Mindfulness Meditation and Cognitive Behavioral Therapy for Insomnia: A Naturalistic 12-Month Follow-up

Jason C. Ong, PhD,[1,#] Shauna L. Shapiro, PhD,[2] and Rachel Manber, PhD[1]

A unique intervention combining mindfulness meditation with cognitive behavioral therapy for insomnia (CBT-I) has been shown to have acute benefits at posttreatment in an open label study. The aim of the present study was to examine the long-term effects of this integrated intervention on measures of sleep and sleep-related distress in an attempt to characterize the natural course of insomnia following this treatment and to identify predictors of poor long-term outcome. Analyses were conducted on 21 participants, who provided follow-up data at six and 12 months posttreatment. At each time point, participants completed one week of sleep and meditation diaries and questionnaires related to mindfulness, sleep, and sleep-related distress, including the Pre-Sleep Arousal Scale, the Glasgow Sleep Effort Scale, the Kentucky Inventory of Mindfulness Skills, and the Insomnia Episode Questionnaire. Analyses examining the pattern of change across time (baseline, end of treatment, six months, and 12 months) revealed that several sleep-related benefits were maintained during the 12-month follow-up period. Participants who reported at least one insomnia episode (≥1 month) during the follow-up period had higher scores on the Pre-Sleep Arousal Scale ($P < .05$) and the Glasgow Sleep Effort Scale ($P < .05$) at end of treatment compared with those with no insomnia episodes. Correlations between mindfulness skills and insomnia symptoms revealed significant negative correlations ($P < .05$) between mindfulness skills and daytime sleepiness at each of the three time points but not with nocturnal symptoms of insomnia. These results suggest that most sleep-related benefits of an intervention combining CBT-I and mindfulness meditation were maintained during the 12-month follow-up period, with indications that higher presleep arousal and sleep effort at end of treatment constitute a risk for occurrence of insomnia during the 12 months following treatment.

Key words: Insomnia, mindfulness meditation, arousal, sleep, cognitive-behavioral therapy

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INTRODUCTION

Chronic insomnia is estimated to impact approximately one of 10 adults and has significant negative implications on quality of life.[1] Cognitive behavioral therapy for insomnia (CBT-I) has demonstrated efficacy and is currently recommended as the first line treatment for chronic insomnia.[2] One notable advantage of CBT-I is its long-term effects beyond the completion of treatment, especially when compared with sedative-hypnotic medication. Long-term superiority of CBT-I was established relative to a variety of medications for different lengths of follow-up periods and different target outcomes. In a seminal study using a 24-month follow-up period, CBT-I was found to have the most durable sleep benefits when compared with temazepam, a combination of CBT-I and temazepam, and placebo.[3] Cognitive behavioral therapy for insomnia was also found to be superior to zolpidem for reducing sleep onset latency, with these gains maintained during a 12-month follow-up period.[4] Finally, CBT-I was more effective in improving sleep efficiency when compared with zopiclone at posttreatment and at six-month follow-up.[5] Although these findings are impressive, these studies only evaluated sleep measures at each follow-up time point and did not provide information about patients' sleep between follow-up visits. Importantly, these studies provided a snapshot of patients' sleep at the follow-up visits and did not evaluate the rates of occurrence of insomnia episodes during the follow-up period. Thus, the natural course of the insomnia disorder following treatment has not been well characterized, and risk factors associated with occurrence of future episodes of insomnia have not been identified.

Mindfulness meditation is a self-regulation practice that has several health benefits when taught in a short-term group program known as mindfulness-based stress reduction. Similar to CBT-I, the mindfulness-based stress reduction program has been found to have long-term benefits that extend beyond the end of treatment. In a three-year follow-up study of individuals diagnosed with anxiety disorders, improvements in symptoms of anxiety and depression achieved at posttreatment were maintained at the three-year follow-up, with 56% of the participants maintaining a meditation practice.[6] Mindfulness-based stress reduction has also been found to have durable effects on symptoms of depression, anxiety, and pain during a three-year follow-up of individuals with fibromyalgia.[7] Mindfulness-based cognitive therapy is a similar mindfulness-based program that is

