Original Article

Comparative Effectiveness of Mindfulness-Based Therapy in Sleep Quality of Chronic Insomnia Compared to Standard Cognitive Behavioral Therapy [CBT-I]: A Randomized Controlled Trial

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Objective: To find the influences of mindfulness-based approach and compare them with standard treatment outcomes.

Materials and Methods: Prospective randomized control trial was conducted by two treatment groups (n = 10 each) for eight-week duration. Sleep-related parameters consisted of the Clinical Global Impression - severity [CGI-S], the Pittsburgh Sleep Quality Index-Thai version [Thai-PSQI], the Hospital Anxiety and Depression Scale Thai version [Thai HADS] and the Philadelphia Mindfulness Scale [PHLMS] were collected before and after both treatments.

Results: Mindfulness-based group had statistically significant improvement of better sleep quality and clinical impression improvement-severity (*p*-value 0.0032 and <0.0001, respectively). Mindfulness level and sleep profiles improved, although there was no significant difference when both treatments were compared.

Conclusion: Mindfulness-based intervention improves sleep quality, and could be decreased impact of daily-life stress and lowered severity of insomnia symptoms.

Keywords: Mindfulness, Sleep disturbance, Insomnia, Thai-PSQI, CGI-S, PHLMS, Thai HADS, CBT-I

In Thailand, insomnia is a common complaint in all varieties of clinics especially general practitioner and psychiatric clinics. It has wide ranges of severity, from transient to chronic insomnia. The prevalence of insomnia in Thailand in general populations is estimated around 40.8%[1], which is higher than the US[2]. It is an important issue at present because the patients with insomnia, besides from physiological and psychological consequences, also have disturbed functions in daily life, such as reduce working efficiency and productivity, and increase the risks of accident[3].

Nowadays, It is known that insomnia can be treated with non-pharmacological treatment which is cognitive behavior therapy for insomnia [CBT-I]. CBT-I are composed of sleep restriction, stimulus control, relaxation techniques, and sleep hygiene. The outcomes are statistically satisfactory in multiple areas[4] and it has become a standard treatment to encounter with insomnia. Besides CBT-I, researchers also continued to study other non-pharmacological treatments and found that mindfulness-based therapy also had effective results[5]. However, the previous study were limited and related only to the elderly. In addition, no previous study compared the usefulness of mindfulness-based therapy with a standard treatment, such as CBT-I.

The objective of the present study aimed to find the impacts of mindfulness-based approach on insomnia symptom both before and after treatment group programs, and compare its usefulness with CBT-I.

Materials and Methods
Study design
The study was prospective randomized control trial conducted between March and August 2016. Subjects were recruited through an advertisement posted at Ramathibodi Hospital and on a social media.

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Inclusion criteria were age 18 to 60 year, and diagnosis of insomnia by the criteria of DSM-V. The subject was regular meditators; those with psychiatric disorders, cognitive impairment, obesity, or substance abuse were excluded from the study.

All of participants were underwent two assessments before the enrollment. The first one was a telephone screening for eligibility. The second assessment, the subject had to visit our clinic for definite diagnosis of insomnia. At this process, the applicants with exclusion criteria were ruled out.

Quasi randomization was utilized to generate the two treatment groups i.e., mindfulness-based (experimental group) and a standard treatment (control group), with 10 to 12 subjects for each group[6]. Duration for group therapy was 1.5 to 2 hours per session per week[7], lasted for eight consecutive weeks. If a subject was absent more than two sessions, it was counted as "discontinue" (Figure 1).

Ethical approval for the present study was obtained from the Ethic Committee, Faculty of Medicine, Ramathibodi Hospital, Mahidol University (IRB ID01-59-29).

Outcome and assessments

Self-assessment questionnaires were administered before and after the eight-week program in both groups of participants. It was composed of three domains: demographic data, sleep profile, and collateral data. Demographic data consisted of age, sex, weight, height, and body mass index [BMI]. Sleep profile was described by sleep quality, sleep latency [SL], number of awakening [NOA], sleep efficiency [SE], and wake after sleep onset [WASO]. And collateral data including severity of illness, impact of daily life functioning, depression and anxiety levels, and mindfulness level were all gathered.
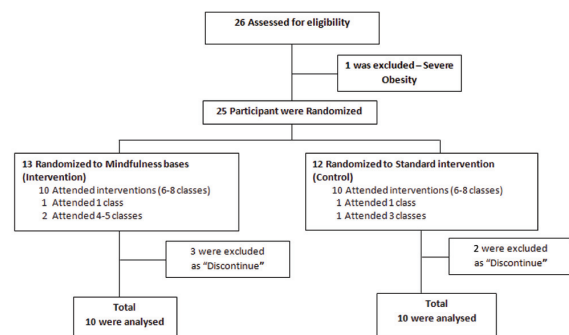

Figure 1. Flow of study.

