

Two sessions of sleep-focused mind–body bridging improve self-reported symptoms of sleep and PTSD in veterans: A pilot randomized controlled trial

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Abstract

Objective: Sleep disturbance is highly prevalent among veterans. As an alternative to sleep medications with their undesirable side effects, nonpharmacological mind–body interventions may be beneficial for sleep management in primary care. The aim of this pilot study was to investigate whether a novel mind–body intervention, mind–body bridging (MBB), focusing on sleep, could improve self-reported sleep disturbance and comorbid symptoms in veterans. **Methods:** This pilot study was a randomized controlled trial at the Veterans Affairs Salt Lake City Health Care System in which 63 veterans with self-reported sleep disturbance received MBB or an active sleep education control. Both interventions were conducted in two sessions, once per week. Patient-reported outcomes included the following: primary—Medical Outcomes Study (MOS) Sleep Survey, MOS Short Form-36V; secondary—Center for Epidemiological Studies—

Depression, PTSD Check List–Military, Five-Factor Mindfulness Questionnaire. **Results:** At both Week 1 (1 week after the first session) and post-intervention assessments, while sleep disturbance decreased in both groups, MBB performed significantly better than did the control group. Furthermore, self-reported PTSD symptoms improved in MBB, while they remained unchanged in the control. Overall mindfulness increased in MBB, while it remained unchanged in the control. **Conclusions:** This study provides preliminary evidence that a brief sleep-focused MBB could be a promising intervention for sleep and potentially other comorbid symptoms (e.g., PTSD). MBB could help patients develop awareness skills to deal with sleep-related symptoms. Integration of MBB into primary care settings may enhance care of patients with sleep disturbance and co-morbid symptoms.

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Keywords: Awareness training program; Mind–body bridging; Mindfulness; PTSD; Sleep; Veterans;

Introduction

Sleep disturbance and lack of adequate sleep are a major health concern in both the civilian [1] and military

populations [2]. In currently deployed and post-deployed military personnel, sleep disturbance may be as high as 74–90% [3,4]. Perpetuating sleep problems in veterans may lead to reduced quality of life (QOL) and well-being,

Abbreviations: ANCOVA, analysis of covariance; ANOVA, analysis of variance; ATP, awareness training program; CBT, cognitive behavioral therapy; CES-D, Center for Epidemiological Studies–Depression; CI, confidence interval; ES, effect size; 5F-MQ, Five-Facet Mindfulness Questionnaire; MBB, mind–body bridging; MBCT, mindfulness-based cognitive therapy; MBSR, mindfulness-based stress reduction; MOS, Medical Outcomes Study; MOS-SS, Medical Outcomes Study Sleep Survey; PCL-M, PTSD Check List–Military; PTSD, post-traumatic stress disorder; QOL, quality of life; SF-36V, MOS Short Form-36 for Veterans; SH, sleep hygiene; VASLCHCS, Veterans Affairs Salt Lake City Health Care System.

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and may contribute to worsening of both mental (e.g., post-traumatic stress disorder or PTSD, depression, and anxiety) [5–8] and physical health conditions (e.g., obesity, hypertension, and chronic pain [2,9,10]). Thus, given the increased physical and mental health comorbidities in veterans, treating sleep disturbance may be an important approach because improving sleep may lead to decreasing their health symptoms and improving their health status, QOL, and well-being.

In recent years, sleep has received increased attention in military personnel with PTSD, since these patients almost always report some form of sleep disturbance [3,5]. In fact, since sleep disturbance is so prevalent in PTSD, it is considered a hallmark of PTSD diagnosis [11]. Two classical PTSD symptoms, hyperarousal and re-experiencing the traumatic event, comprise sleep difficulty and nightmares, respectively [6]. Preliminary evidence suggests that interventions targeting sleep may be beneficial in the treatment of PTSD [12,13].

Sleep disturbance in veterans may not always be diagnosed or properly treated. Many veterans may not even disclose to their primary care physicians that they suffer from sleep disturbance since they may regard it as a commonly occurring symptom that afflicts many people. Another reason for lack of attention to sleep is that veterans' sleep disturbance is embedded within a constellation of co-morbid health symptoms, which are a higher priority in their treatment. Under conditions of persistent sleep disturbance, treatment usually involves use of antidepressants and benzodiazepines, which are generally effective over the short-term, but these have many side effects and their usage is not advisable over the long-term [14–16].

A search for more effective alternative approaches to pharmacotherapy for sleep management has led to the development of a variety of cognitive and behavioral interventions, such as cognitive behavioral therapy (CBT [1]). Studies have shown that short-term sleep improvements following CBT compare favorably with those achieved using pharmacotherapy, and CBT's effects are enduring over the longer term, even more so than pharmacological treatments [15]. Other alternative nonpharmacotherapy treatments include mind–body interventions such as mindfulness-based stress reduction (MBSR [17]) and mindfulness-based cognitive therapy (MBCT [18,19]). These programs are examples of awareness training programs (ATPs), which focus on the power of “mind training” in regulating mental and physical states of the person [20]. These interventions have been shown to ameliorate or reduce the severity of a wide variety of health conditions, such as cancer, depression, anxiety, chronic pain, and hypertension [21]. In particular, sleep disturbance has improved using these approaches [22–29].

