

# MINDFULNESS-BASED STRESS REDUCTION FOR CHRONIC INSOMNIA IN ADULTS OLDER THAN 75 YEARS: A RANDOMIZED, CONTROLLED, SINGLE-BLIND CLINICAL TRIAL

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**Objective:** To assess the effectiveness of mindfulness-based stress reduction (MBSR) for chronic insomnia and combined depressive or anxiety symptoms of older adults aged 75 years and over.

**Design:** A randomized, controlled, single-blind clinical trial.

**Patients and Methods:** Participants included 60 adults aged 75 years and over with chronic insomnia. Participants were randomly assigned to the eight-week MBSR group or the wait-list control group. Assessments using the Pittsburgh Sleep Quality Index (PSQI), Self-rating Anxiety Scale (SAS), and Geriatric Depression Scale (GDS) were taken at baseline and post-treatment. For each outcome measure, a repeated measures analysis of variance was used to detect changes across assessments.

**Results:** There was a significant time  $\times$  group interaction for the PSQI global score ( $P = .006$ ); the MBSR group had a decrease in the PSQI global score (Cohen's  $d = 1.12$ ), while the

control group did not (Cohen's  $d = -0.06$ ). Among the PSQI components, there was a significant time  $\times$  group interaction for daytime dysfunction ( $P = .048$ ); Cohen's  $d$  of the MBSR group was 0.76, while Cohen's  $d$  of control group was  $-0.04$ . There was no significant time  $\times$  group interaction for the SAS score ( $P = .116$ ), while for the GDS there was a significant time  $\times$  group interaction ( $P = .039$ ); the Cohen's  $d$  value for the MBSR group was 1.20, and it was 0.12 for the control group.

**Conclusion:** This study demonstrated that the MBSR program could be a beneficial treatment for chronic insomnia in adults aged 75 years and older.

**Key words:** Mindfulness, chronic insomnia, depression, anxiety, old age

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## INTRODUCTION

Chronic insomnia is defined as having difficulty initiating or maintaining sleep and waking very early or waking without feeling restored, and it is accompanied by daytime dysfunction.<sup>1,2</sup> Insomnia is widespread<sup>3</sup>; about 10% of adults in the United States experience it, and 9.2% of adults have it in China, with higher rates among women, clinical populations, and especially older adults.<sup>4-7</sup> Approximately 50% of elderly people suffer from insomnia.<sup>8</sup> Symptoms of insomnia have been described among the elderly, worldwide. Chronic insomnia is associated with many comorbidities; the most common psychological comorbidities are anxiety and depression, which can lead to impaired quality of life,<sup>4,9-11</sup> and for the elderly, impairments caused by insomnia are more serious. Chronic insomnia may also lead to increasing health-care payments, which could be an enormous cost for the elderly.<sup>12</sup> Recent data also suggests a strong link between insomnia and symptoms of both depression and anxiety.<sup>13</sup> Compared with controls, people with insomnia have shown higher levels of depression or anxiety.<sup>14</sup> In addition, a significant connection was found between insomnia and mental disorders, such as depression and/or anxiety, among elderly people.<sup>15,16</sup>

Mindfulness-based stress reduction (MBSR), cognitive behavioral therapy, pharmacotherapies, and some other therapies have been developed for chronic insomnia and shown to be robustly effective. Due to their convenience, doctors have preferred pharmacotherapies,<sup>17</sup> while patients prefer behavioral therapies.<sup>18,19</sup> Several meta-analyses have shown that middle-aged adults with insomnia may benefit from interventions based on CBT.<sup>20–22</sup> A Cochrane systematic review also showed that cognitive behavior therapy (CBT) may have a mild effect on older adults suffering from insomnia.<sup>23</sup>

