



ORIGINAL ARTICLE

Brief behavioral treatment for insomnia improves psychosocial functioning in veterans: results from a randomized controlled trial

Shira Maguen^{1,2,3,*}, Rebecca Gloria¹, Joy Huggins¹, Lizabeth A. Goldstein^{1,2,3}, Jennifer C. Kanady^{1,2,3}, Laura D. Straus^{1,2,3}, Thomas J. Metzler^{1,2,3}, Callan Lujan^{1,4}, Thomas C. Neylan^{1,2,3}

¹San Francisco Veterans Affairs Health Care System, San Francisco, CA, ²Department of Psychiatry and Behavioral Sciences, University of California, San Francisco, CA. ³Sierra Pacific Mental Illness Research Education, and Clinical Center, San Francisco, CA and ⁴Department of Psychology, Washington State University, Pullman, WA

*Corresponding author. Shira Maguen, Department of Mental Health, San Francisco VA Health Care System, 4150 Clement Street (116-P), San Francisco, CA 94121. Email: shira.maguen@va.gov.

Abstract

Study Objectives: Our goal was to compare brief behavioral treatment for insomnia (BBTI) to a progressive muscle relaxation training (PMRT) control condition among veterans with insomnia, examining psychosocial functioning as a primary outcome and sleep-related outcomes, mood, cognition, and pain as secondary outcomes.

Methods: Veterans were randomly assigned to either BBTI or PMRT ($N = 91$; 24–74 years; $M = 49$ years). BBTI consisted of two in-person (60-min and 30-min sessions) and two telephone sessions (20-min each), and the PMRT control condition was matched to BBTI for session duration and type. Veterans were assessed through clinical interview at baseline and self-report measures at pre-, mid-, and posttreatment, as well as 6-month follow-up for the BBTI condition to assess sustained response. Measures also included continuous sleep monitoring with sleep diary.

Results: Intent-to-treat analyses demonstrated that individuals who completed BBTI versus PMRT reported greater improvements in work, home, social and cognitive functioning, insomnia symptom severity, mood, and energy. Improvements in psychosocial functioning, insomnia symptoms, and mood were maintained 6-months following BBTI treatment completion.

Conclusions: Veterans who received BBTI improved and maintained gains in psychosocial functioning, insomnia, and mood. BBTI is a treatment that can be implemented in primary care, mental health, or integrated care settings and provide symptom relief and improved functioning among those with insomnia, one of the most commonly reported mental health problems among veterans.

Clinical trial registration: NCT02571452.

Statement of Significance

Veterans with insomnia receiving a four-session brief behavioral treatment for insomnia (BBTI) made significant gains in work, home, social and cognitive functioning, insomnia severity symptoms, mood, and energy, compared with those receiving progressive muscle relaxation training. This is an important advancement given that insomnia and sleep problems are one of the most commonly reported mental health problems among veterans, who also experience barriers and stigma when seeking mental health treatment. BBTI can be integrated into primary care and integrated care settings to minimize stigma and provide immediate care to veterans with sleep problems. Future research should explore the impact of BBTI administered remotely, gender differences with BBTI, and the impact of BBTI for active duty personnel with insomnia.

Key words: insomnia; sleep; functioning; mental health; treatment; veteran

Submitted: 29 May, 2020; Revised: 28 July, 2020

Published by Oxford University Press on behalf of Sleep Research Society (SRS) 2020.

This work is written by (a) US Government employee(s) and is in the public domain in the US.

Introduction

Insomnia is a growing public health concern and is associated with a number of negative outcomes including social and occupational impairment, concentration and memory problems, fatigue, chronic pain, motor impairments, and motor vehicle accidents [1–3]. Individuals with inadequate sleep take more risks, make poorer decisions, and demonstrate worse performance on a number of tasks [1, 3–5]. Sleep disturbances are highly prevalent in military personnel returning from recent deployments; impact psychosocial functioning, cognitive functioning, productivity, and quality of life; and are one of the most common reasons that veterans seek treatment [6–11]. In fact, 72% of veterans reported sleep duration of 6 h or less after deployment to Iraq, and short sleep duration was more common among those reporting combat exposure [9]. Even after controlling for combat exposure, less sleep was associated with a host of mental health diagnoses and high-risk health behaviors including smoking, alcohol use, and suicide.

Much of the prior research examining the efficacy of insomnia treatment among veterans has focused on sleep medications rather than behavioral interventions [12–14], though several recent studies have begun to examine behavioral sleep treatments for veterans [15, 16]. The American Academy of Sleep Medicine and American College of Physician practice guidelines recommend a behavioral intervention, Cognitive Behavioral Therapy for Insomnia (CBT-I), as the first-line intervention for insomnia, and younger and older adults both prefer behavioral interventions over sleep medications when treating insomnia [17–20]. Cognitive Behavioral Therapy for Insomnia is generally provided in mental health clinics and lasts 6–8 sessions [21]. In response, the VA rolled out CBT-I and has provided system-wide trainings to interested clinicians, mainly to mental health providers [22]. A rapid evidence assessment focusing on psychological interventions for veterans with sleep disturbances found that CBT-I was promising in treating veterans with general sleep disturbance, yet the importance of future studies to dismantle the critical components of CBT-I is also highlighted [16]. Importantly, most veterans who need these treatments report a large number of barriers to seeking mental healthcare [23]. As a result, many veterans who could benefit from behavioral interventions do not get needed care. There is also evidence that even veterans who come to a mental health clinic once or twice may not follow through with care [24]. Furthermore, there is support for briefer insomnia treatment in a study of recently returning veterans, who reported a preference for insomnia treatment lasting 5 weeks or less [25]. Consequently, Phelps and colleagues call for insomnia treatment that is accessible, targeted, time-efficient, and stigma reducing to best serve veterans [16].

Brief behavioral treatment for insomnia (BBTI) is a four-session behavioral insomnia treatment that consists of two in-person (60-min and 30-min sessions) and two telephone sessions (20-min each) with a clinician. A recent noninferiority trial of BBTI and CBT-I among veterans found that both treatments resulted in significant reductions of insomnia symptoms and that there were no significant differences in the groups on any outcome (although further evidence was needed to establish noninferiority) [26]. In a randomized, controlled trial of 79 patients with chronic insomnia and common comorbidities in primary care, BBTI resulted in significant improvements in self-reported and objective sleep, depression and health measures,

with results maintained at 6-month follow-up [27]. Subsequent trials of BBTI with older adults have found improvements in multiple measures of sleep, but findings have been mixed with respect to depression symptoms and cognitive outcomes [28, 29]. Although the BBTI studies found excellent improvements in primary care patients, these individuals were older adults in community clinics. Gunn and colleagues reviewed six BBTI studies and reported favorable results in each study, with some cases resulting in full remission of insomnia [15]. There is one known study of BBTI in younger veterans [30]. In this preliminary randomized controlled trial of BBTI versus informational control in 40 Iraq and Afghanistan veterans, both conditions were associated with clinically significant improvements in insomnia outcomes, yet a larger trial was recommended.

Different than past insomnia treatment studies, our main outcome of interest was psychosocial functioning. Although less commonly explored as a main outcome, among Iraq and Afghanistan combat veterans using VA care, 40% reported functional difficulties in the last month, with a quarter of veterans reporting psychosocial functioning problems in all of the areas assessed (e.g. social relations, productivity, community participation, and self-care and leisure activities) [31]. In our trial of CBT-I in PTSD patients, we found robust improvement in psychosocial functioning [32]. This supports our premise that a scalable and feasible behavioral intervention for insomnia has great potential to improve the functional capacity of veterans. Outcomes such as psychosocial functioning are rarely measured in insomnia treatment. Functioning outcomes are critical to track in veterans, given significant reintegration problems in these domains [31]. Consequently, our goal was to evaluate the efficacy of BBTI in a larger veteran sample that was diverse in age. In addition, we employed an active control group, using progressive muscle relaxation that was matched for time and attention. We chose PMRT as our control group because we believe it would be feasible, acceptable, and credible to participants, likely to keep them engaged, and would result in new skills that could be beneficial in their lives. Furthermore, despite its benefits, there was a precedent for using PMRT as a control group in other insomnia trials [33]. Our goal was to examine functional outcomes, including work and social functioning as a primary outcome, and sleep-related outcomes as a secondary outcome. As additional secondary outcomes, we examined mood and cognitive outcomes, given that prior BBTI studies have found mixed results with these outcomes.