The primary outcome was derived from the Pittsburgh Sleep Quality Index-Thai version [Thai-PSQI], a questionnaire translated by Sitasuwan et al[8]. It was composed of nineteen self-rated questions in seven factors, namely sleep quality, SL, sleep duration, habitual SE, sleep disturbance, use of sleep medication and daytime functioning. The score was calculated by summarizing scaled points in each factor. A subject was labeled as "poor sleep quality" if its score was higher than 5[9]. Thai-PSQI was declared the internal consistency reliability and test-retest reliability has Cronbach's alpha co-efficiency = 0.837 and intraclass correlation coefficient = 0.89[8]. The present study also used self-rate sleep quality in PSQI to evaluate how well the subject's sleep quality was. The scoring was based on a scale of "0 to 3", whereby "3" reflected the poorest sleep.

Questionnaires for the secondary outcome were derived from the Sleep Profile, the Clinical Global Impression - severity [CGI-S] scale, the Hospital Anxiety and Depression Scale Thai version [Thai HADS] and the Srithanya Sati Scale [SSS]. Sleep profiles are the parameters indicated overall sleep parameters in each subject. It included SL, SE (for weekdays and weekends), NOA, and WASO. In CGI-S scale, it objectively indicated the severity of illness, both symptoms and daily life impacts[10]. The score ranged from 1 to 7, the higher, the greater severity. The cut-off score for the illness was above 2. The Thai HADS, translated by Nilchaikovit et al[11], was used for evaluating mood symptoms in each subject. It contained two domains: HAD-D for depressive symptoms and HAD-A for anxiety symptoms, seven items for each section. Each section had full 21 score range and cut-off point was above 11[12]. Thai HADS studied was declared the internal consistency reliability has Cronbach's alpha co-efficiency = 0.8551 and 0.8259 for anxiety and depression section respectively[11]. The present data was collected by trained staffs who did not know about each group assignment. Mindfulness level was evaluated by SSS from Silpakit and Silpakit[13]. This 20-item questionnaire has scale rating for each item, from 0 (none) to 5 (always)[14]. The score was divided into 3 subscales: awareness, acceptance and self-recollection. For the co-efficient value, Pearson's correlation = 0.79 and Cronbach's alpha co-efficiency = 0.77, 0.73 and 0.63 by the subscale, respectively[13,15].

Statistical analysis

Overall variables had less than 2% of missing values. Assumptions that data were missing at random

and normally distributed were checked for each variable. Variables with normal distributions were determined using Shapiro-Wilk test for normality. They were reported as mean (standard deviation). Variables with non-normal distributions were reported as median (interquartile range). Demographic and sleep features were compared across the groups, between before and after intervention, using t-test. The analysis of differences after the treatment was processed by paired t-test. Differences were considered significant at *p*-value <0.05. Statistical analysis was conducted by using Stata: Data Analysis and Statistical Software version 14 (College Station, TX: StataCorp LP).

Results

The number of interested participants from advertised media was 60, 23 of them were selected for an in-person assessment. One participant with obesity was excluded before the intervention begun, according to the screening criteria. Twenty patients (90.9%) completed the entire eight-week schedule, while two participants were excluded later during the intervention because of their absences more than 2 sessions. Total participants in the present analysis were divided into two groups, ten for each.

The Demographic data were shown in Table 1. The mean age, sex, weight, height, and BMI showed no significant difference between the two groups. The mean age was 48.75 years old. Populations in both groups were mainly female.

Table 2 showed the comparisons between before and after mindfulness-based therapy. After interventions, Thai-PSQI, with a statistical significance, was decreased by 4.1 (*p*-value 0.003). Mean CGI-S score was lowered significantly from markedly ill to normal (*p*-value <0.001). Sleep profiles tended to lower in every parameter. For example, SE was increased by 8.05% and 6.38% in weekdays and weekend, respectively. Mean WASO was decreased by 25 minutes. However, an improvement in sleep profile was not high enough to be statistically significant. Subjective sleep quality in mindfulness-based group was improved statistically significant (*p*-value 0.004). Mood symptoms, both anxiety and depression, were improved, but their differences were not statistically significant. Mindfulness score was increased by 5.5 points, mainly in awareness subscale, although it was not significant.