1 Department of Psychiatry and Behavioral Sciences, Stanford University, Stanford, CA
2 Department of Counseling Psychology, Santa Clara University, Santa Clara, CA
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Corresponding Author. Address:
1653 W. Congress Parkway Chicago, IL 60612-3833
e-mail: jason_c_ong@rush.edu

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specifically designed to prevent the relapse of depression. Over a 60-week period, mindfulness-based cognitive therapy was found to significantly reduce the risk of relapse compared with treatment as usual among individuals who reported at least three previous episodes of depression.[8] It has been hypothesized that the emphasis on self-regulation and the application of the principles of mindfulness meditation into participants' daily lives might account for the long-term benefits of a mindfulness-based program.[6,7]

The practice of mindfulness meditation has been previously linked to sleep improvements; however, its effects on people seeking treatment for chronic insomnia are not entirely clear. The mindfulness-based stress reduction program has been found to improve sleep among cancer patients[9,10] and adolescents with substance abuse history.[11] However, Winbush and colleagues[12] conducted a systematic review of the effects of mindfulness-based stress reduction on sleep disturbances and identified several methodological limitations in the literature that precluded conclusions about the efficacy of mindfulness-based stress reduction for disturbed sleep. We recently reported that a unique intervention integrating mindfulness meditation with CBT-I had benefits at posttreatment on both sleep and sleep-related distress for individuals with psychophysiological insomnia.[13] We reported statistically and clinically significant improvements in several nighttime symptoms of insomnia as well as statistically significant reductions in presleep arousal, sleep effort, and dysfunctional sleep-related cognitions. The long-term benefits of mindfulness-based stress reduction and CBT-I on their targeted symptoms suggest that combining the two could potentially improve the long-term management of chronic insomnia by leading to sustained improvements in both sleep and associated daytime distress.

The purpose of this paper is to report on the 12-month naturalistic follow-up period following an open trial of a treatment of chronic insomnia that combines mindfulness meditation and CBT for insomnia. Although evidence of the acute treatment effects and the feasibility and acceptability of the treatment have been reported,[13] the specific aims of this paper were to (1) examine the long-term effects of the intervention at six and 12 months posttreatment on indices of insomnia severity; (2) document the occurrence of insomnia episodes during the follow-up period; and (3) explore the relationship between insomnia symptoms, mindfulness skills, and meditation practice during the follow-up period. We hypothesized the integrated intervention would show long-term benefits on indices of insomnia consistent with previous nonpharmacological treatments for insomnia.

METHODS

The present study examined a subgroup of participants who completed a stage I treatment-development study that followed the guidelines for developing behavior treatments.[14] Given this early stage of testing, the focus was on developing the intervention and examining possible effects of treatment rather than testing treatment efficacy. Therefore, no control condition was employed and participants were assessed on a variety of measures to examine possible treatment effects and to guide the design of future studies in this area.

Participants

Participants included adults aged between 18 and 65 years who met research diagnostic criteria for psychophysiological insomnia.[15] They were recruited via advertisements posted on bulletin boards, internet listings, and referrals from other clinics and research studies within the local institution. The screening process consisted of a brief telephone screen to determine general eligibility, followed by an in-person interview that consisted of a semistructured interview to assess the inclusion and exclusion criteria and completion of baseline questionnaires. Participants who met all criteria for the study were then contacted to schedule the first treatment session. Participants were excluded if they reported symptoms suggestive of another sleep disorder (eg, excessive daytime sleepiness, loud snoring), untreated mood, anxiety, or psychotic disorder, frequent use of alcohol within two hours before bedtime, or were experiencing a current medical condition requiring treatment not provided in this study. Thirty participants met inclusion and exclusion criteria and began the intervention and 27 completed the treatment program. Of these 27 participants, 21 individuals provided follow-up data. For the present study, analyses were conducted on these 21 participants. The study protocol was approved by the local institutional review board and all participants provided written informed consent during the screening interview. Please see Ong et al[13] for further details on screening and intervention procedures of the treatment phase of the study.