Methods

Participants

Participants were military veterans between the ages of 18 and 75 years who had chronic insomnia based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) diagnostic criteria. Participants were recruited from January 2016 to August 2018 through local advertisements and referrals from local VA medical center research studies or VA clinicians. Participants were also recruited through direct mailings to veterans who were establishing or had been receiving care at VA hospitals in the San Francisco Bay Area and to veterans listed in the Department of Defense Manpower Data Center Reporting System (<https://www.dmdc.osd.mil/dmdcrs/>) who lived within a 40-mile radius of San Francisco. Individuals who were engaged

in psychiatric treatment, including psychotherapy or medications, were included in the study provided they had been in psychotherapy for at least 3 months and had been stable on psychotropic medications for a least 1 month prior to screening procedures, with no plans to discontinue or begin new treatment during the course of study treatment. Veterans with chronic pain, traumatic brain injury, untreated mild obstructive sleep apnea (OSA; apnea-hypopnea index [AHI] score of ≤ 15), and treated OSA were also included in the study, given that prior research has found that these individuals can benefit from behavioral interventions for insomnia [27, 34–37]. Treated OSA was determined by asking individuals whether they were using a positive airway pressure (PAP) device and about frequency of use of the device. Reported use of a PAP device a minimum of 4 h per night was considered treated OSA. When available in the VA medical records system, records were reviewed to confirm participant report.

Exclusion criteria were: (1) lifetime history of any psychiatric disorder with psychotic features, bipolar disorder, or moderate to severe alcohol or substance use disorder within the past year. Individuals who met criteria for mild alcohol or substance use disorders were asked to reduce alcohol consumption to recommended limits during the course of the study and/or refrain from drug use to be included, (2) working night or rotating shifts, (3) pregnancy, (4) prominent suicidal or homicidal ideation, (5) unstable housing, (6) high-risk for OSA, indexed by a positive score on three categories on the Berlin Questionnaire (BQ) [38, 39], (7) untreated moderate to severe OSA, as indicated by self-report, medical chart review or an AHI score of >15 assessed by home sleep apnea testing (HSAT), (8) untreated medical conditions that affect sleep (e.g. restless legs syndrome), and (9) non-clinically significant or subthreshold insomnia, as indexed by a score of 0–14 on the Insomnia Severity Index (ISI) [40].

See Figure 1 for the Consolidated Standards of Reporting Trials (CONSORT) flow diagram. A total of 628 individuals completed a brief phone screen to assess initial eligibility criteria. A total of 453 individuals were not eligible to participate in the study. Of the 175 individuals who were not excluded during the phone screen, 63 people endorsed symptoms resulting in a positive score in two categories on the BQ and completed HSAT using a Type III device (ApneaLink; ResMed Corporation, Poway, CA) to determine eligibility to continue the screening process. A total of 40 people had an AHI score of ≤ 15 , and were eligible to continue screening. Twenty-three individuals were excluded based on HSAT. A total of 152 individuals met initial criteria based on the phone screen ($n = 112$) and HSAT ($n = 40$) and were invited to the lab to complete additional screening procedures to determine eligibility for treatment randomization. These procedures included providing a medical history and completion of a diagnostic interview that included the Structured Clinical Interview for DSM-5, Research Version (SCID-5-RV; American Psychiatric Publishing) [41], the Clinician-Administered PTSD Scale (CAPS-5) [42], and the Ohio State University Traumatic Brain Injury Identification Method (OSU TBI-ID) [43]. Sixty-one individuals were excluded after this final screening procedure.

A total of 91 participants completed all screening procedures, met inclusion criteria, and were randomized to treatment. Informed consent was obtained from all participants at their initial in-person screening appointment (i.e. at HSAT or diagnostic clinical interview appointment). This project was approved by the Institutional Review Boards at the University

of California, San Francisco and San Francisco VA Health Care System and was registered at clinicaltrials.gov with registration number NCT02571452.

Procedures

Study design

The study was a randomized controlled trial design with two parallel groups comparing BBTI to a progressive muscle relaxation training (PMRT) control treatment. Figure 2 illustrates the general study design and procedures. Participants were randomly assigned to condition by computer-generated block randomization (block sizes = 4, 6, and 8). Randomization was stratified by age (50 years old or younger versus over 50 years old) and study therapist (3 therapists), resulting in 6 separate block randomization lists to represent all combinations of age and therapist. Diagnostic clinical interviewers were blind to participant treatment condition during both eligibility screening and posttreatment interviews. These interviewers were not involved in treatment provision or any other data collection procedures and had minimal contact with other research staff to ensure the integrity of their blind status.

Screening

During the first phase of screening, study recruiters conducted a brief telephone interview to inquire about inclusion/exclusion criteria and determine probable OSA and insomnia diagnoses. Individuals who had positive scores in two categories on the BQ during the phone screen were invited to complete HSAT to rule-out the possibility of undiagnosed moderate to severe OSA before continuing the screening process. Individuals with an AHI score ≤ 15 and individuals who passed the telephone screen were invited to continue to the second phase of screening. Participants completed a diagnostic clinical interview at the lab to determine eligibility for treatment. Individuals who had previously come to the lab to provide informed consent were given the option to complete the clinical interview by phone. Participants who met inclusion/exclusion criteria following the diagnostic clinical interview were randomized to one of the two treatment conditions.

Treatment and follow-up

The treatment phase of the study included a baseline appointment, four treatment sessions, and a posttreatment appointment. At the baseline appointment, participants completed web-based self-report measures that were administered using Qualtrics software (Qualtrics, Provo, UT). They also met with their assigned study therapist to provide a brief history of their sleep difficulties, review instructions for completing sleep diaries, and receive treatment group assignment. Participants completed a daily sleep diary for the 1-week baseline period through the posttreatment appointment, for a total of 5 weeks of sleep diary recordings. The self-reported measures were also completed before the third treatment session and at the posttreatment appointment. Participants attended a posttreatment appointment to return all sleep diaries, complete self-report measures, and undergo a second diagnostic clinical interview. Individuals assigned to the BBTI treatment condition completed follow-up assessments that included 1 week of sleep diary recordings and self-report measures at 6 months posttreatment.

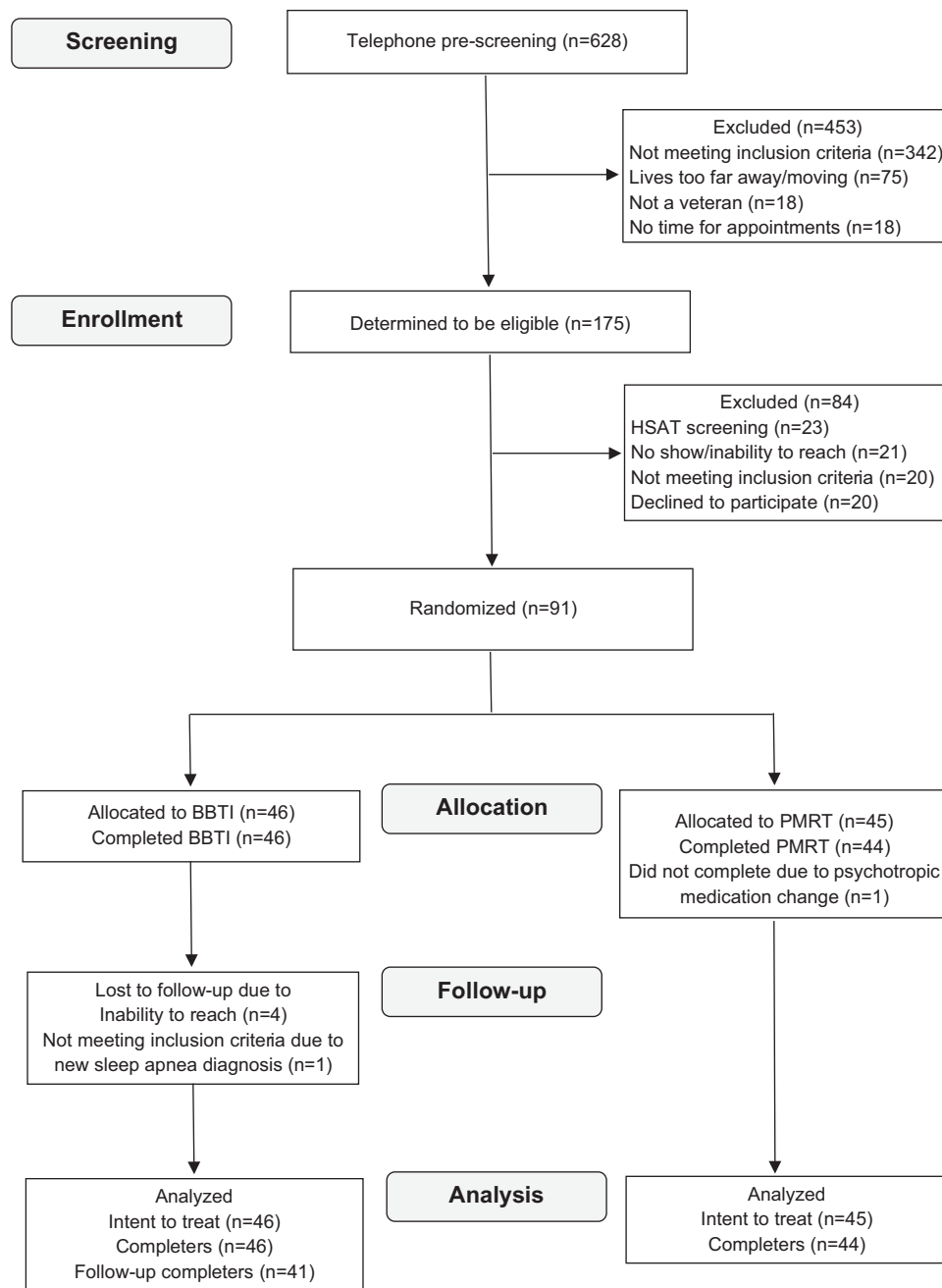


Figure 1. Consort diagram. Flowchart of participant numbers through the trial. HSAT, home sleep apnea testing; BBTI, brief behavioral treatment for insomnia; PMRT, progressive muscle relaxation training.

