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Mindfulness meditation for insomnia: A meta-analysis of randomized controlled trials

Hong Gong [a], Chen-Xu Ni [b], Yun-Zi Liu [a], Yi Zhang [a], Wen-Jun Su [a], Yong-Jie Lian [a], Wei Peng [a], Chun-Lei Jiang [a,*]

[a] Laboratory of Stress Medicine, Faculty of Psychology and Mental Health, Second Military Medical University, Shanghai, 200433, People's Republic of China
[b] Department of Pharmacy, Shanghai Tenth People's Hospital, Tongji University School of Medicine, Shanghai 200072, People's Republic of China

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ABSTRACT

Background: Insomnia is a widespread and debilitating condition that affects sleep quality and daily productivity. Although mindfulness meditation (MM) has been suggested as a potentially effective supplement to medical treatment for insomnia, no comprehensively quantitative research has been conducted in this field. Therefore, we performed a meta-analysis on the findings of related randomized controlled trials (RCTs) to evaluate the effects of MM on insomnia.

Methods: Related publications in PubMed, EMBASE, the Cochrane Library and PsycINFO were searched up to July 2015. To calculate the standardized mean differences (SMDs) and 95% confidence intervals (CIs), we used a fixed effect model when heterogeneity was negligible and a random effect model when heterogeneity was significant.

Results: A total of 330 participants in 6 RCTs that met the selection criteria were included in this meta-analysis. Analysis of overall effect revealed that MM significantly improved total wake time and sleep quality, but had no significant effects on sleep onset latency, total sleep time, wake after sleep onset, sleep efficiency, total wake time, ISI, PSQI and DBAS. Subgroup analyses showed that although there were no significant differences between MM and control groups in terms of total sleep time, significant effects were found in total wake time, sleep onset latency, sleep quality, sleep efficiency, and PSQI global score (absolute value of SMD range: 0.44–1.09, all $p < 0.05$).

Conclusions: The results suggest that MM may mildly improve some sleep parameters in patients with insomnia. MM can serve as an auxiliary treatment to medication for sleep complaints.

1. Introduction

Insomnia is a prevalent sleep disorder, characterized by difficulties in initiating and/or maintaining sleep, and is associated with significant distress or daytime impairments, despite adequate sleep opportunity [1]. Sleep plays vital roles in maintaining the well function of brain, immune system, metabolic system and cardiovascular system [2–5]. Insomnia is closely associated with hypertension, cancer, and psychiatric disorders like anxiety and depression [6–9]. Insomnia can cause significant distress or impairment in social, occupational, and other functioning. According to recent epidemiological studies, 20–40% of adults in China, the United States, Spain, Sweden, Japan and other countries suffer from insomnia and 10–15% of them meet the diagnostic criteria for an insomnia disorder [10–13]. Therefore, it is very necessary to manage insomnia effectively.

To better understand the role of sleep in daily life, sleep is usually measured by two parameters, sleep quantity and sleep quality. Some measures of sleep are more easily quantifiable, including sleep latency, awakenings at night, sleep duration, etc. However, sleep quality, including depth of sleep, general satisfaction with sleep, etc., is usually investigated by subjective sleep quality indexes [14]. Take Pittsburgh Sleep Quality Index for example, sleep quality is defined as a composite score of seven subcategories: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction [15].

Pharmacotherapy is a traditional treatment for insomnia. The mostly used medicines include benzodiazepines, benzodiazepine-receptor agonists and the first orexin receptor antagonist. Recently, cognitive behavioral therapy is well demonstrated as an efficacious treatment for insomnia [16,17]. Okajima et al. revealed that cognitive behavioral therapy could reduce insomnia symptoms as well as the daily dose of hypnotic medication in patients with chronic insomnia resistant to pharmacological treatment [18]. In addition to cognitive behavioral therapy, several other promising psychological interventions intended to facilitate sleep health have focused on mindfulness meditation (MM) over the past two decades. Mindfulness refers to a state of conscious that is characterized by an intentional and non-judgmental awareness of present-moment experiences, rather than attempts to

* Corresponding author at: Faculty of Psychology and Mental Health, Second Military Medical University, 800 Xiangyin Road, Shanghai 200433, People's Republic of China.
E-mail address: cljiang@vip.163.com (C.-L. Jiang).

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alter current experience or to eliminate them from awareness. Higher level of mindfulness is associated with better cognitive performance, physical and mental health, as well as less experience of stress. Mindfulness meditation consists of practice in interactive processes of attention regulation, body awareness, emotion regulation, and changing views regarding self and others [19].

In recent years, there is also some evidence suggesting that consistent practice of MM contributes to the improvement of sleep quality and the reduction of insomnia symptoms [20]. However, there is no systematic review regarding the effects of MM on insomnia. In order to examine the evidence that MM may improve the sleep health of insomnia patients, we carried out this systematic review and meta-analysis on the basis of several randomized controlled trials (RCTs) published up to July 2015.