In control group (Table 3), there was significant improvement in Thai-PSQI, CGI-S, and HAD-D and sleep quality. Sleep profiles were declining, such as

Table 1. Demographic Characteristics between mindfulness-based group and control group

Characteristics	Mindful group mean (SD)	Control group mean (SD)	*p*-value
Age (years)	49.2 (10.5)	48.3 (9.3)	1.00
Female, n (%)	8 (80.0)	9 (90.0)	0.84
Weight (kg)	52.6 (8.9)	54.2 (8.0)	0.69
Height (cm)	158.8 (6.1)	158.4 (3.6)	0.80
BMI (m²)	20.8 (3.2)	21.5 (2.7)	0.61

BMI = body mass index

Table 2. Mindfulness based group subjective results

	Before (10 cases)	After (10 cases)	*p*-value
PSQI[a]	12.5 (2.32)	8.4 (3.02)	0.003
CGI-S[a]	5.0 (1.33)	1.2 (0.42)	<0.001
HAD-A[a]	4.3 (2.50)	4.1 (2.42)	0.860
HAD-D[b]	1.5 (0, 9)	0.5 (0, 5)	0.143
Mindfulness[a]	41.2 (7.29)	46.7 (5.38)	0.071
SL-weekday[b]	45.0 (15, 120)	30.0 (10, 90)	0.402
SL-weekend[b]	60.0 (15, 120)	30.0 (10, 90)	0.177
NOA[b]	2.0 (1, 9)	1.0 (0, 4)	0.255
WASO[b]	45.0 (1, 120)	20.0 (0, 60)	0.839
SE-weekday[a]	75.3 (23.45)	83.3 (3.58)	0.346
SE-weekend[a]	74.8 (7.91)	81.2 (10.26)	0.449
Sleep quality[a]	2.0 (0.67)	2.9 (0.50)	0.004

CGI-S = Clinical Global Impression - severity; HAD-A = Hospital Anxiety and Depression Scale for anxiety; HAD-D = Hospital Anxiety and Depression Scale for depressive; NOA = number of awakening; PSQI = Pittsburgh Sleep Quality Index; SE = sleep efficiency; SL = sleep latency; WASO = wake after sleep onset

[a] Mean (SD), [b] Median (interquartile range minimum, maximum)

p-value <0.05 was statistically significant

Table 3. Control group subjective result

	Before (10 cases)	After (10 cases)	*p*-value
PSQI[a]	14.3 (3.30)	7.9 (4.09)	0.001
CGI-S[b]	5.5 (3, 7)	1.0 (1, 3)	<0.001
HAD-A[a]	8.2 (3.58)	6.5 (4.27)	0.348
HAD-D[a]	7.0 (4.0)	2.8 (3.70)	0.002
Mindfulness[a]	45.5 (5.84)	43.7 (5.81)	0.498
SL-weekday[b]	52.5 (10, 180)	30.0 (10, 150)	0.240
SL-weekend[b]	45.0 (10, 300)	30.0 (10, 150)	0.246
NOA[b]	3.0 (1, 4)	2.0 (0, 3)	0.138
WASO[b]	90.0 (60, 270)	10.0 (0, 180)	0.111
SE-weekday[a]	56.5 (33.70)	86.5 (11.69)	0.157
SE-weekend[a]	62.7 (31.92)	84.8 (11.49)	0.054
Sleep quality[a]	1.8 (0.63)	2.9 (0.74)	0.002

CGI-S = Clinical Global Impression - severity; HAD-A = Hospital Anxiety and Depression Scale for anxiety; HAD-D = Hospital Anxiety and Depression Scale for depressive; NOA = number of awakening; PSQI = Pittsburgh Sleep Quality Index; SE = sleep efficiency; SL = sleep latency; WASO = wake after sleep onset

[a] Mean (SD), [b] Median (interquartile range minimum, maximum)

p-value <0.05 was statistically significant

22.5 and 15 minutes lowered in SL for weekdays and weekend, respectively, though not statistically significant.

For the comparative profiles of final results between mindfulness-based group and control group (Table 4), there was no significant difference in every parameter between the two groups.