Measures

Phone screen

Prospective participants were asked questions about their age, military service, pregnancy, work schedule, housing status, alcohol and substance use, psychiatric and medical diagnoses, and medications, as well as questions from the ISI and BQ measures to determine eligibility for in-person screening. The ISI is a self-report inventory of perceived insomnia severity that assess sleep onset, maintenance, satisfaction with sleep, daytime impairment, and degree of distress caused by sleep disturbance [40]. It is a valid and reliable measure that consists of seven items rated on a five-point Likert scale and a total possible score

ranging from 0–28, with higher scores indicating more severe insomnia symptoms. The internal consistency of the ISI was found to be excellent (Cronbach's $\alpha = 0.74$) and has been validated with both sleep diary and polysomnography [40].

The BQ is a widely used brief self-report screen for sleep apnea that has three categories of questions that assess snoring (category 1), waketime somnolence (category 2), and high blood pressure and body mass index (category 3) [38]. Category 1 is positive if respondents report frequent loud snoring or apneas, category 2 is positive if responses indicate frequent and persistent waketime sleepiness, and scores on category 3 are positive if individuals have a body mass index >30 or a history of hypertension.

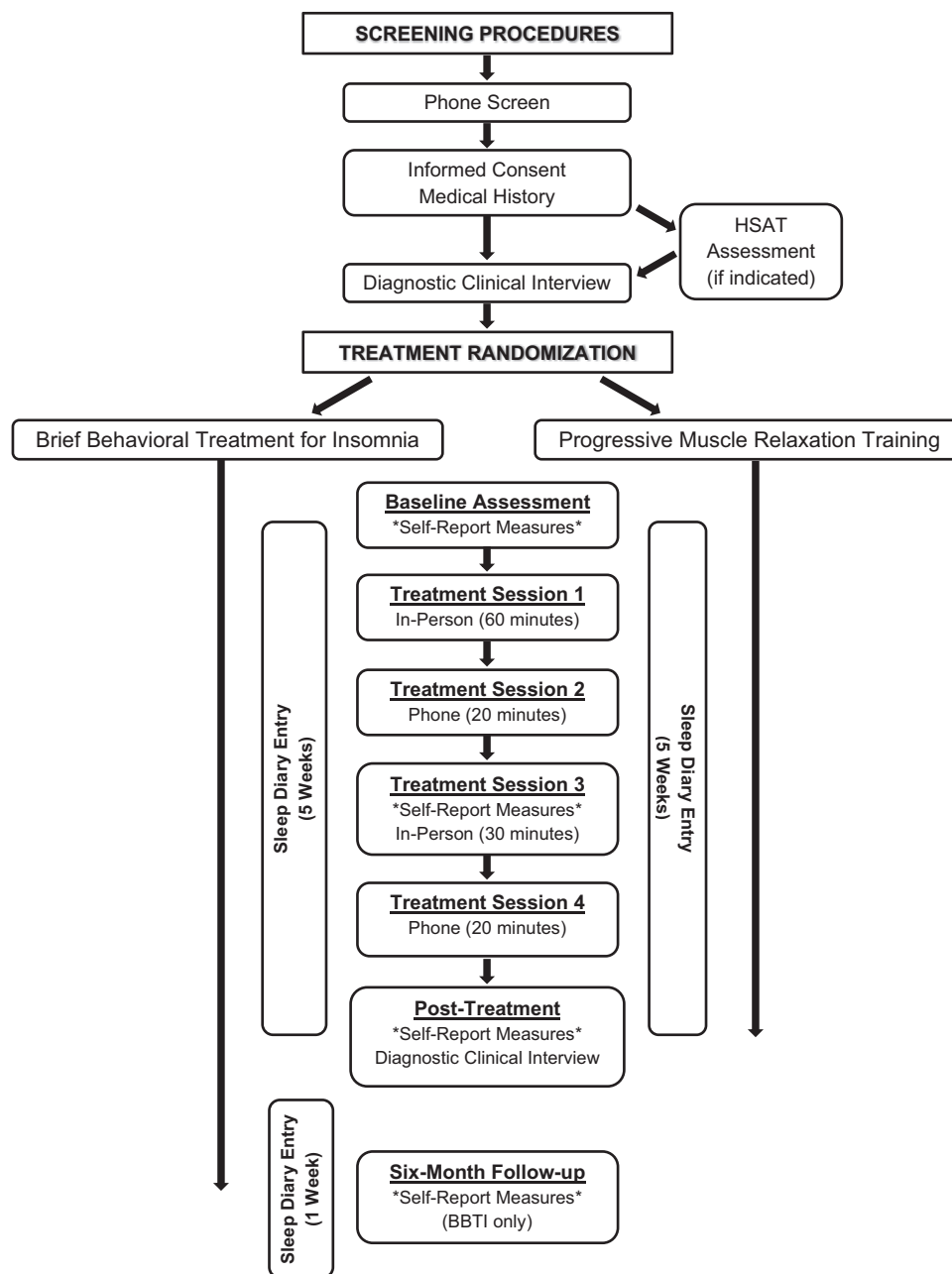


Figure 2. Study design. General procedures for participants. HSAT, home sleep apnea testing; BBTI, brief behavioral treatment for insomnia.

Individuals with positive scores on at least two categories are considered high-risk for OSA. The BQ has excellent internal validity (Cronbach $\alpha = 0.86$ and 0.92 for categories 1 and 2, respectively) and the sensitivity to detect OSA in the general population is high (89%) when validated with polysomnography [38, 39].

Clinical interview assessments

Participants who passed the initial phone screening, and if applicable, HSAT, provided detailed information about their medical history and current medication use. They also participated in an audiotaped diagnostic interview conducted by a masters level clinical evaluator that included the SCID-5-RV, CAPS-5, and OSU TBI-ID. The SCID-5-RV is a semi-structured diagnostic interview used to diagnose DSM-5 disorders. It has been shown to have good reliability [41]. The CAPS-5 is a structured interview

that is a gold standard for assessment of PTSD [42]. It provides both a dimensional and categorical measure of current PTSD and the frequency and intensity of PTSD-related symptoms. The OSU TBI-ID is a standardized procedure to elicit an individual's lifetime history of TBI, with good reliability and predictive validity [43, 44]. All clinical interviews were recorded, and interviews were reviewed for scoring accuracy and consistency of administration by two doctoral-level psychologists. Additionally, clinical evaluators attended weekly training meetings to ensure reliability of ratings and discuss any difficult cases.

Self-report measures

Participants completed self-report measures assessing quality of life, insomnia symptoms, mood, cognition, and physical pain at multiple times during the study.

The primary outcome measure was the Work and Social Adjustment Scale (WSAS) [45]. The WSAS was used to assess functioning in work, home management, social and private leisure activities, and relationships with others. It is a five-item measure, with each item rated on a nine-point Likert scale, and higher scores reflect greater impairment. The WSAS has adequate internal consistency ($\alpha = 0.70\text{--}0.94$) and reliability ($r = 0.73$). In a study of individuals with insomnia, the WSAS had excellent internal consistency (Cronbach's $\alpha = 0.91$) and reliability ($r = 0.99$) [6].

The Insomnia Quality of Life Scale (IQLS) is a 16-item measure that is rated on a five-point Likert scale, with higher scores reflecting greater impairment [46]. It was developed specifically for use in insomnia clinical trials and has five subscales that index physical activity, energy or will to do things, cognition, social impact, and psychological impact. This inventory effectively differentiates quality of life responses of individuals with severe insomnia from those with mild or no insomnia. The internal consistency of the IQLS was found to be good (Cronbach's $\alpha = 0.78$).

The ISI, described above, the Epworth Sleepiness Scale (ESS) and Pittsburgh Sleep Quality Index (PSQI) were administered to assess insomnia symptoms and sleep-related behaviors. The ESS is an eight-item instrument with items addressing daytime sleepiness in common real-life situations rated on a four-point Likert scale, with higher scores indexing more severe symptoms [47]. The ESS has acceptable convergent validity with sleep latency (SL; $r = -0.514$).