A recent addition to ATPs is mind–body bridging (MBB [30–32]). MBB may have the potential to develop into a mind–body intervention for a wide range of mental and physical health problems. First, MBB teaches awareness

skills to help the individual calm the mind and relax the body. Second, MBB teaches the individual to recognize and become aware of a dysfunctional mind–body state characterized by a heightened sense of self-centeredness, as indicated by ruminative thoughts, involuntary contraction of awareness, body tension, and impaired mental or physical functioning. Specific ‘mind–body mapping’ exercises use a technique of written free-association to reveal specific thought patterns called “requirements”, i.e., expectations about how one and the world “should be” at each moment. Requirements that are excessively self-centered and not fulfilled can easily lead to a dysfunctional mind–body state. Defusing requirements through mind–body mapping will lead to a more balanced, harmonious state. When individuals use awareness practices and defuse requirements, their awareness expands, making them more effective in dealing with difficulties in their daily lives. In this way, MBB carries awareness practices one critical step further by addressing the underlying cause of the resistances to clarity, i.e., mental afflictions caused by an individual's fixed idea of who she/he is, known as the “identity system” in MBB teaching language. The increased awareness of the identity system may potentially account for MBB's therapeutic usefulness. Furthermore, MBB is easy to learn and benefits accrue rapidly. These features suggest that MBB may become a viable clinical intervention, especially in primary care service. (See Ref. [32] for more detailed descriptions of MBB program content.)

Thus, a pilot randomized controlled study was conducted to evaluate a novel mind–body awareness training program, MBB, as a new mind–body program for helping veterans with self-reported sleep disturbance. In view of the potential value of MBB as a clinical intervention for managing sleep in particular, this pilot study investigated the effects of a short-term (two-session) sleep-focused MBB program compared with a standard-of-care sleep hygiene (SH) program in veterans. We evaluated whether MBB could improve sleep symptoms as well as other co-morbid symptoms in veterans such as PTSD, depression, and health-related QOL. Finally, we assessed whether MBB could increase mindfulness, which we theorize to be one of the underlying mechanisms driving MBB in particular and ATPs in general. We hypothesized that patients randomly assigned to MBB would exhibit significantly greater improvements in sleep and in other co-morbid symptoms than patients assigned to SH, which may be in part facilitated by increased mindfulness.

Methods

Overview

We conducted a prospective, randomized controlled trial. Subjects were assigned to one of two interventions: a standard-of-care SH arm and an experimental intervention MBB arm.

Participant selection

We recruited patients (male and female US veterans, 18–70 years old) from a primary care clinic at the Veterans Affairs Salt Lake City Health Care System (VASLCHCS). This study was approved by the University of Utah and VASLCHCS Institutional Review Boards. All patients gave written informed consent and were compensated for their time. Patients from VA Primary Care were surveyed and selected in accordance with the main objective of the study (i.e., improving management of self-reported sleep disturbance in veterans from VA Primary Care). Table 1 presents inclusion and exclusion criteria used in the study.

Randomization

Patients visiting a primary care clinic at the VASLCHCS were screened for sleep disturbance with a validated self-report sleep questionnaire, Medical Outcomes Study Sleep Survey (MOS-SS), using the Sleep Problems Index II subscale [33]. Individuals who (a) gave consent for the research team to use their MOS-SS data for study purposes, (b) scored ≥ 35 on MOS-SS (see Table 2), and (c) exhibited no severe mental health issues as determined by a physician were deemed eligible. Prospective subjects were contacted by phone and invited to participate in the study. Patients giving verbal agreement were mailed a packet containing study information, a consent form, and pre-study questionnaires, and were asked to complete all questionnaires in

advance, which on average was within 1 week of the first intervention session. At enrollment, participants first signed the consent form and then submitted their completed questionnaires. Afterwards, participants were randomly assigned in blocks of four (computer-generated random assignment program) to one of the two interventions. Finally, participants attended the first session.

Fig. 1 shows the flow of patients through the study. We recruited patients between September 2008 and January 2009. We screened 421 patients with MOS-SS; 136 fell below the 35 cutoff and were excluded. Of the 285 patients who scored above the 35 cutoff, 222 were ineligible due to severe mental health (72; 25.3%) or medical health issues (3; 1.1%), age (24; 8.4%), or unavailability/declined to participate in the study (123; 43.2%). Sixty-three (22.1%) patients agreed to participate and were randomly assigned to one of the two interventions; 25 participants completed SH and 33 completed MBB.

Demographics collected include age, gender, and ethnicity. Baseline characteristics include sleep disturbance score (MOS-SS), sleep duration, PTSD symptoms (PCL-M) total score, and depression (CES-D) total score, as shown in Table 3.

Interventions

Sleep hygiene program

Good sleeping practices were taught to participants, based on several guidelines that include limiting exercise, eating, alcohol and caffeine intake before bed, using the bed only for sleeping, and establishing a regular bedtime. The instructor encouraged participants to follow guidelines and to maintain a daily sleep diary for their own use to monitor their sleep patterns. During the second session, the instructor reiterated the sleep education guidelines and discussed with participants various sleep issues based on reports from their sleep diaries. The sleep education sessions were presented by a board-certified internist at the VASLCHCS.

Mind–body bridging program for sleep management

Each MBB session comprised several objectives that included teaching participants basic MBB experiential tools to improve their sleep. They learned how to identify a possible cause of their sleep difficulties from a MBB perspective to help them effectively deal with their sleep problems and also help them reduce daytime stress. Participants were encouraged to practice MBB as often as possible throughout the day and especially at bedtime. MBB was taught by a licensed clinical social worker who is a certified instructor of MBB. For more details of MBB procedures, see Ref. [32].