2. Methods

2.1. Literature research

Literature searches were performed in PubMed, EMBASE, the Cochrane Library and PsycINFO from the earliest available dates in the individual databases until July 2015. We developed a PubMed and the Cochrane Library search strategy using medical subject heading (MeSH) terms and text words of key articles that we identified a priority. A similar strategy was carried out in the other electronic sources. The MeSH terms or keywords used in the search included "sleep disorders" or "insomnia" or "sleep disturbance" combined with "mindfulness" or "meditation" or "mind-body therapies" or "vipassana". Although our criteria necessitated publications to be written in English, publications done in other countries, or published in other languages but with abstracts at least written in English, were also searched.

2.2. Study eligibility.

Two reviewers screened the abstracts of all publications obtained by the search strategies. Trials meeting the following inclusion criteria were selected for further review: (1) RCTs of participants who were diagnosed with insomnia or sleep disorders or had a subjective complaint of sleep without a clinical diagnosis; (2) the intervention of mindfulness meditation was investigated; (3) sleep-related data presented both at baseline and after intervention or training; (4) total amount of randomized subjects >20 with a control group either inactive (waiting list) or active (pharmacotherapy, cognitive-behavioral therapy).

Exclusion criteria included (1) nonrandomized or uncontrolled trials; (2) qualitative report including literature review; (3) case reports or trials with fewer than 20 subjects; (4) still incomplete articles after contacting the authors. These selection criteria were confirmed according to the results of searching.

2.3. Data extraction

Of those studies that qualified for the review after the initial title/abstract screening, the full articles were obtained and assessed for their relevance based on the data extraction form. Two qualified reviewers (HG and CN) independently completed data extraction. If there were any dissenting opinions, the third reviewer would discuss with them to reach a consensus. Data extracted included publication year, country, the sample size, the participants' age and the percent of women, the diseases of the participants, the characteristics of the intervention (including interventions, control conditions, study duration and dropouts), and the outcome measures.

2.4. Assessment of quality

We independently graded the strength of evidence for each outcome using a standard quality assessment system proposed by the Cochrane Back Review Group [21]. This quality assessment system was composed of selection bias, performance bias, attrition bias, reporting bias, and detection bias using 12 items. Each item was assessed as "Yes", "Unclear", or "No". Studies that met >8 of the 12 criteria and had no serious flaw were rated as "High" grade. Studies that met fewer than 4 criteria or had a serious flaw were rated as "Low" grade. Other studies were regarded as "Moderate" grade. Conflicts of opinion were discussed with each other authors until consensus was reached. This study was a systematic review of previous studies. Therefore, ethical approval or additional consent from participants was not provided.

2.5. Statistical analysis

Where applicable, results from comparable studies were pooled in a statistical analysis using the Review Manager 5.3 software from the Cochrane Collaboration. Although all enrolled trials were RCTs, the patients' baseline values might vary among studies. Therefore, the difference between the computed post-treatment and pre-treatment effect size of per sleep parameter in per study group was determined according to the Cochrane handbook for systematic reviews of interventions. A global estimation of $r = 0.6$ was used as the correlation coefficient between post-treatment and pre-treatment scores [22,23].

We calculated standardized mean differences (SMDs) and 95% confidence intervals (CIs) by measuring the post-treatment difference between the mean of the treatment conditions and the mean of control conditions, divided by the pooled standard deviation. The non-intervention group was prior to be used as the control group when there were more than two groups besides the MM group in the included RCTs. The I^2 statistic was used to evaluate the percentage of variability due to heterogeneity between studies rather than sampling error. $I^2 \geq 50\%$ or P-value ≤0.1 shows a notable heterogeneity, and a random effect model should be used. Otherwise, a fixed effect model was adopted. Subgroup comparisons were also performed to analyze the efficiency of MM on insomnia when compared with only waitlist control groups. Funnel plots were not carried out to assess publication bias due to the limited number of included studies. All statistical tests were two-sided with a significance level of 0.5, except where otherwise specified.

3. Results

3.1. Study selection

1516 potentially relevant papers were identified, and the process of selection is shown in a PRISMA flow diagram (Fig. 1). Application of inclusion and exclusion criteria resulted in six pioneering RCTs on the efficacy of MM. Some original authors were contacted for additional details of their published studies, but none were available. A total of 330 participants with insomnia were included in the meta-analysis. The diagnoses included chronic, primary insomnia or sleep disturbances [24–27], and insomnia symptoms comorbid with depression [28] or cancer [29].

3.2. Study characteristics

The characteristics of the studies are summarized in Table 1. In brief, all trials were conducted from 2011 to 2015 [24–29]. Four of the studies were performed in the United States [24–26,28], one in Canada [29] and one in China [27]. Among the six reviewed RCTs, four studies applied mindfulness-based stress reduction (MBSR) [24,25,27,29], while one study used MM [26] and one used mindfulness-based cognitive therapy (MBCT) [28]. RCTs with meditative therapies were divided into three categories in terms of the type of control conditions used for comparison: waiting-list control [25,27,28], attention control (education or non-directive therapies) [26] and alternative active treatment (such as pharmacotherapy, or cognitive-behavioral therapy) [24,29]. The study