Discussion

The present prospective randomized control trial examined the effect of mindfulness-based group therapy on insomnia patients. It found that Mindfulness improve PSQI score, similar to the prior study by Blacks et al[5]. The results indicate that it had an ability to improve quality in general aspect of sleep. And the decreasing value of PSQI was considered clinically significant[16]. CGI-S, which represented the severity of functioning impact, also declined. Moreover, sleep quality also improved significantly. The control group had a concordant result with mindfulness-based group therapy. Overall, the parameters related with quality of life were better after any interventions.

When both groups were compared for mindfulness level, it seemed that the difference, which tends to increase in mindfulness-based group, was not significant enough. On the contrary, the control group tended to have decreasing mindfulness score. As previously mentioned, the quality of life was better after the interventions. Despite an improvement in raw data, the

Table 4. Comparison of results between mindfulness and control group after intervention

	Mindful group: after (10 cases)	Control group: after (10 cases)	p-value
PSQI[a]	8.4 (3.02)	7.9 (4.09)	0.760
CGI-S[b]	1.0 (1, 2)	1.0 (1, 3)	0.828
HAD-A[a]	4.1 (2.42)	6.5 (4.28)	0.140
HAD-D[b]	0.5 (0, 5)	0.5 (0, 10)	0.489
Mindfulness[a]	46.7 (5.37)	43.2 (5.81)	0.246
SL-weekday[b]	30.0 (10, 90)	30.0 (10, 150)	0.871
SL-weekend[b]	30.0 (10, 90)	30.0 (10, 150)	0.937
NOA[b]	1.0 (0, 4)	2.0 (0, 3)	0.324
WASO[b]	20.0 (0, 60)	10.0 (0, 180)	0.498
SE-weekday[a]	83.3 (11.32)	86.5 (11.69)	0.542
SE-weekend[a]	81.2 (10.26)	84.8 (11.49)	0.466
Sleep quality[a]	2.9 (0.57)	2.9 (0.74)	1.000

CGI-S = Clinical Global Impression - severity; HAD-A = Hospital Anxiety and Depression Scale for anxiety; HAD-D = Hospital Anxiety and Depression Scale for depressive; NOA = number of awakening; PSQI = Pittsburgh Sleep Quality Index; SE = sleep efficiency; SL = sleep latency; WASO = wake after sleep onset

[a] Mean (SD), [b] Median (interquartile range minimum, maximum)

p-value <0.05 was statistically significant

WASO decreased by 55% and 88% in mindful-based and the control group respectively when compared with a previous study[4]. Sleep profiles remained no statistically different.

The reason why the results cannot be distinguished from one another is probably due to the relatively short-term evaluation. According to prior study, Ong et al[17] showed that higher mindfulness level can improve for long-term follow-up insomnia patients.

The strength of the present study was a low quit rate (9.1%) during interventions even though no reward given to the participants. The subjects responded positively with the assigned activities and had good motivation within the groups. This can be implied that participants gain benefit from the interventions. Another noted point was that the present study was created for comparing the effect of a standard treatment and a newer intervention.

A limitation to the present study is a relatively small group of samples. It could not distinguish the differences in many parameters, which actually seemed to improve. Evaluation after treatment should be repeated for determining long-term effect of interventions. Studied samples were mainly female, so the results would be varied by other effects such as hormones, menstrual cycles, which were not mentioned in the present study. However, the ratio between female to male was not affected since the prevalence in female is higher than that in male[18]. Other limitation was due to the similarity of misunderstanding concepts between mindfulness and relaxation in Thais. It may influence malpractice outside intervention group.

Conclusion

Mindfulness-based group therapy showed benefits for treating patients with insomnia, especially quality of sleeping and daily-life function impact. It is also easy to apply in Thailand because of cultural belief, which could be influenced for effective treating psychiatric symptoms. The outcomes from the mindfulness-based and standard treatment were conjugative direction.

What is already known on this topic?

Previous studies, conducted outside Thailand, shows mindfulness therapy give positive results in countering insomnia. Its effectiveness is closed to that of CBT-I.

What this study adds?

This study, the first in Thailand, compares the effectiveness of the mindfulness-based therapy with

the standard treatments CBT-I. The results show both conventions produce positive improvement in sleeping quality and severity of insomnia symptoms. It also shows that both promote improvement in sleep profiles and mood symptoms. The differences of both approaches are not statistically significant, but the duration of the treatments can be explored further for a longer period.

Potential conflicts of interest

The authors declare no conflict of interest.

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