Outcome measures

Primary and secondary outcome measures used in the study are presented in Table 2 [33,36–39].

Table 1
Selection criteria for patient enrollment

Selection criteria	
Inclusion criteria	Participants exhibited self-reported sleep disturbance as assessed by a validated sleep questionnaire, MOS-SS [33]; they were not required to have formal diagnosis of either primary or secondary insomnia, including sleep-disordered breathing, chronic obstructive pulmonary disease, or restless leg syndrome. Since we are broadly interested in MBB's beneficial impact on co-morbid symptoms, patients currently treated for depression, pain, and any general medical conditions (e.g., hypertension, diabetes) are not excluded. Additionally, patients on sleep medication, antidepressants, pain medications, and other medications for any condition that is not under exclusion criteria were admitted into the study. Thus, our inclusion criteria are much broader than those used in a typical treatment study, consistent with the main objective of the study.
Exclusion criteria	Patients were excluded if they presented with significant mental health issues, such as severe psychosis or major depression, or were under intensive mental health case management, as determined by an attending physician in VA Primary Care, or were on antipsychotic medication.

Table 2
Outcome measures

Scale	Description	Reference
<i>Primary outcomes</i>		
<i>Sleep</i> —Medical Outcomes Study-Sleep Scale (MOS-SS)	This 12-item questionnaire evaluates sleep performance. We used this modified version since it was already validated to assess sleep over the previous 7 days. Use of other questionnaires such as the Pittsburgh Sleep Quality Inventory [34] and Insomnia Severity Index [35] is not validated for a 1-week time frame, and thus given the brief duration of the interventions (two sessions, 1 week apart), we opted to use the MOS-SS for our study. Subscales derived from the questions were (1) Sleep Disturbance, (2) Sleep Adequacy, (3) Daytime Somnolence, (4) Snoring, (5) Waking Up Short of Breath/With a Headache, (6) Sleep Problems Index I, (7) Sleep Problems Index II. As an assessment of general changes in overall sleep performance, we used Sleep Problems Index II, which comprises sleep onset latency, sleep disturbance, sleep adequacy, and waking up with shortness of breath and/or headache. We also used the Sleep Problems Index II for screening potential participants and used a cutoff score ≥ 35 , which can serve as a proxy indicator of clinically diagnosed sleep disturbance (Dr. R. Hayes, personal communication, 8/11/2009).	[33]
<i>Quality of Life</i> —MOS-SF-36 for Veterans (MOS SF-36V or VR-36)	MOS-SF-36V is a well-established quality of life (QOL) scale, adapted for veterans.	[36]
<i>Secondary Outcomes</i>		
<i>Depression</i> —Center for Epidemiological Studies Depression Scale (CES-D)	This scale is a common screening test determining an individual's depression quotient.	[37]
<i>Mindfulness</i> —5-Factor Mindfulness Questionnaire (5F-MQ)	The 5F-MQ contains five clear, interpretable facets of mindfulness based on other mindfulness questionnaires: (1) observing, (2) describing, (3) acting with awareness, (4) nonjudging of inner experience, and (5) nonreactivity to inner experience.	[38]
<i>PTSD Symptoms</i> —PTSD Check List—Military (PCL-M)	The PCL-M is a 17-item reliable self-report measure assessing PTSD severity in people experiencing a traumatic event, specifically for the military. Total scores above 50 are considered to reflect moderate, and above 65 severe, PTSD symptoms.	[39]

Study procedures

The study was conducted over 3 weeks. Participants underwent two sessions of either SH or MBB, both specifically targeting sleep problems. Sessions ran concurrently over two consecutive weeks, one per week for approximately 1 h (SH) or 1.5 h (MBB).

Participants completed all self-report questionnaires approximately within 1 week prior to the first session (Pre) and at least 7 days after the second session (Post). Additionally, MOS-SS was completed at Week 1 (just before the start of the second session).

Statistics

We employed a linear mixed-effects model with repeated measures analysis of variance (ANOVA) with intervention and period as two factors, using SPSS software (SPSS, Inc., Chicago, IL, USA). Unlike more conventional statistical analysis methods (e.g., ANOVA), modern mixed-effects model will never discard nor impute data [40,41]. If significant, we then examined specific contrasts corresponding to customized hypothesis tests comparing Pre with Post scores within and between groups. For the sleep measure, we

additionally compared Pre to Week 1 to determine whether sleep was affected by one intervention session. For the PTSD symptoms, we used a mixed-effects analysis of covariance (ANCOVA) regressing Pre scores on Post scores (Pre was used as a covariate). Adjusted means at Post was the focus.

Results

Attendance

Sixty-three enrolled and 58 completed the study: 25 in SH and 33 in MBB. Five dropped out after completing pre-intervention questionnaires and participating in the first session. Three of the five were in SH and two in MBB. Demographics and levels of baseline self-reported symptoms were not different between the two groups.

While there were relatively few drop-outs (8%, five out of 63), we included all 'intent-to-treat' subjects in the analysis, using mixed-effects model. Thus, data were used from all participants, regardless of whether they completed the study or not, because the statistical approach used (mixed-effects model) was able to handle missing observations without discarding or imputing data.