The PSQI provides a subjective assessment of sleep quality, SL, sleep duration, sleep efficiency, sleep disturbances (including nightmares), use of sedative-hypnotics, and daytime energy [48]. It is a widely used 19-item measure, with higher scores indicating poorer sleep quality. The PSQI has good internal consistency (Cronbach's $\alpha = 0.70\text{--}0.83$) and construct validity when compared with polysomnography, actigraphy, and ISI scores [49].

The Multiple Abilities Self-Report Questionnaire (MASQ) was administered to assess cognitive functioning in the domains of verbal memory, attention and concentration, language, visual memory, and visual-perceptual ability [50]. The MASQ is a 38-item self-report measure and each item is rated on a five-point Likert scale, with higher scores representing greater perceived cognitive difficulties. The internal consistency of the MASQ is excellent (Cronbach's $\alpha = 0.92$) and it has good concurrent validity compared with neuropsychological test results.

The PTSD Checklist was administered to assess DSM-5 symptoms of PTSD (PCL-5). The PCL-5 consists of 20 items scored on a five-point Likert scale, with higher scores suggesting more severe PTSD symptoms [51]. The PCL-5 has excellent reliability (Cronbach's $\alpha = 0.95$) in military samples [52].

The Beck Depression Inventory, revised (BDI) is a widely used self-report measure assessing the severity of 21 depressive symptoms in the past week [53]. The BDI has good internal consistency (Cronbach's $\alpha = 0.79\text{--}0.90$) and validity ($r = 0.72$) in psychiatric samples [54].

The Patient-Reported Outcomes Measurement Information System (PROMIS) Pain Intensity and Pain Interference scales were used to assess subjective severity of pain and the extent to which pain impedes daily functioning [55]. The PROMIS Pain Intensity Scale is a single item, 0–10 self-report numeric rating scale for assessing current level of pain and has excellent construct validity when compared with the Brief Pain Inventory

severity measure ($r = 0.81$). The PROMIS Pain Interference Scale is an eight-item questionnaire that assesses the consequences of pain on social, cognitive, emotional, physical, and recreational activities, as well as sleep and enjoyment in life. Items are rated on a five-point Likert scale, and higher scores reflect greater impairment. The PROMIS Pain Interference Scale has adequate to excellent construct validity when compared with other pain-related inventories (Rho = 0.48, 0.84, and 0.90) and excellent reliability (Cronbach's $\alpha = 0.96\text{--}0.99$) [56].

Sleep diary

The sleep diary is the gold standard of subjective measurement of sleep and was designed to follow the recommendations for sleep assessment for research [57, 58]. Participants completed a sleep diary twice daily (morning and evening) by recording information about their sleep that allowed for the calculation of SL, wake after sleep onset (WASO), total sleep time (TST), and sleep efficiency (SE). Participants also rated their subjective sleep quality and fatigue level on a 0–100 scale, with higher ratings demonstrating better sleep quality and higher energy levels.

Treatment conditions

Brief behavioral treatment for insomnia

BBTI was administered based on a published structured research protocol developed by Dr. Daniel Buysse at the University of Pittsburgh, School of Medicine [27]. The treatment consists of two in-person sessions (sessions 1 and 3) and two sessions conducted via telephone (sessions 2 and 4). The first treatment session consists of a 60-min in-person appointment in which therapists discuss homeostatic and circadian mechanisms of human sleep regulation. Therapists also introduce guidelines to promote better sleep derived from sleep restriction and stimulus control techniques. The five key elements of treatment include: (1) reducing time in bed, (2) getting up at the same time each day, (3) not going to bed unless sleepy, (4) not staying in bed unless asleep, and (5) eliminating naps to consolidate sleep. A personalized sleep plan of the total time allowed in bed, including targeted wake time, is calculated by adding 30 minutes to the average self-reported TST during the baseline week, with a minimum of 5 h total time allowed in bed. Therapists also review sleep hygiene guidelines. The second treatment session is a 20-min phone call that includes a brief review of sleep education and treatment guidelines that were introduced in the first session, review of the sleep diary from the past week, and discussion of any problems the participant had adhering to the sleep plan. The third session is a 30-min in-person appointment in which the therapist reviews the sleep diary from the past week, addresses any problems with treatment adherence, and when appropriate, adjusts the sleep plan by adding or subtracting minutes to time allowed in bed based on SE in the past week. The fourth and final treatment session consists of a 20-min phone call that involves review of the sleep diary and how to adjust the sleep plan, as well as a discussion of expectations for improvement in sleep and techniques to address future insomnia. Note that relaxation techniques are not a component of BBTI.

Progressive muscle relaxation training

Participants randomized to the control condition received PMRT, which has been used in other controlled trials of behavioral sleep

treatment [33, 59–64]. We created a manualized, four-session version of PMRT that was matched to BBTI for session duration and type (i.e. in-person vs. by phone) based on the guidebook for PMRT by Bernstein and colleagues [65]. Sleep diaries were reviewed in each session to ensure participants were completing these correctly, and therapists did not comment on the content of the entries (e.g. time in bed, sleep efficiency, etc.) in any way that could constitute an intervention for any of the subsequent sessions in which sleep diaries were completed. In the first session, therapists review the sleep diary, provide a history of the development of PMRT, and rationale for the treatment. The fundamentals of PMRT are introduced, followed by a guided practice of PMRT that includes alternating from a state of muscle tension to relaxation in 14 major muscle groups. Therapists assign twice daily home practice sessions of PMRT for the coming week. The second session of PMRT involves a review of the sleep diary from the past week and home practice of PMRT, as well as a discussion of problems practicing PMRT and generation of solutions to help increase frequency of practice. In the third session, therapists review the sleep diary and PMRT home practice from the past week. A more efficient tension–relaxation method is introduced that combines the 14 muscle groups to create a seven-muscle group version of the practice. During the session, therapists guide participants through the seven-muscle group practice and reassign twice daily PMRT home practice. The fourth and final session includes review of the sleep diary and PMRT home practice, troubleshooting problems that interfered with practice and discussion of how to maintain regular PMRT practice after treatment completion.

Therapist Training and Treatment Fidelity

The treatments were administered by a licensed clinical psychologist and two post-doctoral clinical psychologists. The licensed clinical psychologist provided therapy to 57 participants and the 2 post-doctoral psychologists provided therapy to 11 and 23 participants. Study therapists were trained and supervised by coauthors Drs. Maguen and Neylan. Initial didactic training was conducted over 2 days, followed by weekly group supervision and consultation on an as-needed basis. Each therapist completed a training case for both treatments prior to administering treatment to study participants. Therapists used a guiding checklist of individual components of each session for both treatments (e.g. review of sleep hygiene, introduction of stimulus control and sleep restriction, explanation of PMRT, in-session PMRT practice, etc.) to ensure that the protocols were conducted according to specification. Treatment sessions were audiotaped and monitored by an independent PhD-level clinical psychologist who reviewed fidelity to the individual components of each treatment (see fidelity section for more information). The independent reviewer monitored all sessions for the first two participants assigned to each treatment type for each study therapist, and for the remaining participants, monitored a random selection of one of the four treatment appointments for each participant. The psychologist reviewer joined weekly supervision meetings to provide feedback to study therapists to identify and address any barriers to therapist adherence.

Statistical analyses

An intention-to-treat analysis was used to compare treatment group outcomes. The primary outcome was the WSAS measure

of psychosocial functioning. Secondary outcomes included self-report measures of insomnia symptoms (ISI, ESS, and PSQI), quality of life (IQLS), cognitive functioning (MASQ), PTSD (PCL-5), mood (BDI), and physical pain (PROMIS intensity and severity), as well as subjective sleep quality and sleep behaviors reported in the sleep diary. Sleep diary weekly averages were computed and used as outcome variables for analysis. The sample size was estimated using a power analysis with 80% power, with two-sided alpha = 0.05, to detect an interaction effect corresponding to an absolute between-arm difference of 6.2 points on the WSAS post-trial compared with baseline. An absolute difference of 6.2 points corresponds to a standardized effect size of approximately $d = 0.5$.

Primary and secondary outcome variables were analyzed with separate linear mixed effects models, with participants as a random effect in the model. Fixed factors in the model were assessment time point (mid-treatment, posttreatment, and follow-up), age group (≤ 50 and > 50), and therapist. For each analysis, baseline values of the outcome variables were included as a covariate, with the first outcome time point being the first post-baseline observation (i.e. mid-treatment) [66]. Residuals from models were approximately normally distributed, so no transformations were considered. Treatment effects were defined as the difference between treatment arms at end of treatment time point, after adjusting for baseline and stratification variables (age group and therapist). BBTI treatment durability was assessed using simple marginal contrasts comparing outcomes at the end of treatment to the follow-up time period. Data analyses were conducted using Stata (v 15.1) statistical software [67].