Measures

Daily Sleep and Meditation Diaries. Self-reports of sleep patterns were completed each morning for one week, at the end of treatment, and at six and 12 months posttreatment by using sleep diaries. The sleep variables derived from the diary included (a) total sleep time; (b) total wake time, which is the sum of sleep onset latency, wake time after sleep onset, and terminal wakefulness; (c) time in bed; and (d) number of awakenings. Using this data, sleep efficiency was calculated as (total sleep time/time in bed) $\times$ 100. Ratings of sleep quality, daytime sleepiness, and daytime tiredness were also assessed using a 10-point Likert scale (1-10) with higher numbers reflecting greater sleep quality, sleepiness, and tiredness. In addition to the sleep items, prospective self-report data on the frequency and duration of meditation activity were completed daily for one week, at end of treatment, and at six and 12 months posttreatment. These data were collected to monitor the extent of daily practice of mindfulness meditation. The means and standard deviations across the week at each time point (end of treatment and six- and 12-month follow-up) were calculated for each sleep and meditation variable.

Insomnia Severity Index. The Insomnia Severity Index (ISI) is a brief five-item scale that has been used as both a screening and outcome measure in insomnia treatment research.[16] It provides an index of the severity of insomnia over the past week, taking into account both nighttime and daytime symptoms. The scale has adequate internal consistency (Cronbach's α = .74-.78), with evidence supporting concurrent, predictive, and content validity.[16]

Kentucky Inventory of Mindfulness Skills. The Kentucky Inventory of Mindfulness Skills (KIMS) is a 39-item self-report measure developed by Baer and colleagues[17] to measure mindfulness skills. This scale has adequate to good internal consistency (coefficient α = .83-.91) and evidence for validity was supported.[17] Factor analysis revealed four factors: (1) observe, (2) describe, (3) act with awareness, and (4) accept without judgment.

Pre-Sleep Arousal Scale. The Pre-Sleep Arousal Scale (PSAS) is a 16-item self-report measure that assesses somatic and cognitive arousal in the period prior to sleep. The scale is organized into two subscales (somatic and cognitive arousal), and a five-point Likert scale (1, "not at all" to 5, "extremely") is used to rate the extent to which each item is experienced. Adequate internal consistency has been reported for the PSAS (α = .76 and .81 for the somatic and cognitive scales, respectively), and elevated PSAS scores have been found to be associated with sleep onset difficulties.[18] In this study, a time frame of the past week was used.

Glasgow Sleep Effort Scale. The Glasgow Sleep Effort Scale (GSES) is a seven-item self-report measure of sleep effort during the prior week scored on a three-point Likert scale (0, 1, 2). The scale has adequate internal consistency (Cronbach's α = .77), with evidence discriminating insomnia patients from good sleepers.[19]

Positive and Negative Affect Schedule. The Positive and Negative Affect Schedule (PANAS) consists of a 10-item positive affect scale and a 10-item negative affect scale used as a brief assessment of mood.[20] Participants are asked to rate the extent to which they have experienced each of the items on a five-point Likert scale (1, "very little/not at all" to 5, "extremely"). The two scales have high internal consistency (positive affect α = .86-.90; negative affect α = .84-.87), are stable over a two-month period, and are largely uncorrelated.

Insomnia Episode Questionnaire. The Insomnia Episode Questionnaire (IEQ) is a questionnaire developed for this study to determine whether an insomnia episode occurred during the six months preceding the assessment. It provides a clinically meaningful measure of the long-term effects of treatment. The IEQ consists of a six-month timeline in weekly intervals and was given at both follow-up assessments. For each weekly interval, participants retrospectively recorded whether or not they experienced insomnia symptoms, defined as sleep onset latency greater than 30 minutes or wake time after sleep onset greater than 30 minutes at least three times that week. These criteria follow the recommendations for the quantitative criteria of insomnia.[21] Subsequently, the pattern of insomnia symptoms over the six-month time frame was examined for insomnia episodes, defined as four consecutive weeks of having insomnia symptoms described above. This criteria follows recommendations for duration of psychophysiological insomnia.[15]