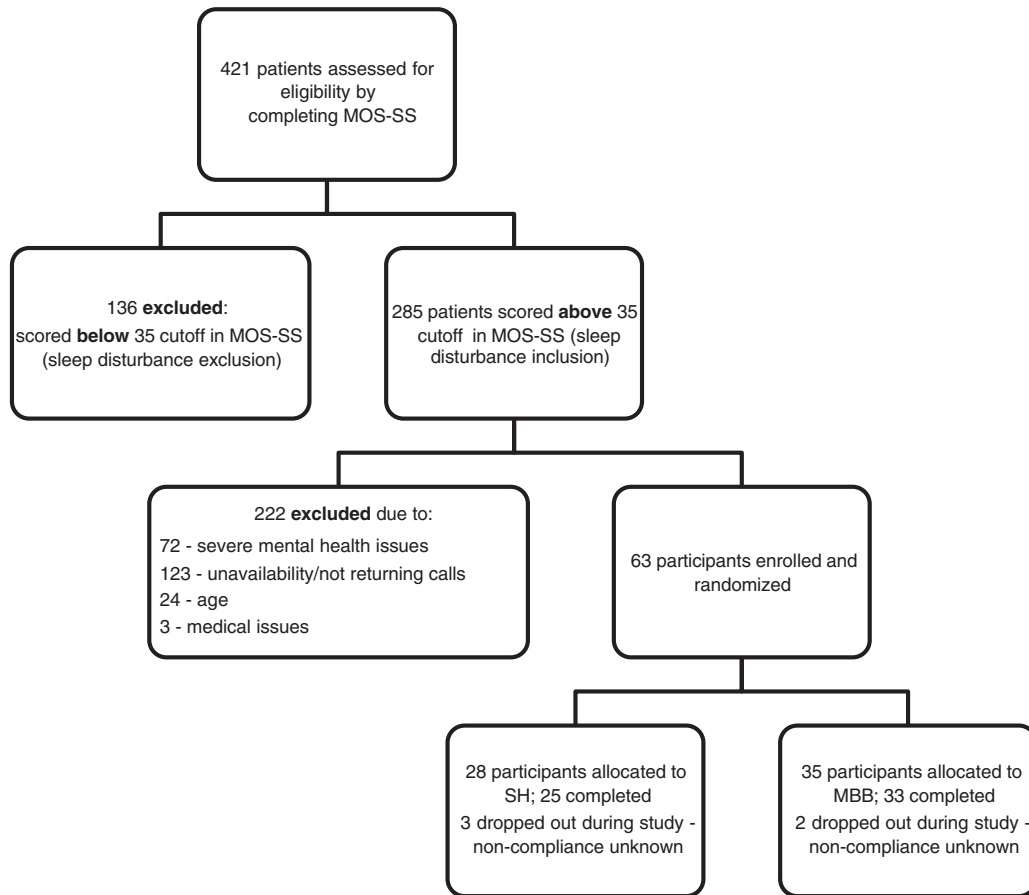


Fig. 1. Study flow diagram.

Descriptive statistics

As shown in Table 3, there were no differences between MBB and SH for demographics (age and sex) and symptom conditions at baseline. While the study comprised predominantly white male veterans, female veterans and other ethnic groups were included.

Table 3
Demographics of participants in each of the interventions in the study

	SH	MBB
Age	49.9 (10.3) *	53.8 (10.4)
Males	27	33
Females	1	2
Enrolled	28	35
Completed	25	33
Baseline characteristics		
Sleep Problems Index II score	56.4 (16.6)	61.4 (14.1)
Total sleep time (h)	5.5 (1.6)	5.7 (1.7)
Depression rating (CES-D)	24.0 (11.1)	24.5 (12.2)
PTSD Symptoms (PCL-M)	43.5 (18.0)	42.2 (16.6)

* Standard deviation in parentheses.

Hypothesis-driven statistical analyses

Primary outcomes

Sleep. Fig. 2 represents the distribution of change scores from Pre to Post for the MOS-SS subscale Sleep Problems Index II. Results are highly similar when Sleep Problems Index I was used. The proportion of individuals who reported no improvement or a deterioration in sleep performance from Pre to Post was smaller in MBB (3%, one out of 33) than that in SH (24%, six out of 25). Furthermore, the most frequent improvement change score observed in MBB was between 20 and 30, while that in SH was between 0 and 10.

Fig. 3 shows the means for Sleep Problems Index II across the interventions as a function of period. The horizontal line in the figure represents the 35 cut-off, identifying individuals with a high probability of exhibiting clinically relevant sleep problems. Subjects in both MBB and SH groups reported marked improvements in sleep after both one (Week 1) and two (Post) sessions, which appear to be more pronounced in MBB.

Confirming these observations, the mixed-effects analysis indicated a significant intervention by period interaction

