI) | I², % | Studies, n Participants, n | Random effects, SMD (95% CI) | I², % |
| 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                         | 3.10 (−0.67 to 6.87)         | NA    | 9 1056                       | −0.32 (−0.56 to −0.08)       | 71    |
| 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.
### Table 3  Subgroup analysis of MBSR versus controls in sleep-related daytime impairments

| Category | Depression | Anxiety | Stress |Fatigue | Quality of life |
|----------|------------|---------|--------|---------|-----------------|
|          | Random effects, SMD (95% CI) | I², % | Studies, Participants, N | Random effects, SMD (95% CI) | I², % | Studies, Participants, N | Random effects, SMD (95% CI) | I², % | Studies, Participants, N | Random effects, SMD (95% CI) | I², % | Studies, Participants, N |
| Overall pooled estimates | | | | | | | | | | | | |
| | 10 | 1059 | -0.35 (−0.68 to −0.02) | | 79 | 624 | -0.32 (-0.70 to 0.06) | | 85 | 750 | -0.23 (-0.51 to 0.04) | | 66 | 3 | 589 | 0.05 (-0.12 to 0.23) | |
| Participants' type | | | | | | | | | | | | |
| Chronic insomnia | 3 | 132 | 0.11 (−0.26 to 0.47) | | 47 | | | | | | |
| Cancers | 4 | 533 | -0.50 (-1.07 to 0.07) | | 74 | 629 | -0.14 (-0.43 to 0.15) | | 66 | 611 | -0.25 (-0.63 to 0.12) | | 77 | | |
| Others | 3 | 394 | -0.57 (-1.22 to 0.06) | | 91 | 195 | -0.67 (-1.79 to 0.46) | | 93 | 91 | -0.27 (-0.68 to 0.15) | | NA | |
| Control group | | | | | | | | | | | | |
| Active | 6 | 557 | -0.13 (-0.31 to 0.05) | | 0 | 2 | 235 | -0.06 (-0.57 to 0.45) | | 74 | 243 | -0.05 (-0.31 to 0.21) | | 0 | |
| Passive | 4 | 502 | -0.84 (-1.68 to 0.00) | | 90 | 589 | -0.46 (-1.01 to 0.10) | | 89 | 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.15 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 insomnia16 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.31 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.31 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.

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Supplemental material
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