Procedures

The six-week group intervention consisted of an integration of the mindfulness training and exercises from the mindfulness-based stress reduction program[22] and group CBT-I.[23,24] A novel aspect of this intervention was the dual emphasis placed on alleviating the nocturnal symptoms of insomnia and decreasing emotional and physiological arousal (eg, coping with sleep-related distress). The intervention was conducted in two-hour weekly sessions over a six-week period. Starting from the second session, formal meditation practice (body scan, sitting and walking meditation) was taught for approximately 30 minutes, followed by a discussion of the application of mindfulness principles to real-world situations. Participants were instructed to engage in meditation practice between sessions for at least 30 minutes per day, five days per week. The second half of the session was spent discussing behavioral changes focusing on nocturnal symptoms (sleep restriction, stimulus control, sleep education, and sleep hygiene) that are taught in most CBT-I treatment packages.

Following the intervention, participants were sent a follow-up questionnaire packet at six and 12 months posttreatment. In the packets, participants were instructed to first complete the sleep and meditation diary for one week and then complete the questionnaires to synchronize the time frame between the responses on the questionnaires with the sleep and meditation diaries. The packet included a self-addressed, prestamped envelope for participants to return. Reminders were sent to participants who did not return the packets within one week of the follow-up date. No financial compensation was offered for completing the follow-up data.

Data Analysis

Given the aims of treatment-development research and the small sample size in this pilot study, nonparametric statistics were conducted for all analyses. First, a series of Friedman tests, a nonparametric alternative to repeated measures analysis of variance, were conducted comparing baseline, end of treatment, six-month follow-up, and 12-month follow-up data. Dependent variables were selected to capture a wide range of effects and included total wake time, total sleep time, sleep efficiency, sleep quality, daytime sleepiness, daytime tiredness, ISI, PSAS (total), GSES, KIMS (total), and PANAS (positive and negative scales). The last observation was carried forward to replace any missing follow-up data (six or 12 months). For significant findings, post hoc comparisons were conducted to examine the pattern of change across time. Following recommendations by Sheldon and colleagues,[25] the following formula was used to determine significance: $|R_j - R_i| \geq z \sqrt{(Nk(k+1)/6)}$, where $R_j - R_i$ is the difference in the sums of ranks being compared (eg, baseline – 6-month follow-up), $z = 2.64$ (the z score from the normal curve corresponding to α = .05 adjusted for multiple comparisons), N is the sample size, and k is the number of measurements (k = 4). Second, a series of Mann-Whitney U tests were conducted to identify which end of treatment variables distinguished between those who did and those who did not experience an insomnia episode during the 12-month follow-up period. Each model included occurrence (n = 7) versus nonoccurrence (n = 11) as the independent variable and an end of treatment variable (same as

above) as the dependent variable. To explore the relationship between mindfulness meditation and sleep, Spearman rho correlations (ρ) were computed separately at each of the three time point s(end of treatment, six-month follow-up, 12-month follow-up) between two mindfulness variables (KIMS total score, total minutes of meditation practice during past week) and six sleep-related variables (ISI, total wake time, total sleep time, sleep quality, sleepiness, tiredness) for a total of 12 ρ correlations at each time point. An α level = .05 was selected for all analyses (except post hoc comparisons) to balance both type I and type II errors as recommended in pilot studies.[26]

RESULTS

Demographics

The average age of the participants was 38.7 years (SD, 13.6; range, 21-62 years) and 52% were female. The ethnic distribution was as follows: 66.7% Caucasian, 23.8% Asian, and 9.5% other. All participants had a high school education or above, with an average of 17.6 years of education (range, 14-22 years). With regard to marital status, 52.4% of the participants were single and 47.6% were married.