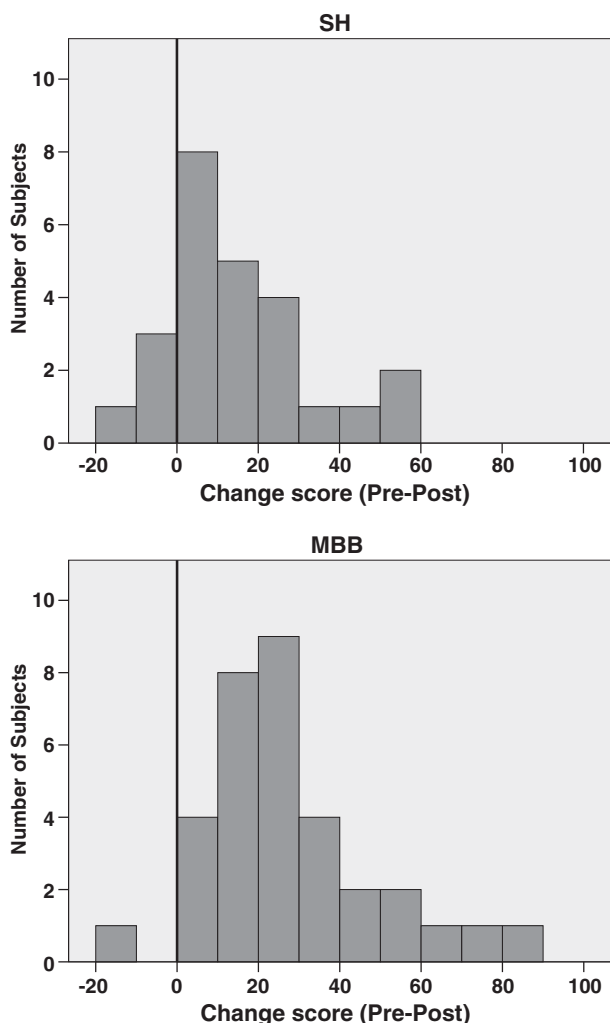


Fig. 2. Histogram distribution for interventions depicting the magnitude of change in sleep symptoms from Pre- to Post-interventions, based on MOS-SS Sleep Problems Index II. A fewer subjects in MBB showed no improvement or worsening of sleep symptoms (3%, one out of 33) than in SH (24%, six out of 25). Note that two of the six SH individuals had change scores of 0, included in the third bin; positive values=sleep symptom improvement, negative values=worsening of sleep symptoms.

effect ($P=.028$) with a corresponding effect size (ES) of .74. Specific (a priori) contrasts showed that the magnitude of improvement in sleep for MBB was significantly greater than that for SH at both Week 1 [MBB (21.0, ES=1.3) vs. SH (12.8, ES=.73); $P=.047$] and at Post [MBB (28.0, ES=1.89) vs. SH (14.8, ES=.71); $P=.012$] (Fig. 3).

Table 4 presents the means for each individual MOS-SS subscale. Mixed-effects analysis indicated a significant intervention by period interaction effect for the sleep disturbance subscale ($P=.006$). Specific contrasts showed that the mean sleep disturbance score in MBB was significantly lower than that in SH at Week 1 ($P=.021$) and Post ($P=.002$). For within-groups analyses, mean sleep disturbance scores declined significantly at Week 1 (MBB, $P<.001$; SH $P<.01$) and Post (MBB, $P<.001$; SH $P<.001$). No other subscale exhibited significant intervention by period

interaction effects. Thus, improvements in the sleep disturbance subscale may account for the results obtained based on the Sleep Problems Index II, in terms of the effects of both interventions to facilitate improvements in sleep symptoms.

Quality of life. Table 5 presents the results obtained for all subscales in SF-36V. Observed changes in subscale and overall QOL indicators were in the expected direction for MBB participants compared to those in SH participants. However, mixed-effects analysis revealed that the intervention by period interaction was not significant for any one of these subscales.

Secondary outcomes

PTSD Symptoms. Fig. 4A indicates mean PCL-M scores across the interventions as a function of period. The MBB group showed a greater decline in scores than did the SH group from Pre and Post.

Confirming this observation, the two-factor mixed-effects model analysis revealed a significant intervention by period interaction effect ($P=.029$, ES=.32), indicating that the severity of PTSD symptoms based on PCL-M scores at Post was significantly lessened in MBB (change score=8.1, ES=.54) than in SH (change score=2.6, ES=.13).

Since mean PCL-M Pre scores in both groups were below the 50 cutoff indicative of more severe PTSD symptoms, we examined whether the two interventions differed for those participants whose PCL-M score was greater than 50. Fig. 4B shows that PTSD symptoms were reduced at Post to a greater extent in MBB ($n=11$) than in SH ($n=9$), which replicates the same pattern of change observed across all

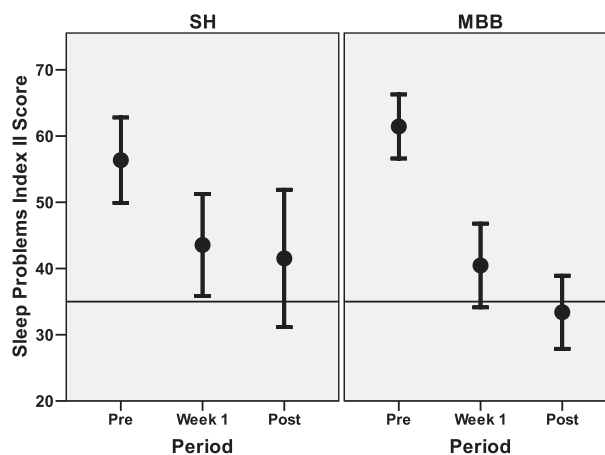


Fig. 3. Effects of sleep interventions on sleep performance. Means and 95% CIs of MOS-SS Sleep Problems Index II scores for MBB and SH at Week 1 (just prior to the start of the second session) and Post. Mixed-effects analysis of sleep scores indicated a significant overall intervention by period interaction effect ($P=.028$), in which MBB led to greater improvements in sleep performance than did SH at both Week 1 ($P=.047$) and Post ($P=.012$). In addition, at Post, mean sleep score in MBB declined below the 35 cutoff, indicating that the majority of MBB subjects reported sleep improvements reaching subclinical levels.