Results

Participant characteristics

Tables 1–3 depict baseline participant demographic, military history, veteran characteristics, and current psychiatric diagnoses by treatment group. A total of 91 individuals (male = 73, female = 17, and transgender = 1) were randomized to receive BBTI ($n = 46$) or PMRT ($n = 45$). The mean age for participants in the BBTI arm was 49.5 years ($SD = 15.7$) and mean duration of military service was 13.5 years ($SD = 9.8$). For the PMRT group, participant mean age was 50 years ($SD = 15.3$) and mean duration of military service was 14.4 years ($SD = 10.8$).

Data attrition and treatment fidelity

Only one participant, randomized to PMRT, dropped out during the treatment phase of the study after baseline measures were collected. One mid-treatment observation in the BBTI arm was lost due to computer failure. There were no missing data on any of the psychometric variables, other than those caused by dropout. All analyses were intent-to-treat analyses, meaning that all non-missing time points were included in each analysis regardless of dropout. The maximum likelihood estimator used in the mixed model algorithm is not biased by missing observations under the assumption that data are missing at random. This is a reasonable assumption given the extremely low dropout rate from baseline to end of treatment and significant bias from the single potentially nonrandom dropout in the PMRT arm is unlikely. However, 5 of the 46 BBTI completers were

Table 1. Participant demographics by treatment arm

Variable	Level	PMRT (N = 45)	BBTI (N = 46)
Sex			
	Female	8 (18%)	9 (20%)
	Male	36 (80%)	37 (80%)
	Transgender	1 (2%)	0 (0%)
Age, mean (SD)		50.0 (15.3)	49.5 (15.7)
Race/ethnicity			
	Asian	7 (16%)	10 (22%)
	Black or African American	4 (9%)	8 (17%)
	Caucasian/White	23 (51%)	20 (43%)
	Hispanic or Latino	5 (11%)	4 (9%)
	Multi-racial	3 (7%)	3 (7%)
	Native Hawaiian/ Pacific Islander	2 (4%)	1 (2%)
	Other	1 (2%)	0 (0%)
Education			
	High school graduate/GED	3 (7%)	2 (4%)
	Some college	8 (18%)	9 (20%)
	Associate degree	1 (2%)	6 (13%)
	College graduate, Bachelor's degree	16 (36%)	15 (33%)
	Some graduate school	8 (18%)	2 (4%)
	Master's level degree	8 (18%)	8 (17%)
	Doctoral degree: MD, PhD or similar	1 (2%)	4 (9%)
Marital status			
	Never married	10 (22%)	15 (33%)
	Married	20 (44%)	22 (48%)
	Living with domestic partner	5 (11%)	3 (7%)
	Divorced	9 (20%)	6 (13%)
	Widowed	1 (2%)	0 (0%)
Employment status			
	Employed full time	13 (29%)	22 (48%)
	Employed part time	4 (9%)	5 (11%)
	Looking for work	2 (4%)	0 (0%)
	VA service-connection disability	3 (7%)	3 (7%)
	In school (full time)	3 (7%)	4 (9%)
	Retired	13 (29%)	9 (20%)
	Other	7 (16%)	3 (7%)

Baseline participant demographic information for the PMRT and BBTI groups. PMRT, progressive muscle relaxation training; BBTI, brief behavioral treatment for insomnia.

lost to follow-up at 6 months (11%). This could possibly bias comparisons between end of treatment and follow-up, although this loss-to-follow-up rate was also very low.

Therapist treatment fidelity was evaluated for the BBTI and PMRT treatments by a PhD-level clinical psychologist with over 10 years of experience in behavioral sleep medicine treatment and research. Study therapists were given high ratings on the delivery of treatment components, delivery of treatment in a compelling manner, knowledge, and attentiveness to participants. Average overall treatment quality ratings for BBTI and PMRT on a scale from 1 ("not at all") to 5 ("very much") were 4.96 ($SD = 0.14$, range 4–5) and 5 ($SD = 0.0$), respectively, indicating skillful treatment delivery for both treatments. Therapists were also rated on whether they conducted any off-protocol

Table 2. Participant military/veteran characteristics by treatment arm

Variable	Level	PMRT (N = 45)	BBTI (N = 46)
VA patient	Yes	33 (73%)	32 (70%)
Receiving mental health care	Yes	11 (24%)	14 (30%)
VA service-connection	Yes	24 (53%)	31 (67%)
Period served			
	Vietnam (1964–1975)	6 (13%)	7 (15%)
	May 1975–July 1990	1 (2%)	2 (4%)
	Persian Gulf (Aug 1990–Feb 1991)	0 (0%)	1 (2%)
	Mar 1991–Aug 2001	3 (7%)	0 (0%)
	OEF/OIF/OND (Sep 2001–Present)	19 (42%)	22 (48%)
	Multiple	16 (36%)	14 (30%)
Service branch			
	Air Force	7 (16%)	5 (11%)
	Army	18 (40%)	21 (46%)
	Marine Corps	5 (11%)	10 (22%)
	Navy	12 (27%)	7 (15%)
	Other	3 (7%)	3 (7%)
Component type			
	Active Duty	36 (80%)	35 (76%)
	National Guard	0 (0%)	3 (7%)
	Reserves	9 (20%)	8 (17%)
Military rank			
	Enlisted	33 (73%)	31 (67%)
	Officer	11 (24%)	15 (33%)
	Warrant Officer	1 (2%)	0 (0%)
Years of service, mean (SD) [range]		14.4 (10.8) [1–39]	13.5 (9.8) [2–31]
Times deployed to war zone			
	0	17 (38%)	15 (33%)
	1	13 (29%)	21 (46%)
	2	7 (16%)	6 (13%)
	3	5 (11%)	2 (4%)
	4	2 (4%)	1 (2%)
	5	0 (0%)	1 (2%)
	6	1 (2%)	0 (0%)
Total months deployed, mean (SD) [range]		8.2 (9.2) [0–40]	8.0 (8.0) [0–31]

Baseline participant demographic information for the PMRT and BBTI groups. PMRT, progressive muscle relaxation training; BBTI, brief behavioral treatment for insomnia.

treatment interventions using the same 1–5 scale. Therapists were rated a "1" for all treatment sessions for both treatments, indicating no off-protocol interventions were conducted throughout the study.

Primary outcome: psychosocial functioning

Table 4 provides unadjusted means and standard deviations of the primary outcome of WSAS scores at each time point in both treatment arms. Table 5 shows the difference between mean posttreatment scores on the WSAS by treatment group,

adjusted for baseline, and stratification variables. On average, participants in the BBTI group showed a difference of -3.60 in posttreatment WSAS scores relative to individuals that completed PMRT (see Figure 3). Participants in the BBTI treatment group demonstrated greater improvement in psychosocial functioning at posttreatment than individuals in the PMRT group [95% CI $-6.65, -0.55$], $t(85) = -2.35, p = 0.021$. Table 6 depicts the adjusted means for the BBTI group at posttreatment and follow-up. At the 6-month follow-up period, participants in BBTI reported a difference of 0.17 in WSAS scores compared with

posttreatment. This difference was not significant ($p = 0.870$), indicating improvements in psychosocial functioning remained stable 6 months after BBTI treatment ended.

Secondary outcomes: quality of life, insomnia, mood, cognition, PTSD, and pain

Table 4 lists the unadjusted means and standard deviations for each treatment arm by time point on the secondary outcome measures that assessed quality of life (IQLS), insomnia symptoms (ISI, PSQI, and ESS), mood (BDI), cognition (MASQ), PTSD (PCL), and pain (PROMIS intensity and severity). Table 5 depicts the difference between the baseline- and stratum-adjusted posttreatment means for BBTI and PMRT. For each secondary outcome measure, the difference between treatments was tested by the contrast in adjusted means posttreatment. Participants in BBTI, compared with PMRT, showed significantly greater improvement in quality of life indexed by IQLS total score [95% CI $-107.46, -16.09$], $t(85) = -2.69, p = 0.009$. Moreover, the BBTI group had significantly greater improvements in ratings on IQLS subscales assessing energy [95% CI $-199.77, -26.76$], $t(85) = -2.60, p = 0.011$ and cognition [95% CI $-184.67, -29.60$], $t(85) = -2.75, p = 0.007$. Analysis of insomnia symptoms in the BBTI and PMRT groups revealed that participants in BBTI had significantly greater improvement on scores on the ISI [95% CI $-5.87, -2.33$], $t(85) = -4.60, p < 0.001$ and PSQI [95% CI $-3.73, -1.51$], $t(85) = -4.70, p < 0.001$ relative to individuals treated with PMRT (see Figure 3). There was greater improvement in scores on the BDI for participants in the BBTI group compared with the PMRT group [95% CI $-4.49, -0.00$], $t(85) = -1.99, p = 0.050$. Comparisons between participants in BBTI and PMRT at posttreatment revealed no significant effect of treatment group on the ESS, MASQ, PCL-5, and PROMIS pain measures.