Long-term Effects

The means and standard deviations of the sleep and daytime variables collected at baseline, end of treatment, six-month follow-up, and 12-month follow-up are presented in Table 1. Friedman tests conducted on the dependent variables selected above revealed significant results on total wake time (Friedman χ^2 (3) = 21.37, $P < .005$), sleep efficiency (Friedman χ^2 (3) = 24.84, $P < .005$), sleep quality (Friedman χ^2 (3) = 7.97, $P < .05$), daytime tiredness (Friedman χ^2 (3) = 11.35, $P < .05$), PSAS (Friedman χ^2 (3) = 17.10, $P < .01$), GSES (Friedman χ^2 (3) = 19.68, $P < .005$), and ISI (Friedman χ^2 (3) = 35.53, $P < .005$). Post hoc tests revealed that baseline levels were significantly different than end of treatment, six-month, and 12-month follow-up for total wake

Table 1. Long-term Effects of Treatment

	Baseline		End of Treatment		6-Month Follow-up		12-Month Follow-up	
Measures	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Sleep diaries								
Total sleep time, min	384.19	63.76	382.41	59.39	390.33	72.13	380.32	109.00
Total wake time, min	100.21	60.84	42.56[a]	32.93	49.23[a]	34.64	47.65[a]	31.69
Sleep onset latency, min	33.15	23.69	15.58	10.13	20.37	15.03	20.16	19.56
Wake time after sleep onset, min	42.94	45.32	14.04	12.80	17.01	16.23	20.50	17.90
Terminal wakefulness, min	24.12	21.76	12.93	16.93	11.85	17.19	11.50	16.11
Time in bed, min	483.41	78.14	424.97	53.03	439.36	75.81	422.76	116.86
Sleep efficiency, %	79.97	10.17	89.93[a]	7.97	88.93[a]	7.95	89.91[a]	10.28
No. of awakenings	2.37	1.82	1.28	1.33	0.87	0.62	1.40	1.31
Sleep quality	5.85	1.09	6.49	1.13	6.79[a]	1.30	6.70	1.23
Daytime sleepiness	4.18	1.84	3.97	2.04	3.54	1.88	3.53	1.89
Daytime tiredness	4.21	1.63	4.23	1.75	3.49[a]	1.79	3.46	2.02
PSAS total	32.90	8.04	25.14[a]	5.84	27.33[a]	8.06	27.57	6.55
Cognitive	19.86	5.65	14.76	5.20	16.05	5.81	16.24	4.41
Somatic	13.05	3.69	10.38	2.27	11.29	3.29	11.33	3.06
GSES	6.70	2.92	3.00[a]	2.17	3.05[a]	3.05	2.81[a]	3.14
ISI	14.65	4.18	8.29[a]	3.38	8.02[a]	4.40	7.10[a]	3.55
KIMS total	132.48	11.79	135.52	15.80	136.24	13.84	136.95	14.85
Observe	34.33	5.78	36.52	7.30	36.43	5.91	39.76	7.15
Describe	29.10	5.71	29.81	6.51	29.38	5.97	29.43	6.19
Awareness	30.67	5.56	31.57	6.19	31.62	6.60	31.19	5.61
Accept	34.19	5.10	33.48	6.87	34.95	7.03	35.48	6.40
PANAS								
Positive	33.71	6.01	34.95	6.08	32.57	6.45	34.33	6.61
Negative	17.14	4.97	15.52	4.07	16.05	4.19	15.52	4.07

PSAS, Pre-Sleep Arousal Scale; GSES, Glasgow Sleep Effort Scale; ISI, Insomnia Severity Index; KIMS, Kentucky Inventory of Mindfulness Skills; PANAS, Positive and Negative Affect Schedule.

Analyses were conducted on selected variables of interest.

[a]Levels that were significantly different from baseline on post hoc comparisons. Sleep quality ranges from 1 ("very poor") to 10 ("excellent"). Daytime sleepiness and tiredness are rated from 1-10 with higher numbers reflecting higher levels of sleepiness/tiredness. Baseline means and standard deviations for ISI and GSES are based on n = 20 due to incomplete data for one participant.

time, sleep efficiency, GSES, and ISI, indicating that treatment gains were present at end of treatment and maintained throughout the follow-up period. For PSAS, baseline levels were significantly different than end of treatment and six-month follow-up, but not the 12-month follow-up. For sleep quality and daytime tiredness, baseline levels were only significantly different than six-month follow-up. No significant results were found on total sleep time, daytime sleepiness, KIMS, or PANAS.