Table 4
Means and standard deviations of MOS-SS subscale scores for comparisons between SH and MBB

MOS-SS Subscales	SH			MBB		
	Pre	Week 1	Post	Pre	Week 1	Post
Sleep Adequacy	33.21 (21.44) *	42.80 (23.90)	45.60 (27.85)	29.43 (19.39)	48.24 (23.67)	54.24 (22.50)
Sleep Disturbance	56.35 (23.11)	43.40 [#] (22.97)	41.58 ⁺ (27.69)	62.68 (16.69)	37.79 [#] (19.83)	31.97 ⁺ (19.04)
Somnolence	55.95 (20.56)	38.13 (24.69)	34.93 (28.11)	53.90 (24.11)	37.45 (24.51)	30.91 (23.14)
Snoring	50.71 (36.71)	40.00 (35.39)	36.80 (33.51)	60.00 (34.82)	45.81 (35.48)	44.67 (38.12)
Wake Up Short of Breath/With a Headache	27.14 (28.40)	14.40 (24.85)	18.40 (28.82)	38.29 (30.82)	28.24 (31.57)	17.58 (21.07)
Sleep Problems Index I	54.52 (16.11)	42.53 [#] (18.74)	41.60 ⁺ (24.70)	60.29 (15.39)	40.78 [#] (19.76)	32.93 ⁺ (16.72)

* Standard deviation in parentheses.

[#] For Week 1–Pre, $P < .01$.

⁺ For Post–Pre, $P < .01$.

subjects (Fig. 4A). Since statistical analysis of this subsample was not appropriate, we analyzed the entire data set using a mixed-effects ANCOVA with Pre score as a covariate and Post score as a dependent variable.

Fig. 5 presents scatter plots of Post plotted against Pre PCL-M scores. Each line corresponds to the regression of the Post measure on the Pre for SH and MBB, respectively. Since there is a significant interaction ($P = .011$) between intervention and the covariate (Pre PCL-M score) revealing nonhomogeneity of regression, this shows that MBB and SH slopes are not parallel, indicating that one cannot interpret the intervention effect as a test of adjusted means. (This nonhomogeneity of regression can be translated as a relational outcome of the intervention on the PCL-M scores from Pre to Post [42,43].) Instead, we employed the Johnson–Neyman [44] procedure, examining adjusted differences for various values of Pre (covariate) scores. Mean Post scores between the two interventions were significantly different ($P = .049$), conditional on Pre scores greater than or equal to 38.9, as indicated by the shaded region of the graph in Fig. 5. At the clinically meaningful value of 50 in Pre PCL-M total score, the adjusted mean Post

PCL-M score for MBB was significantly lower ($P = .001$) than that for SH group. Thus, MBB did have a positive impact in reducing Post scores, relative to SH, in individuals with Pre PCL-M scores of 50 and greater. This suggests that MBB was effective for reducing self-reported PTSD symptoms in veterans whose initial PCL-M scores were above 50, supporting potential impact of MBB on self-reported PTSD symptoms.

Mindfulness. Fig. 6 shows 5F-MQ means for overall levels of mindfulness across the two interventions as a function of period. A two-factor mixed-effects model analysis revealed a significant intervention by period interaction effect ($P = .052$, $ES = .46$). Thus, MBB showed a greater increase from Pre to Post in mindfulness scores (9.3, $ES = .46$) than did SH (-0.16 , $ES = -.01$).

Depression. Depression symptoms, as reflected in CES-D scores from Pre to Post, decreased in both interventions. While the decrease was greater for MBB (5.8) than for SH (2.0), the mixed-effects model analysis indicated that the intervention by period interaction effect was not significant.

Table 5
Means and standard deviations of (1) SF-36V subscales and total scores and (2) CES-D total scores, for comparisons between SH and MBB

	SH		MBB	
	Pre	Post	Pre	Post
<i>(1) SF-36V</i>				
Physical functioning	65.42 (23.57) *	65.20 (21.38)	61.00 (26.17)	65.48 (26.26)
Role limitations due to physical health	52.68 (29.83)	59.50 (28.36)	56.85 (26.78)	70.08 (22.08)
Role limitations due to emotional problems	57.44 (28.09)	64.33 (29.22)	62.38 (42.02)	72.98 (24.65)
Energy/fatigue	42.50 (13.30)	44.40 (16.48)	42.14 (15.59)	46.21 (14.09)
Emotional well-being	38.71 (9.62)	35.84 (14.81)	39.20 (11.67)	39.76 (13.53)
Social functioning	50.45 (26.02)	59.00 (31.15)	57.50 (28.79)	65.15 (21.60)
Pain	49.29 (27.59)	52.40 (27.09)	50.50 (24.73)	59.39 (19.05)
General health	53.35 (9.18)	51.30 (7.68)	55.11 (10.83)	51.52 (10.21)
One year physical health	40.18 (25.77)	45.00 (29.76)	44.29 (24.32)	49.24 (26.13)
One year emotional problems	38.39 (24.98)	45.00 (25.00)	42.14 (19.90)	53.79 (26.61)
Total SF-36V score	488.40 (138.66)	521.97 (162.09)	511.10 (127.90)	573.60 (115.95)
<i>(2) CES-D</i>				
Total CES-D score	23.96 (11.12)	22.00 (14.37)	24.51 (12.21)	18.73 (11.67)

* Standard deviation in parentheses.