In 1979, Jon Kabat-Zinn created the MBSR program; similar to behavioral therapy, the MBSR program was used to alleviate the stresses of living with chronic illness.<sup>24,25</sup> The program teaches the participants to focus their attention using a series of meditative skills; MBSR is a structured group program, which involves the cultivation of open, curious, and non-judgmental awareness of present moment experience. The MBSR program includes different forms of mindfulness meditation practices, including body scan, sitting meditation, mindful yoga, and sitting and walking meditations. A key component of MBSR is that participants should incorporate mindfulness into everyday life.<sup>26</sup> Participants are taught to perceive their immediate emotional and physical state. The MBSR had shown beneficial effects in some patients, including reductions in depression, anxiety, pain, psychological distress, etc.<sup>27</sup> The exercise of mindfulness helps people to skillfully deal with stressors with appropriate actions by “breaking up” cycles of worry and rumination, which means that mindfulness training could improve their sleep quality.<sup>28</sup> MBSR is the most commonly used mindfulness-based intervention.<sup>29</sup> Because of its simplicity and effectiveness, it has been widely used to treat insomnia or as an adjunct therapy, and it has been reported to significantly and efficiently improve sleep quality in several types of patients, such as cancer patients,<sup>30,31</sup> recipients of organ transplants,<sup>32,33</sup> and other patients with medical or psychiatric illnesses.<sup>34</sup> Two studies of mindfulness-based cognitive therapy (MBCT) also reported improved sleep quality in patients suffering from mood and anxiety disorders.<sup>33,35</sup> Mindfulness tells people to be patient to their physical and mental condition of the moment and have a peaceful coexistence with them, trust themselves, believe in their own wisdom and ability, and let all sorts of good and evil go, all these mindfulness practice could be good to insomnia. It helps them to know that insomnia could be overcome and enhance their confidence. In addition, a recent meta-analysis demonstrated that mindfulness-based therapies could play a useful role in treating anxiety and mood disorders.<sup>36</sup> Therefore, we suggest that MBSR could also be efficient for insomnia in elderly patients. However, relevant clinical trials are still insufficient, especially since this is the first randomized control trial for adults aged 75 years and older.

### Research Objective

The present study is a randomized, controlled, single-blind clinical trial conducted to evaluate the efficacy of MBSR for chronic insomnia in adults aged 75 years and older. We hypothesized that MBSR would be an effective treatment for insomnia in elderly patients and may also reduce symptoms of anxiety and depression.

## METHODS

### Ethics

The study protocol was approved by the institutional review panels of PLA General Hospital, and all patients gave written informed consent.

### Design

Our study was a two-group randomized, controlled, single-blind clinical trial. Participants were randomly assigned to the MBSR group ( $n = 30$ ) or the wait-list control group ( $n = 30$ ) by using computer-generated randomization schedules. Outcomes were measured at two time points: baseline and again, at the end of the intervention period.

### Participants

Participants were recruited through advertisements, flyers, and by clinician referral between November 2011 and February 2013.

### Inclusion Criteria

The following were the inclusion criteria: (1) age >75 years, (2) fulfill the Diagnostic and Statistical Manual of Mental Disorders: the Fourth Edition (DSM-IV)<sup>37</sup> criteria for insomnia, (3) insomnia duration of at least six months, and (4) complaints of impaired daytime functioning.

### Exclusion Criteria

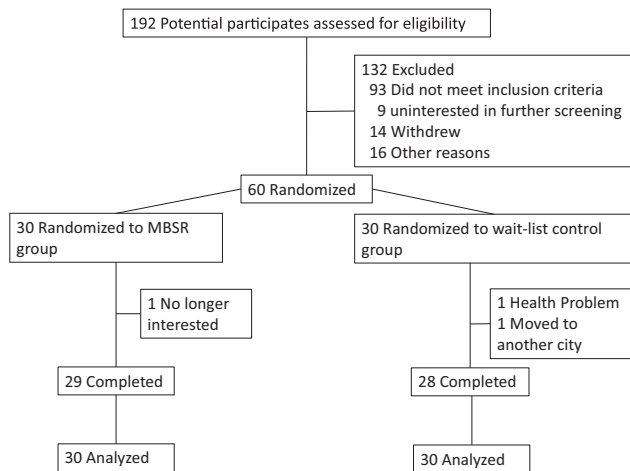
The following were the exclusion criteria: (1) presence of other mental disorders; (2) presence of other serious physical illnesses; (3) dementia; (4) previous training history that used contemplation, meditation, or Zen training; and (5) bed-ridden or otherwise unable to attend the MBSR program.

A 30-min interview was conducted by a clinical psychiatrist and a physician to ensure that participants fulfilled the basic criteria for inclusion. Accepted participants ( $n = 60$ ) were gathered at the Department of Psychiatry, PLA General Hospital, for a structured clinical interview (SCID-I) screening by two psychiatrists. Participants were assigned to either the experimental or control group based on a preset computer-generated randomization schedule. The flowchart in [Figure 1](#) illustrates the design of this study.