Episodes of Insomnia

Data from the IEQ revealed that seven of the 18 participants (38.9%) who completed the questionnaire had an episode of insomnia (as defined above) during the 12-month follow-up period (Figure 1). Only one of these seven participants met criteria for insomnia symptoms (sleep onset latency greater than 30 minutes or wake time after sleep onset greater than 30 minutes at least three times that week) during the first month following end of treatment. The other six developed an insomnia episode later in the follow-up period. The average length of an episode for this group lasted 16.3 weeks (SD, 11.5 weeks). The means and standard deviations of sleep- and mindfulness-related constructs for those who experienced an insomnia episode and those who did not are summarized in Table 2. Comparisons between the two groups revealed that participants with an occurrence had significantly higher scores on the PSAS at end of treatment (mean, 29.14; SD, 6.62) compared with those with no occurrence (mean, 22.64; SD, 3.91), Mann-Whitney $U = 16.00$, $P < .05$. In addition, those with an occurrence had significantly higher scores on the GSES at end of treatment (mean, 4.86; SD, 2.41) compared with those with no occurrence (mean, 2.18; SD, 1.40), Mann-Whitney $U = 13.00$, $P < .05$. No other significant differences were found between the two groups at end of treatment.

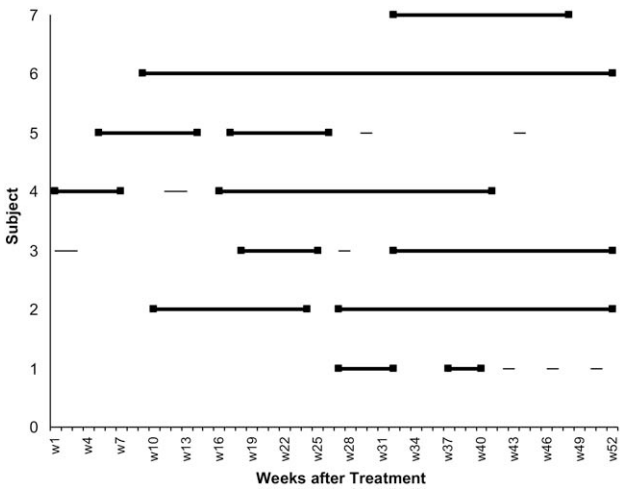

Figure 1. Occurrence of insomnia episodes (n = 7) across the 52 weeks of follow-up, based on data from the Insomnia Episode Questionnaire. An episode of insomnia consisted of at least four consecutive weeks with difficulty initiating or maintaining sleep for at least three nights each week. The beginning and end point of each episode is marked by a solid square. Brief periods of insomnia not meeting criteria for an episode do not have solid squares. *w,* week.

Table 2. End of Treatment Data for Presence or Absence of Insomnia Episodes

Measures at End of Treatment	Occurrence of Insomnia		No Occurrence of Insomnia	
	Mean	SD	Mean	SD
Sleep diaries				
Total sleep time, min	369.18	49.98	405.51	52.69
Total wake time, min	31.02	11.01	39.10	17.86
Sleep onset latency, min	12.96	5.04	16.39	10.98
Wake time after sleep onset, min	8.88	7.11	12.77	10.43
Terminal wakefulness, min	9.18	7.64	9.95	7.04
Time in bed, min	400.20	45.76	444.61	58.74
Sleep efficiency, %	92.14	3.02	91.24	3.56
No. of awakenings	0.86	0.91	1.27	1.12
Sleep quality	6.51	1.26	6.72	0.98
Daytime sleepiness	4.41	2.07	3.73	2.16
Daytime tiredness	4.61	1.85	4.02	1.85
PSAS total[a]	29.14	6.62	22.64	3.91
Cognitive	18.29	6.47	12.64	2.62
Somatic	10.86	1.77	10.00	2.79
GSES[a]	4.86	2.41	2.18	1.40
ISI	10.14	3.48	7.45	3.24
KIMS total	141.14	18.77	131.82	15.40
Observe	40.29	7.70	35.00	6.59
Describe	29.86	6.74	30.09	7.33
Awareness	31.43	7.76	31.82	6.01
Accept	35.14	5.93	31.00	6.51
PANAS				
Positive	36.14	6.57	35.00	6.37
Negative	17.86	5.40	14.27	2.94
Total weeks with insomnia	30.71	11.01	1.91	2.81

PSAS, Pre-Sleep Arousal Scale; GSES, Glasgow Sleep Effort Scale; ISI, Insomnia Severity Index; KIMS, Kentucky Inventory of Mindfulness Skills; PANAS, Positive and Negative Affect Schedule.