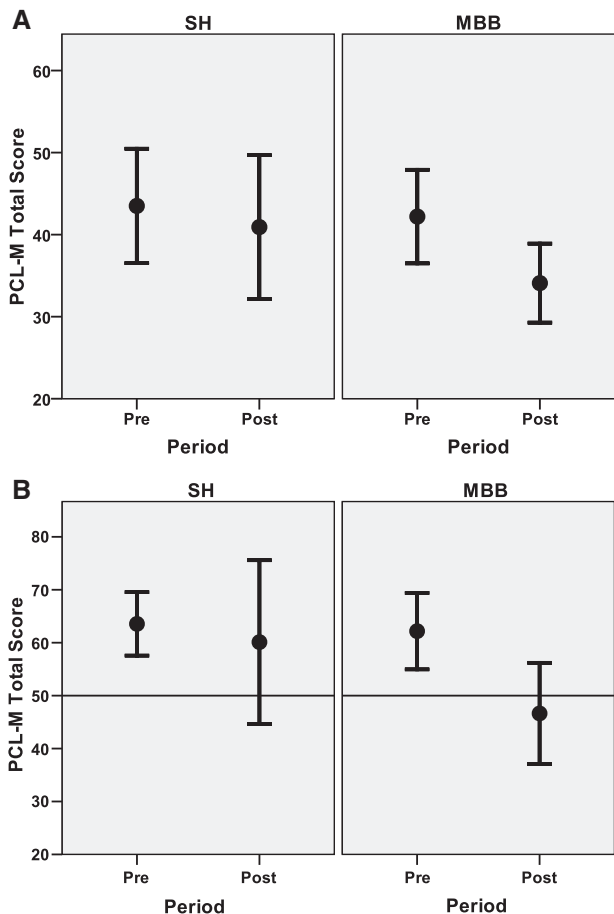


Fig. 4. Effects of sleep interventions on PTSD symptoms. (A) Means and 95% CIs of PCL-M total scores across interventions as a function of period. Mixed-effects analysis of PCL-M total scores showed a significant intervention by period interaction effect ($P=.029$). PTSD symptom scores were significantly lower for MBB than for SH at Post. (B) Mean (95% CI) PCL-M total scores between interventions for participants with Pre scores greater than 50. At Post, MBB participants ($n=11$) showed reductions in PTSD symptoms, while SH participants did not ($n=9$).

Table 5 at the bottom presents means and standard deviations of CES-D for both groups.

Discussion

Sleep-focused MBB in two sessions greatly reduced patient-reported sleep disturbance and PTSD symptoms, and increased higher overall levels of mindfulness than those observed in the standard-of-care SH intervention. These outcomes are notable, since significant reductions in self-reported PTSD symptoms were observed when MBB was specifically tailored for improving sleep without explicitly targeting PTSD. Similarly, mindfulness increased even though MBB involved no specific formal practice of mindfulness meditation. These results provide preliminary support for the possibility that sleep-focused MBB is a potentially beneficial intervention for individuals with sleep disturbance and other co-morbid symptoms (e.g., PTSD).

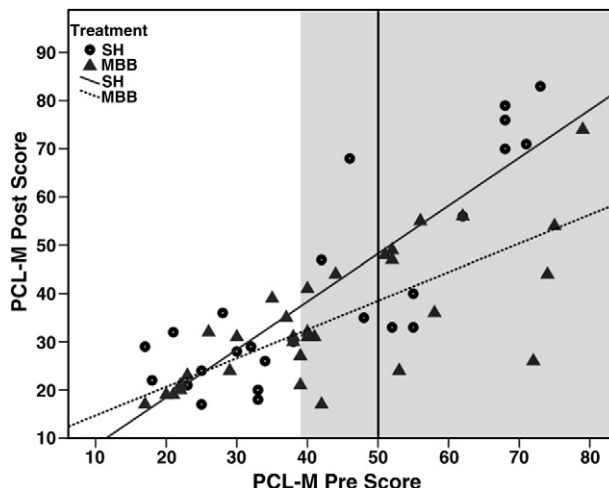


Fig. 5. Scatter plots with regression lines for Post vs. Pre PCL-M scores for each intervention. Slopes across the two groups are significantly different from each other ($P=.011$; slopes: SH, $r=0.99$; MBB, $r=0.59$), which required that the data should be analyzed by the Johnson–Neyman [44] procedure. PCL-M Post scores declined significantly in MBB than in SH for Pre scores 38.9 and greater ($P=.049$). Shaded region corresponds to values of Post PCL-M scores in which the two groups were significantly different (see text for more details).

In contrast, there were no reliable improvements in either depression symptoms or in quality-of-life indices such as pain, overall physical and mental health, or energy and vitality, in either intervention. It is possible that these indicators may be more resistant to short-term changes, and more beneficial outcomes may require longer intervention durations and increased number of intervention sessions. A future study should explore the issue of the minimum number of MBB sessions required to optimally produce changes in those indicators.