Table 3. Current psychiatric diagnoses by treatment arm

Diagnosis	Level	PMRT (N = 45)	BBTI (N = 46)
PTSD	Present	7 (15.6%)	9 (19.6%)
MDD	Present	5 (11.1%)	9 (19.6%)
GAD	Present	5 (11.1%)	5 (10.9%)
Panic disorder	Present	0 (0%)	2 (4.4%)
Agoraphobia	Present	0 (0%)	0 (0%)
Social anxiety disorder	Present	5 (11.1%)	1 (2.2%)
Specific phobia	Present	2 (4.4%)	1 (2.2%)
OCD	Present	0 (0%)	3 (6.5%)
Substance use disorders			
Alcohol	Mild	1 (2.2%)	1 (2.2%)
Cannabis	Mild	2 (4.4%)	0 (0%)
Opioid	Mild	0 (0%)	0 (0%)
Hallucinogen	Mild	0 (0%)	0 (0%)
Sedative	Mild	0 (0%)	0 (0%)
Stimulant	Mild	0 (0%)	0 (0%)

Baseline participant psychiatric diagnosis information by treatment group. PMRT, progressive muscle relaxation training; BBTI, brief behavioral treatment for insomnia; PTSD, posttraumatic stress disorder; MDD, major depressive disorder; GAD, generalized anxiety disorder; OCD, obsessive compulsive disorder.

Table 4. Means and standard deviations of self-report measures by treatment arm and time point

	PMRT (N = 45)						BBTI (N = 46)							
	Baseline		Mid-treatment		Posttreatment		Baseline		Mid-treatment		Posttreatment		Follow-up	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
WSAS	19.7	8.9	15.8	9.5	14.1	10.0	20.1	9.6	14.1	9.1	10.8	9.3	11.2	10.3
IQLS														
Total score	133.8	161.7	124.1	164.6	103.6	177.3	168.4	161.4	117.0	177.4	59.5	182.8	63.9	192.5
Physical activity	214.7	183.0	214.3	214.0	171.7	215.7	233.6	209.5	185.8	200.2	115.3	200.1	115.2	219.8
Energy	206.1	289.9	188.1	270.4	156.3	295.0	271.0	264.6	174.2	286.5	88.8	297.6	107.8	315.4
Cognition	99.6	257.7	62.0	260.9	85.7	287.7	137.3	251.9	55.9	292.9	-6.02	276.4	-2.5	274.6
Social	69.7	159.4	73.7	153.8	39.2	158.6	90.1	156.2	79.7	179.6	39.7	172.9	15.1	177.7
Psychological	70.9	144.2	69.5	117.4	60.5	127.7	105.1	140.4	78.0	129.6	48.2	131.4	75.0	148.5
ISI	17.4	4.0	14.2	4.3	12.4	5.4	17.1	3.6	10.4	4.6	8.1	5.4	7.5	5.6
ESS	8.7	5.7	7.8	5.3	6.9	4.8	9.7	5.0	9.0	5.0	7.4	4.9	6.9	5.0
PSQI	11.4	3.5	9.7	3.7	8.8	3.8	11.2	3.4	7.6	3.2	6.0	2.9	6.1	4.2
MASQ	89.1	23.5	89.1	24.8	87.4	25.9	88.7	18.6	85.5	20.1	82.8	21.6	81.9	18.5
PCL	22.5	17.9	19.8	18.8	14.1	10.0	25.8	17.6	117.0	177.4	17.5	17.6	18.4	18.2
BDI	13.4	7.7	10.5	8.1	10.3	8.8	15.8	8.8	11.0	8.4	9.4	9.3	10.0	8.2
PROMIS intensity	3.1	2.8	3.0	2.7	3.1	2.8	3.4	2.4	3.1	2.6	3.2	2.7	2.9	2.5
PROMIS	53.8	10.3	49.0	14.0	52.4	10.2	53.8	11.9	53.5	9.7	52.4	9.5	51.3	11.7
Interference T-score														

Unadjusted means and standard deviations for the PMRT and BBTI groups by time point on outcome measures. PMRT, progressive muscle relaxation training; BBTI, brief behavioral treatment for insomnia; WSAS, work and social adjustment scale; IQLS, insomnia and quality of life scale; ISI, insomnia severity index; ESS, epworth sleepiness scale; PSQI, pittsburgh sleep quality index; MASQ, multiple abilities self-report questionnaire; PCL, PTSD checklist; BDI, beck depression inventory; PROMIS, patient reported outcomes measurement information system.

Table 5. Comparison of PMRT and BBTI treatment outcomes

Outcome	PMRT Posttreatment predictive mean	BBTI Posttreatment predictive mean	Treatment difference	Std. error	95% CI	Std. effect size	t (85)	P
WSAS	14.33	10.73	-3.60	1.53	[-6.65, -0.55]	-0.39	-2.35	0.021
IQLS								
Total score	109.52	47.74	-61.78	22.98	[-107.46, -16.09]	-0.38	-2.69	0.009
Physical activity	164.34	111.72	-52.62	32.61	[-117.46, 12.21]	-0.27	-1.61	0.110
Energy	182.77	69.50	-113.26	43.51	[-199.77, -26.76]	-0.41	-2.60	0.011
Cognition	88.90	-18.23	-107.13	39.00	[-184.67, -29.60]	-0.42	-2.75	0.007
Social	34.86	33.79	-1.07	22.96	[-46.70, 44.57]	-0.01	-0.05	0.963
Psychological	59.61	40.37	-19.24	19.93	[-58.86, 20.38]	-0.14	-0.97	0.337
ISI	12.38	8.28	-4.10	0.89	[-5.87, -2.33]	-0.99	-4.60	<0.001
ESS	6.75	7.25	0.50	0.78	[-1.06, 2.05]	0.09	0.64	0.525
PSQI	8.73	6.11	-2.62	0.56	[-3.73, -1.51]	-0.73	-4.70	<0.001
MASQ	86.26	83.27	-3.00	2.48	[-7.92, 1.93]	-0.12	-1.21	0.230
PCL	19.22	16.47	-2.74	1.97	[-6.66, 1.17]	-0.15	-1.39	0.167
BDI	10.13	8.65	-2.25	1.12	[-4.49, -0.00]	-0.28	-1.99	0.050
PROMIS Intensity	3.13	3.14	0.01	0.36	[-0.71, 0.73]	0.00	0.04	0.971
PROMIS Interference	52.05	52.47	0.42	1.69	[-2.93, 3.77]	0.03	0.25	0.803
T-score								

Baseline- and stratum-adjusted post-treatment means estimated from the linear mixed models for the PMRT and BBTI groups at post-treatment on outcome measures. Standardized effect size is the treatment difference divided by the pooled baseline standard deviation. PMRT, progressive muscle relaxation training; BBTI, brief behavioral treatment for insomnia; WSAS, work and social adjustment scale; IQLS, insomnia and quality of life scale; ISI, insomnia severity index; ESS, epworth sleepiness scale; PSQI, pittsburgh sleep quality index; MASQ, multiple abilities self-report questionnaire; PCL, PTSD checklist; BDI, beck depression inventory; PROMIS, patient reported outcomes measurement information system.

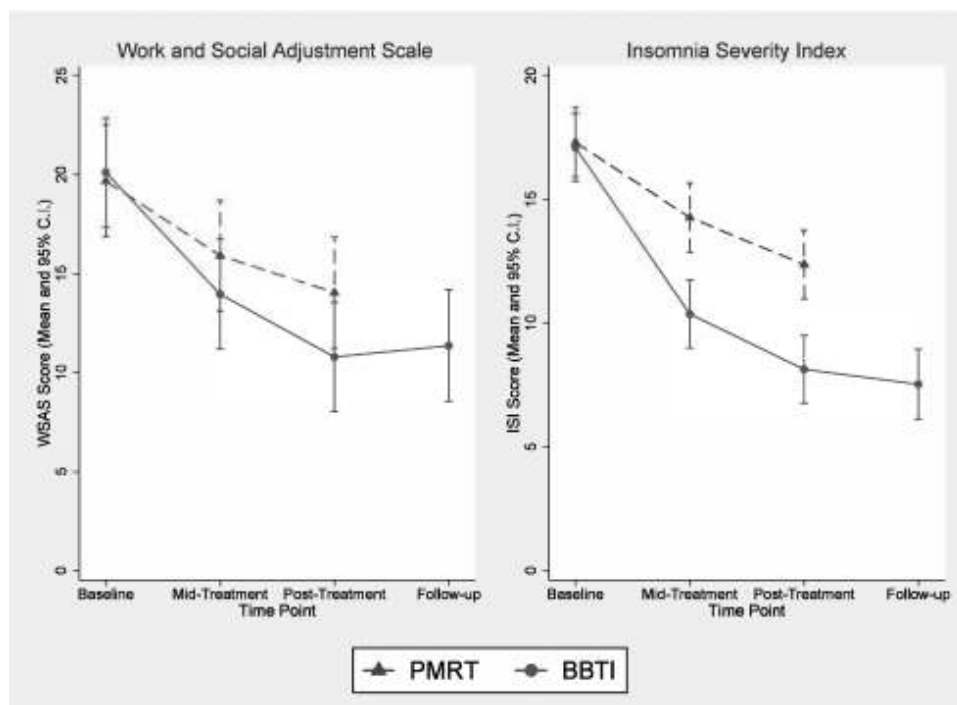


Figure 3. Scores on the WSAS and ISI for participants in BBTI and PMRT groups. WSAS, work and social adjustment scale; ISI, insomnia severity index; BBTI, brief behavioral treatment for insomnia; PMRT, progressive muscle relaxation training.