### Assessment

**Pittsburgh sleep quality index (PSQI).** The PSQI was compiled by Buysse et al. in 1989 and was used in this study to assess the subjects' sleep quality in the last month of the study.<sup>38</sup> This 19-item questionnaire is widely used as an outcome measure in insomnia; it covers qualitative (sleep quality, daytime fatigue, etc.) and quantitative (sleep latency, total sleep time, etc.) aspects of sleep and delivers both an overall (global) score and domain-specific component scores. The global PSQI score ranges from 0 to 21, with higher scores indicating an increased severity of sleep disturbance. Global PSQI scores are calculated as the sum of component scores for seven domains: sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbance, use of medication, and daytime dysfunction. The PSQI was subjected to a reliability and validity test by Chinese scholars—the boundary line is 7.

**Self-rating anxiety scale (SAS).** The SAS was compiled by Zung in 1971 and was used to assess the patients' subjective



**Figure 1.** Study flow.

feelings of anxiety.<sup>39</sup> This 20-item questionnaire used four ratings for assessment [(1) with little or no time, (2) a small part of the time, (3) quite a lot of time, and (4) most or all of the time]. The higher the SAS score, the more serious the subject's symptoms of anxiety. According to a common mental checklist manual, a standard score of <50 points means no anxiety, ≥50 points means mild anxiety, ≥60 points means moderate anxiety, and ≥70 points means severe anxiety.

**Geriatric depression scale (GDS).** The GDS was compiled and standardized for elderly people by Brink and Yesavage in 1982.<sup>40</sup> The GDS contains 30 items and asks subjects to use “yes” (1 point) or “No” (0 points) to answer the questions, of which 10 items used reverse scoring. The global GDS score ranges from 0 to 30; the higher the score, the more severe the depression.

Patients were evaluated before and after treatment; evaluation time points were baseline (T0) and after the MBSR program (T1). Scale statisticians were blind to the participants' grouping.

### Intervention

The MBSR program was provided through the Medical Psychology Division, PLA General Hospital. MBSR was conducted using a mild modified format for eight weeks, with two-hour classes and a 0.5-day retreat.<sup>41</sup> Meditation techniques included the body scan, standing, sitting, and walking meditations, but we canceled the gentle hatha yoga due to the age of the subjects. A two-hour silent retreat was held on the weekend between the sixth and seventh weeks. Home practice expectations were 45 min of meditation every day. The MBSR teacher completed basic and advanced MBSR instructor training at the Center for Mindfulness in Medicine, Chinese Psychological Society. The study objective was blind to the MBSR teacher. Every participant was given audio recordings of guided meditations for his/her home use. Wait-list control group participants continued to receive their standard care. After eight weeks, the wait-list control group

could attend a MBSR program if they wished, but no further data were collected.

### Data Analysis

Data were analyzed using SPSS 16.0. Demographic and clinical measure variables were compared between two groups using an independent *t* test (for continuous variables) or Mann–Whitney *U* test (for categorical variables and questionnaire scores) at baseline. A repeated measures analysis of variance (RM-ANOVA) (2 group × 2 time) was used to detect changes across assessments. Data analyses were performed based on the intent-to-treat (ITT) principle using last observation carried forward (LOCF) for the one participant who did not provide data at the end of the treatment period. The alpha criterion level was set at  $P < .05$ . The effect size calculation utilized was the Cohen's *d* index.<sup>42</sup> Cohen's criteria for small, medium, and large treatment effects were 0.2, 0.5, and 0.8, respectively. Sample size calculations were based on previous MBSR programs for insomnia trial data<sup>25,43,44</sup> following the principles set out by Chow et al.<sup>45</sup> Therefore, expecting post-treatment differences between the MBSR intervention for insomnia and the wait-list control groups using a medium effect size of 0.5 with power of 0.80,  $P = .05$ , a minimum of 54 participants (27 in each group) were needed. Finally, we decided to enroll 60 participants (30 in each group), considering about 10% attrition.

### RESULTS

There was no statistically significant differences found between the MBSR group and the wait-list control group on any baseline parameters, including age, sex, years of education, and PSQI, SAS, or GDS scores (Table 1).