Our objective in this study was to assess the potential value of MBB in improving self-reported sleep and

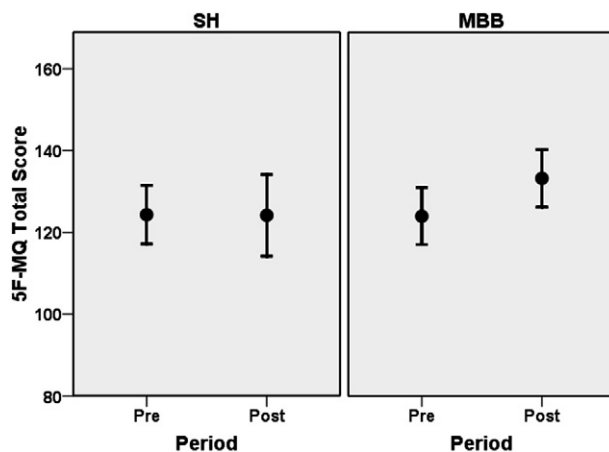


Fig. 6. Effects of sleep interventions on mindfulness measures. Means and 95% CIs of 5F-MQ scores for mindfulness across interventions as a function of period. Mixed-effects analysis revealed a significant intervention by period interaction effect ($P=.052$). Mindfulness increased significantly from Pre to Post in MBB but not in SH.

comorbid symptoms in a cross section of veterans visiting the VASLCHCS Primary Care clinics, without specifying what specific type of sleep problems they may have been experiencing. At post-assessment, mean self-reported sleep scores from MBB declined below the cutoff point indicative of sleep problems (greater than 35). The data are consistent with the hypothesis that MBB would improve self-reported sleep quality in veterans, encouraging a future clinical study of MBB with patients who may suffer from a specific sleep condition such as primary or secondary insomnia. However, at this point, we cannot claim that MBB effectively treated specific sleep disorders as assessed by clinical evaluation, including insomnia, sleep apnea, restless leg syndrome, or sleep-disordered breathing.

Improving sleep in individuals with PTSD using an adjuvant sleep intervention has begun to attract attention because of the known links between sleep disturbance and psychological health [7,45]. However, unlike other studies that examined whether a sleep intervention could improve PTSD symptoms as part of a general PTSD treatment regimen [12], in our study, we opted to target sleep exclusively, given the possibility that improved sleep can influence other health conditions, and we hypothesized that other co-morbid symptoms might be altered by a mind–body intervention selectively targeting sleep. For those patients with moderate to severe self-reported PTSD symptoms at pre-assessment, their post PCL-M scores in MBB dropped below the standard cutoff point of 50, a clinically meaningful severity level requiring more extensive clinical assessment. While the study did not confirm that any of our subjects had PTSD diagnosis, the data provide promising initial evidence that MBB positively altered self-reported PTSD symptoms in veterans. Our study showed that primary care patients self-reporting moderate to severe PTSD symptoms may be responsive to a mind–body intervention focusing on sleep even when it is not specifically targeting PTSD.

These data are consistent with findings obtained using other intervention approaches showing efficacy in treating sleep disturbance. CBT was effective over a short-term period (one to four sessions) [46,47] as was observed for MBB in two sessions in the present study. Conversely, MBSR-type therapies may require longer intervention durations (i.e., six sessions or longer) to exert their effects (for a more extensive discussion on this issue, see Ref. [48]). Nonetheless, these findings are generally consistent with another study reported in the literature demonstrating the effectiveness of a brief behavioral intervention targeting insomnia and post-traumatic nightmares [12].

The effectiveness of mindfulness practice facilitating health and well-being, including sleep, has been reported in numerous studies utilizing several interventions [21–29]. We postulated that increased mindfulness or awareness might have in part led to improvements in sleep and reductions in self-reported PTSD symptoms. Changes in mindfulness in this study are notable, especially given (1) the brief nature of the intervention (two sessions, once per

week), and (2) unlike other mindfulness-based interventions (MBSR, MBCT) in which mindfulness meditation practices are core interventional components and are intrinsic to their effectiveness, MBB curriculum does not include formal meditation practice *per se*. This raises an interesting question as to how MBB exerted its effects, and future studies should examine this question empirically.

Our study population comprised a diverse group of veterans currently treated by VA physicians. We strategically selected primary care clinics at the VASLCHCS to recruit these subjects since (1) a high proportion of veterans suffer from sleep disturbance that is often unreported and untreated, and (b) in veterans, sleep disturbance is commonly associated with numerous physical and mental health co-morbidities, especially PTSD and depression [5,6]. Since this study assessed the efficacy of MBB as a novel sleep management intervention in veterans, we did not restrict our selection criteria to a specific sleep problem. The more inclusive selection criteria in this study as well as the screening and testing of veterans over the course of 6 months may enhance the generalizability (i.e., external validity) of these findings to other veterans, since those enrolled in the study may be representative of the larger veteran population seen at primary care clinics within the VA Health Care System. The results of our study have important implications for targeting sleep in veterans, with potential additional benefits to co-morbid health symptoms.

Nonetheless, we are keenly aware of limitations of this pilot study that we plan to address in future clinical trials testing MBB. Limitations include the following: no clinical evaluation of participants by clinicians (veterans who participated in the study, however, had been seeing their primary care physicians for any medical problems), no explicit assessment of intervention fidelity, a small difference of approximately 30 min in the duration of the two intervention programs, assessment of intervention efficacy solely based on self-report questionnaires, no measures of daily changes in sleep patterns based on sleep diary data, and no follow-up assessment. While these limitations do not entirely detract from the results obtained, future studies for testing MBB should implement stronger measures to improve these shortcomings.

The present findings suggest that MBB can serve as a cost-effective nonpharmacological intervention program for sleep management in primary care settings in veterans with self-reported sleep disturbance. Furthermore, because MBB is easy to learn and cumulative benefits are obtained in only a few sessions, MBB can develop into an ideal vehicle for managing multiple co-morbid symptoms and may specifically serve as a front-loaded program for addressing sleep problems among VA patients with psychological co-morbid conditions (e.g., PTSD). Future studies might investigate the degree to which veterans may reduce the need for and use of sleep medications and may include an assessment of well-being in veterans enhanced by MBB.

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