Table 6 displays the difference between baseline- and stratum-adjusted means at posttreatment and follow-up on the secondary outcome measures for the BBTI group. There was no significant difference between posttreatment and follow-up for the BBTI group on the IQLS ($p = 0.825$), ISI ($p = 0.189$), PSQI ($p = 0.711$), and BDI ($p = 0.932$), indicating

the significant treatment improvements in quality of life, insomnia symptoms, and mood were maintained at 6-month follow-up. Statistical analyses showed no significant changes in scores on the ESS, MASQ, PCL, and PROMIS pain measures for the BBTI group from posttreatment to follow-up.

Table 6. Durability of BBTI treatment effects at 6-month follow-up

Outcome	BBTI Posttreatment adjusted mean	BBTI Follow-up adjusted mean	Change at follow-up	Std. error	95% CI	t (40)	P
WSAS	11.00	11.17	0.17	1.04	[-1.93, 2.27]	0.16	0.870
IQLS							
Total score	60.37	63.90	3.53	15.87	[-28.54, 35.61]	0.22	0.825
Physical activity	109.77	115.19	5.42	22.76	[-40.54, 51.38]	0.24	0.813
Energy	85.77	107.79	22.02	39.92	[-56.45, 100.49]	0.57	0.574
Cognition	-5.57	-2.51	3.06	27.22	[-51.80, 57.92]	0.11	0.911
Social	47.81	15.09	-32.72	18.10	[-69.18, 3.74]	-1.81	0.077
Psychological	52.41	75.00	22.59	16.22	[-10.09, 55.27]	1.39	0.171
ISI	8.22	7.51	-0.71	0.53	[-1.78, 0.36]	-1.34	0.189
ESS	7.37	6.88	-0.49	0.70	[-1.89, 0.92]	-0.70	0.487
PSQI	5.95	6.12	0.17	0.46	[-0.76, 1.10]	0.37	0.711
MASQ	82.95	81.85	-1.10	1.93	[-5.00, 2.81]	-0.57	0.573
PCL	18.71	18.39	-0.32	1.29	[-2.92, 2.29]	-0.25	0.807
BDI	10.07	10.00	-0.07	0.85	[-1.79, 1.65]	-0.09	0.932
PROMIS intensity	3.17	2.88	-0.29	0.22	[-0.73, 0.15]	-1.36	0.138
PROMIS interference T-score	52.72	51.28	-1.45	1.25	[-3.98, 1.09]	-1.16	0.254

Baseline- and stratum-adjusted means estimated from the linear mixed models at post-treatment and 6-month follow-up for the BBTI group; BBTI, brief behavioral treatment for insomnia; WSAS, work and social adjustment scale; IQLS, insomnia and quality of life scale; ISI, insomnia severity index; ESS, epworth sleepiness scale; PSQI, pittsburgh sleep quality index; MASQ, multiple abilities self-report questionnaire; PCL, PTSD checklist; BDI, beck depression inventory; PROMIS, patient reported outcomes measurement information system.

Table 7. Means and standard deviations of sleep diary measures by treatment arm and time point

Treatment	Session	TST (h)		SL (min)		WASO (min)		Sleep efficiency (%)		Sleep quality		Fatigue	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
PMRT	Baseline	5.8	1.4	28.1	19.3	39.4	44.3	83.3	12.3	55.3	16.8	51.9	18.3
	Week 1	6.2	1.2	23.3	20.3	27.7	29.4	87.9	9.2	59.5	17.5	58.8	17.5
	Week 2	6.4	1.2	22.6	16.7	28.4	26.4	88.4	8.3	60.9	18.5	60.8	17.6
	Week 3	6.3	1.3	23.8	19.6	27.7	26.3	87.9	9.1	64.4	18.2	61.8	16.6
	Week 4	6.3	1.2	21.3	15.8	22.8	26.1	89.7	8.3	65.7	18.5	61.3	18.2
BBTI	Baseline	6.2	1.4	31.3	28.8	44.3	40.3	83.0	11.4	50.7	17.0	53.3	16.0
	Week 1	5.8	1.3	19.5	15.5	22.7	23.0	88.8	8.3	57.2	13.9	50.8	17.7
	Week 2	5.9	1.2	14.8	9.8	16.0	16.5	91.6	6.1	58.9	17.2	56.2	17.9
	Week 3	5.9	1.2	13.8	8.4	17.6	17.5	91.5	6.0	62.4	15.5	57.4	20.0
	Week 4	6.1	1.2	12.7	10.3	17.5	19.2	92.0	6.5	63.7	15.9	57.9	20.5
	6-mo f/u	6.9	1.3	14.0	10.8	16.6	18.5	92.8	5.2	67.9	18.5	61.0	22.3

Unadjusted means and standard deviations for BBTI and PMRT groups by time point on the sleep diary. BBTI, brief behavioral treatment for insomnia; PMRT, progressive muscle relaxation training; TST, total sleep time; SL, sleep latency; WASO, wake after sleep onset.

Table 8. Comparison of PMRT and BBTI sleep diary treatment outcomes

Outcome	PMRT Posttreatment predictive mean	BBTI Posttreatment predictive mean	Treatment difference	Std. error	95% CI	Std. effect size	t (85)	P
TST	6.37	5.97	-0.39	0.20	[-0.79, 0.01]	-0.28	-1.93	0.058
SL	21.8	12.3	-9.5	2.8	[-15.0, -4.04]	-0.39	-3.41	0.001
WASO	23.9	17.0	-7.0	4.3	[-15.4, 1.4]	-0.17	-1.62	0.108
Sleep efficiency	89.6	92.1	2.5	1.4	[-0.3, 5.3]	0.21	1.77	0.081
Sleep quality	63.5	65.0	1.4	3.0	[-4.4, 7.3]	0.08	0.48	0.629
Fatigue	61.3	57.6	-3.7	3.0	[-9.7, 2.2]	-0.22	-1.22	0.224

Baseline- and stratum-adjusted posttreatment means estimated from the linear mixed models for BBTI and PMRT groups by time point on the sleep diary. Standardized effect size is the treatment difference divided by the pooled baseline standard deviation. BBTI, brief behavioral treatment for insomnia; PMRT, progressive muscle relaxation training; TST, total sleep time; SL, sleep latency; WASO, wake after sleep onset.

Table 9. Durability of BBTI sleep diary treatment effects at 6-month follow-up

Outcome	Posttreatment adjusted mean	Follow-up adjusted mean	Change at follow-up	Std. error	95% CI	t (40)	P
TST	6.04	6.95	0.91	0.16	[0.59, 1.22]	5.80	<0.001
SL	12.7	14.2	1.5	1.9	[-2.3, 5.3]	0.80	0.429
WASO	17.5	16.6	-0.9	3.6	[-8.2, 6.4]	-0.24	0.808
Sleep efficiency	92.0	92.9	0.8	1.0	[-1.2, 2.9]	0.83	0.413
Sleep quality	63.8	67.8	4.1	2.6	[-1.2, 9.32]	1.56	0.127
Fatigue	58.1	61.4	3.3	2.4	[-1.6, 8.2]	1.37	0.179

Baseline- and stratum-adjusted means estimated from the linear mixed models for the BBTI group at post-treatment and 6-month follow-up time points; BBTI, brief behavioral treatment for insomnia; TST, total sleep time; SL, sleep latency; WASO, wake after sleep onset.