RM-ANOVA examining the pre-assessment and post-assessment data (Table 2) showed a significant time × group interaction for the PSQI global score ( $P = .006$ ); the MBSR group had a decrease in PSQI global score (Cohen's  $d = 1.12$ ) and the control group did not (Cohen's  $d = -0.06$ ). Based on PSQI components, there was a significant time × group interaction for daytime dysfunction ( $P = .048$ ); Cohen's  $d$  of the MBSR group was 0.76, while the Cohen's  $d$  of the control group was  $-0.04$ . The other components of the PSQI are detailed in Table 2.

There was no significant time × group interaction based on SAS score ( $P = .116$ ). On the contrary, based on GDS, there was a significant time × group interaction ( $P = .039$ ); the Cohen's  $d$  value for the MBSR group was 1.20, while the Cohen's  $d$  value for the control group was 0.12.

### DISCUSSION

To our knowledge, our study is the first MBSR RCT focused on chronic insomnia in adults older than 75 years. The results suggest that MBSR is an efficient therapy for chronic insomnia as measured by the PSQI scale. However, the combined anxiety symptoms measured by SAS showed no significant change after MBSR. Conversely, MBSR reduced depression symptoms in elderly patients when measured by GDS.

The results of our study were similar to some positive results from several studies of mindfulness-based treatment for insomnia

**Table 1.** Baseline Characteristics ( $n = 60$ )

	MBSR Group ( $n = 30$ )	Control Group ( $n = 30$ )	$P^a$
<b>Demographics</b>			
Age	78.57 ± 2.94	77.63 ± 3.01	.230
Sex (male/female)	16/14	19/11	.436 <sup>b</sup>
Education (year)	4.73 ± 3.89	6.13 ± 4.74	.216
<b>Sleep characteristics</b>			
PSQI global score	11.50 ± 3.28	11.27 ± 3.62	.794
Sleep quality	1.37 ± 0.72	1.50 ± 0.78	.493
Sleep latency	1.83 ± 1.02	1.90 ± 1.03	.802
Sleep disturbance	1.27 ± 0.45	1.27 ± 0.52	1.000
Sleep duration	1.60 ± 0.72	1.67 ± 0.89	.750
Use of sleeping medication	1.27 ± 1.14	1.10 ± 1.16	.576
Daytime dysfunction	0.93 ± 0.74	0.80 ± 0.76	.494
Habitual sleep efficiency	2.10 ± 0.76	2.07 ± 0.83	.871
<b>Other mental health outcomes</b>			
SAS	33.90 ± 5.52	34.23 ± 5.53	.816
GDS	14.20 ± 2.50	15.97 ± 4.17	.052

MBSR = mindfulness-based stress reduction, PSQI = Pittsburgh sleep quality index, SAS = self-rating anxiety scale, GDS = geriatric depression scale.

<sup>a</sup>By independent  $t$  test.

<sup>b</sup>By Mann-Whitney  $U$  test.

patients. In a study of MBCT for psychiatric insomnia outpatients, Ree and Craigie reported a significant improvement (ISI, Cohen's  $d = 0.84$ ) for 23 patients following the MBCT program. Furthermore, the patients showed that they maintained the benefits of MBCT for three months.<sup>35</sup> Heidenreich et al.<sup>46</sup> reported in a pilot study that 14 patients with refractory chronic insomnia and other mental disorder comorbidities showed improvements in total sleep time and sleep latency after the MBCT course. In another pilot study,<sup>47</sup> Yook et al. reported a significant decrease in the PSQI scores among 19 patients with insomnia and anxiety disorders after an eight-week MBCT

program. In a wait-list controlled trial,<sup>48</sup> adults with insomnia and depression were randomly enrolled in an eight-week MBCT program or a wait-list group. Britton et al.<sup>49</sup> showed that the MBCT participants' sleep diary reports showed significantly shorter wake after sleep onset (WASO) compared to controls. In another earlier study, Britton et al. studied seven women with insomnia who followed an abbreviated MBSR program and found that WASO was also reduced. In a RCT,<sup>25</sup> Cynthia et al. provided original evidence for the efficacy of MBSR as an efficient treatment for chronic insomnia. Garland et al.<sup>50</sup> demonstrated that MBSR could produce significant