Analyses were conducted on selected variables of interest.

[a]Significant difference between groups. Sleep quality ranges from 1 ("very poor") to 10 ("excellent"). Daytime sleepiness and tiredness are rated from 1-10, with higher numbers reflecting higher levels of sleepiness/tiredness.

Relationship Between Mindfulness Meditation and Sleep Diary Variables

Spearman rho correlations between mindfulness and sleep-related variables at the end of treatment revealed significant negative correlations between KIMS total score and daytime sleepiness ($\rho = -.65$, $P < .01$, n = 20) and between the KIMS total score and daytime tiredness ($\rho = -.66$, $P < .01$, n = 20). At the six-month follow-up, significant negative correlations were found between KIMS and daytime sleepiness ($\rho = -.71$, $P < .01$, n = 16) and the KIMS and daytime tiredness ($\rho = -.62$, $P < .05$, n = 16). At the 12-month follow-up, a significant negative

correlation was again found between KIMS and daytime sleepiness ($\rho = -.54$, $P < .05$, n = 15), and a significant positive correlation was found between total sleep time and the amount of meditation during the past week ($\rho = .54$, $P < .05$, n = 17). No other significant correlations were found.

DISCUSSION

This study examined the naturalistic follow-up over a 12-month period of a novel intervention combining mindfulness meditation and CBT-I. The three main findings from this study are (1) benefits of this combined intervention were generally maintained during the 12-month follow-up period in terms of symptom severity at each follow-up time point and the course of insomnia symptoms across the 12-month period, (2) higher presleep arousal and sleep effort at end of treatment were associated with worse long-term outcome (experience of an insomnia episode during the follow-up period), and (3) mindfulness skills were negatively associated with perceived daytime sleepiness across each time point.

In general, the observed long-term benefits of this intervention are consistent with previous findings of the durability of sleep benefits following CBT-I. Most notably, total wake time, sleep efficiency, and overall insomnia severity demonstrated significant improvements at the end of treatment and at both follow-up assessments relative to baseline. The maintenance in decreased total wake time during follow-up is comparable to previous studies examining CBT-I.[3,4] Furthermore, sleep efficiency was relatively stable across the follow-up time points and well within the normal range for good sleepers.[15] Long-term gains were also found on measures of presleep arousal and sleep effort, although the gains in presleep arousal were no longer significant at the 12-month follow-up. The reduction in arousal is consistent with the hypothesized mechanism of this combined intervention.[13] In contrast to the sleep benefits, no significant changes were found on the KIMS and PANAS, suggesting that the current intervention might not have been adequately developed to provide the full benefits of mindfulness meditation that has been reported in other long-term follow-ups.[6,7]

In addition to traditional follow-up measures in sleep, the present study employed the IEQ, a new measure developed for this project to track the longitudinal course of insomnia episodes across the follow-up period. Data from the IEQ revealed that 61% of participants who provided data reported no occurrence of insomnia during the follow-up period. To our knowledge, this is the first study to report on the occurrence of insomnia episodes following treatment. Still, despite equivalent mean scores of the sleep variables at end of treatment and follow-up assessment, 39% of the sample reported at least one episode of insomnia during the follow-up period. This suggests that snapshot evaluations of sleep at discrete follow-up time points (eg, three months) might not be sufficiently sensitive for capturing the natural course of insomnia following treatment. Given the lack of guidelines in the insomnia literature for determining long-term outcomes of treatment, development of standard definitions for response, remission, relapse, and recurrence, such as that proposed for depression,[27] would aid future research in characterizing the course of insomnia following treatment.

Higher presleep arousal and sleep effort at end of treatment were observed in those who experienced an occurrence of an insomnia episode during the follow-up period compared with those who did not. This suggests that residual sleep effort and arousal at the end of treatment might constitute a risk for future occurrence of insomnia episodes. This finding is consistent with the psychophysiological model of insomnia,[28] which posits that elevated arousal is a perpetuating factor in the development of chronic insomnia. Moreover, the temporal relationship of the data in this study indicates that hyperarousal is a cause rather than an epiphenomenon of sleep disturbance. The preliminary findings here provide evidence for future hypothesis-testing studies to examine changes in presleep arousal and sleep effort in relation to long-term outcomes.

Interestingly, we found a general pattern of perceived improvement in daytime functioning that was associated with more self-reported mindfulness skills. There was a significant decrease in perceived daytime tiredness at six months, with only a modest eight-minute increase in total sleep time, indicating that increased sleep time alone was unlikely to account for the improvement in daytime tiredness. We also found a negative relationship between mindfulness skills and daytime tiredness at the end of treatment and six months follow-up, and a negative relationship between mindfulness skills and daytime sleepiness across all three time points. These findings might be explained within Jon Kabat-Zinn's conceptual framework of mindfulness as a state of becoming "awakened".[29] In this context, mindfulness consists of the awareness that arises through intentionally attending to the present moment in an open, accepting, and curious way.[30] This heightened state of awareness is often described as an experience of being awake, alive, and alert–states that are unlikely to coincide with sleepiness and tiredness. Using this framework, one explanation for the present findings is that increases in mindfulness skills contributed to the improvement in daytime functioning. The increase in the "accept without judgment" factor of the KIMS at 12-month follow-up suggests that increased acceptance of tiredness during the day might lead to reduced distress about it and thus to lower perceived tiredness. For example, instead of expending energy judging or reacting to the perception of tiredness, one can note it and attend to it directly. Further, the accepting quality of the attention may have a beneficial impact on daytime tiredness by changing one's relationship to the perception of tiredness. Given the bidirectional nature of correlations, an alternative interpretation is that higher levels of sleepiness may lead to a reduction in mindfulness skills. Taken together, these findings indicate that mindfulness skills and elevated sleepiness appear to be incompatible states. Investigating the hypothesis that cultivating mindfulness skills could decrease daytime sleepiness merits direct testing in future research and could have important clinical implications. This is especially important given that the present data did not find a clear relationship between the length and frequency of mindfulness meditation practice and insomnia symptoms.

Several limitations of this study are inherent in its design as an uncontrolled treatment development study and should be noted. First, the absence of a control group and the small sample limit our ability to conclude that the observed long-term effects can be attributed to this treatment. Further, conclusions regard-

ing the specific benefits attributable to mindfulness meditation cannot be determined from these data, as the present design precludes teasing apart the relative contribution of mindfulness training and CBT-I. Second, the number of comparisons in the analyses could lead to type I errors. As with other uncontrolled pilot studies, the present findings were meant to stimulate and guide the design of subsequent hypothesis-testing studies, which should be conducted before clinical applications can be recommended. Another limitation of this study is its reliance on self-report questionnaires that are subject to recall bias and/or social desirability. This was particularly notable for the IEQ, which required retrospective week-by-week recall of insomnia-related symptoms for the past six months. This limitation is mitigated, in part, by the fact that participants did not have access to previous data and were not paid for completing the follow-up questionnaires.

Despite these limitations, the results suggest that a novel integrated treatment for insomnia has significant benefits that continue up to one year after treatment. Based on these findings, we suggest four specific areas for future study: (1) testing the long-term effect of this intervention and the specific benefits of mindfulness meditation in a randomized controlled trial, (2) the inclusion of occurrence of insomnia episodes as a clinically meaningful measure of long-term outcome, (3) further exploration of the relationship between mindfulness and daytime functioning, and (4) further investigation of residual hyperarousal and sleep effort as a risk of future occurrence of insomnia. Future research building upon these findings will enhance the understanding and treatment of chronic insomnia.

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