**Table 2.** Pre-Post Comparison of MBSR and Control Groups

Measures	MBSR Group ( $n = 30$ )			Control Group ( $n = 30$ )			$F_{(1,58)}$	$P$
	Pre-mean (SD)	Post-mean (SD)	Cohen's $d$	Pre-mean (SD)	Post-mean (SD)	Cohen's $d$		
PSQI global score	11.50 (3.28)	8.17 (2.61)	1.12	11.27 (3.62)	11.47 (3.58)	-0.06	8.121	.006 <sup>b</sup>
Sleep quality	1.37 (0.72)	0.97 (0.62)	0.60	1.50 (0.78)	1.50 (0.73)	0.00	2.071	.155
Sleep latency	1.83 (1.02)	1.47 (0.86)	0.38	1.90 (1.03)	1.97 (0.96)	-0.07	1.501	.225
Sleep disturbance	1.27 (0.45)	1.17 (0.38)	0.24	1.27 (0.52)	1.33 (0.48)	-0.12	1.071	.305
Sleep duration	1.60 (0.72)	1.33 (0.66)	0.39	1.67 (0.89)	1.60 (0.81)	0.08	1.566	.216
Use of sleeping medication	1.27 (1.14)	0.50 (0.73)	0.78	1.10 (1.16)	1.10 (1.06)	0.00	3.723	.059
Daytime dysfunction	0.93 (0.74)	0.43 (0.57)	0.76	0.80 (0.76)	0.83 (0.70)	-0.04	4.093	.048 <sup>a</sup>
Habitual sleep efficiency	2.10 (0.76)	1.57 (0.77)	0.69	2.07 (0.83)	2.00 (0.83)	0.08	2.121	.151
SAS	33.90 (5.52)	32.23 (5.15)	0.31	34.23 (5.53)	34.93 (4.51)	-0.14	2.547	.116
GDS	14.20 (2.50)	11.17 (2.56)	1.20	15.97 (4.17)	15.50 (3.56)	0.12	4.469	.039 <sup>a</sup>

MBSR = mindfulness-based stress reduction, PSQI = Pittsburgh sleep quality index, SAS = self-rating anxiety scale, GDS = geriatric depression scale.

<sup>a</sup> $P < .05$ .

<sup>b</sup> $P < .01$ .



improvements in sleep and psychological outcomes among patients with cancer and insomnia. Several clinical trials and reviews have demonstrated that mindfulness-based therapies also appear to be feasible and acceptable for improving depressive or anxiety symptoms of participants.<sup>51–57</sup> In our study, the results suggest that the MBSR program improves depressive symptoms in elderly adults (over 75 years of age) with chronic insomnia. However, a significant improvement in anxiety symptoms was not observed in the present study. This suggests that the mechanisms underlying depression and anxiety symptoms in elderly adults are different. A point worthy to mention was that in our study, we enrolled a geriatric population who were unable to fully participate in yoga, as we did not use in our program; the positive effects on insomnia can be attributed more to mindfulness practice than to the benefits of exercise on sleep.

Mindfulness meditation has several health benefits and is a novel approach to emotion regulation and stress reduction.<sup>58</sup> Several studies have examined the mechanisms of mindfulness via magnetic resonance imaging, electroencephalogram, and other techniques. Researchers have suggested changes in intrinsic brain connectivity,<sup>59</sup> cognitive-affective neural plasticity,<sup>60</sup> gray matter concentration,<sup>61</sup> gray matter volume change,<sup>62</sup> neuronal function of white matter,<sup>63</sup> and brain oscillatory activity<sup>64</sup> to explain the underlying mechanisms of mindfulness. However, the biological and psychological mechanisms of the benefits of MBSR for insomnia are still not known.

The main limitation of this study is that the sleep assessments were mainly based on a self-reported scale and not on more objective measures like polysomnography (PSG). The use of PSG should be considered, because participants with insomnia often misestimate their actual sleep status.<sup>65,66</sup> However, in consideration of the cost of polysomnography, and the additional burden for the enrolled elderly, we chose not to use PSG. A second limitation is the lack of follow-up durations and the small sample size. However, the sample size was deemed adequate for establishing the statistical effect of MBSR.

## CONCLUSIONS

In conclusion, this RCT demonstrated the benefits of MBSR for treatment of chronic insomnia in elderly adults aged 75 years and older. Future research using MBSR for insomnia should enroll larger sample sizes and employ longer follow-up periods to assess the durability of the treatment effect.

## Acknowledgment

This work was supported by the National Science & Technology Pillar Program (Grant no. 2013BAI08B03). The funder had no role in data collection, decision to publish, or preparation of the manuscript.

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