Sleep diary

The unadjusted means and standard deviations of the sleep diary measures are summarized in Table 7 by treatment arm at each week. Treatment effects of BBTI compared with PMRT are reported in Table 8. TST at end of treatment was moderately reduced in the BBTI condition compared with PMRT (5.97 vs. 6.37 h, $p = 0.058$), suggesting that participants successfully followed the sleep restriction component of the BBTI treatment protocol. As predicted, SL for individuals in BBTI treatment was significantly shorter than it was for the PMRT group [95% CI -15.0, -4.04], $t = -3.41$, $p < 0.001$). WASO and sleep efficiency showed greater mean improvement in the BBTI condition compared with PMRT, but neither of these differences reached the threshold of statistical significance at posttreatment. Table 9 depicts the means at posttreatment and follow-up in the sleep diary ratings for the BBTI group. At 6-month follow-up, TST in the BBTI condition increased significantly from posttreatment by nearly an hour ([95% CI 0.58, 1.23], $t = 5.80$, $p < 0.001$). Further, there was some improvement in sleep quality from posttreatment to 6-month follow-up for the BBTI group, however, this effect was not significant [95% CI -1.2, 9.32], $t = 1.56$, $p = 0.127$). There were no other significant changes in sleep diary outcomes from posttreatment to 6-month follow-up.

Discussion

We found that veterans with insomnia participating in a four-session behavioral treatment for insomnia improved on a series of functioning measures, as well as on some sleep, mood, and energy measures, and that these gains were maintained at 6-month follow-up. Notably, they did not improve on several sleep diary measures, with the exception of SL, nor on measures of fatigue, PTSD, or pain. The treatment provided was brief in duration, including two in-person and two phone sessions, which is shorter than the current behavioral treatment typically provided within VA mental health clinics, lasting six to eight sessions (CBT-I). Being able to offer a shorter treatment as an option could increase treatment engagement for several reasons. First, BBTI can be easily integrated into and offered within a primary care or integrated care setting, which can reduce mental health-related stigma. Second, due to quick symptom improvement, BBTI can serve as a positive mental health experience and serve as a bridge to further mental health treatment, if needed. Third, BBTI is convenient since it requires two in-person and two phone visits, making it easier for busy veterans to obtain needed care. Future research can also examine the impact of BBTI for veterans that is entirely remote.

Our main outcome measures were functioning as well as a number of sleep-related outcomes. We chose to focus on functioning first and foremost because it is a tangible outcome that is not always included in sleep research and can be particularly salient for veterans, who often seek mental health care due to functioning problems in relationships or work/education. Because of the strong link between sleep and multiple domains of functioning, it was important that veterans demonstrated improvement in these areas, compared with the active control condition. We also found that veterans reported improved energy and cognition on our quality of life measure specifically developed for those with insomnia, which can point to potential mechanisms of functional improvement. Those in the BBTI condition also reported depression symptom improvement. Improvements in cognitive functioning and mood are important because a prior study of BBTI ($N = 32$) compared with a self-monitoring control ($N = 30$) did not find improvements in cognition or mood [28]. However, it is important to note that while self-reported cognition improved in our study, we did not find differences on a more objective and comprehensive measure of cognition (MASQ), so further work is needed in this area. The fact that there was depression symptom improvement in our study also warrants further research, given that this can be extremely helpful for those with longstanding problems with sleep and mood. Because most BBTI studies have been conducted with older adults, some of these findings may shed light on potential areas of differential improvement with a slightly younger and more diverse population.

We found that veterans also experienced gains on multiple sleep measures, including the ISI (main sleep outcome measure) and PSQI, as well as SL as measured by weekly sleep diaries. These are important gains in a 4-week treatment with veterans who have entrenched insomnia, demonstrating that BBTI is effective in this population. Interestingly, other than SL, none of the other sleep diary outcomes demonstrated statistically significant improvements, although WASO and sleep efficiency showed greater mean improvement in the BBTI condition compared with PMRT. Though improvements in PSQI and ISI are consistent with other BBTI studies, a lack of improvement in most sleep diary measures, with the exception of SL, diverges from prior findings [15]. Further, the majority of prior BBTI studies have employed an information control condition (or a sleep hygiene or self-monitoring control). However, we used an active control condition that was well-liked by participants and was found to improve sleep in our study as well as in previously published works, which may account for some of these differences with our sleep diary

findings. It may also be that important underlying mechanisms of insomnia, such as hyperarousal and vigilance, which may be particularly salient for veterans who have served in war, were improved through PMRT, minimizing sleep diary between group differences. Furthermore, it may be that to impact measures like sleep efficiency, slightly longer treatments are needed, while functioning can improve more efficiently with brief insomnia treatments. Interestingly, TST improved at the 6-month follow-up, so it may be that these gains simply take more time to manifest. Notably, TST improved by about an hour at follow-up, demonstrating that gains are possible even after treatment ends.

Though we included pain and PTSD because they are frequently diagnosed conditions in veterans, we did not find significant improvements in either measure, but there are important caveats. First, we used a very brief pain measure that was valid and reliable but may not capture the full complexity of pain symptoms experienced by veterans. Second, although PTSD is one of the most frequently diagnosed mental health conditions in veterans who seek VA care, many of our veterans did not have diagnosed PTSD or had low symptoms, so there was a restricted range of these symptoms. Future research should examine the effectiveness of BBTI in veterans with PTSD, given that prior research has found that CBT-I is effective for those with PTSD [32]. Using a more comprehensive pain measure and tracking pain more carefully throughout insomnia treatment can also be a goal of future studies.

There are several limitations of this study that should be noted. First, we conducted this study with veterans, so our findings should not be generalized to adults in general since veterans are a unique group. Second, our study may not generalize to all veterans seeking VA care. Though all of our participants were veterans, not all enrolled in VA care. Third, our findings should not be generalized to BBTI provided in-person or entirely remotely since we conducted both types of sessions, as the treatment was designed. Fourth, we did not assess for nocturia, which may be associated with worse response to BBTI [68]. Finally, there is some evidence that shorter sleep duration at baseline may be associated with less improvement in BBTI [69], and there was some evidence for this in our study as well in post hoc analyses, so future research should examine this in greater detail. Future research can also focus on remote BBTI, which may include BBTI administered through phone or video. There is some preliminary evidence for BBTI administered through an automated mobile application [70], and this could be particularly appealing for younger veterans, who have demonstrated insomnia improvement through similar mobile modalities [71].

Overall, we found that a brief behavioral intervention for veterans is efficacious, even compared with an active control, which may increase engagement in treatment given increased convenience and decreased stigma. This brief treatment was designed to be administered in a primary care or integrated care setting and doing so in settings accessible to veterans can help increase uptake and benefit. Finally, we found that BBTI is helpful beyond just improving sleep outcomes by impacting multiple domains of functioning, mood, energy, and cognition. Veterans who experience insomnia can now have an additional treatment option that is congruent with many of their treatment preferences and may continue to demonstrate efficacy in multiple subsequent trials.

Acknowledgments

The authors would like to acknowledge the helpful assistance and consultation of Daniel Buysse during this study. The views expressed are those of the authors and do not necessarily represent the views or policy of the Department of Veterans Affairs or the United States Government.

Funding

This research was funded by VA Rehabilitation Research & Development grant I01 RX001539 (PI: Maguen). Additional support was provided by VA Career Development Grants RX002952 (Goldstein) and CX002032 (Straus).

Financial disclosures: None.

Non-financial disclosures: None.

References

1. Dinges DF, et al. Cumulative sleepiness, mood disturbance, and psychomotor vigilance performance decrements during a week of sleep restricted to 4–5 hours per night. *Sleep*. 1997;**20**(4):267–277.
2. Morphy H, et al. Epidemiology of insomnia: a longitudinal study in a UK population. *Sleep*. 2007;**30**(3):274–280.
3. Belenky G, et al. Patterns of performance degradation and restoration during sleep restriction and subsequent recovery: a sleep dose-response study. *J Sleep Res*. 2003;**12**(1):1–12.
4. Killgore WD, et al. Impaired decision making following 49 h of sleep deprivation. *J Sleep Res*. 2006;**15**(1):7–13.
5. McKenna BS, et al. The effects of one night of sleep deprivation on known-risk and ambiguous-risk decisions. *J Sleep Res*. 2007;**16**(3):245–252.
6. Jansson-Fröjmark M. The work and social adjustment scale as a measure of dysfunction in chronic insomnia: reliability and validity. *Behav Cogn Psychother*. 2014;**42**(2):186–198.
7. Buysse DJ, et al. Diagnosis, epidemiology and consequences of insomnia. *Prim Psychiatry*. 2005;**12**(8):37–44.
8. Kronholm E, et al. Self-reported sleep duration and cognitive functioning in the general population. *J Sleep Res*. 2009;**18**(4):436–446.
9. Luxton DD, et al. Prevalence and impact of short sleep duration in redeployed OIF soldiers. *Sleep*. 2011;**34**(9):1189–1195.
10. Peterson AL, et al. Sleep disturbance during military deployment. *Mil Med*. 2008;**173**(3):230–235.
11. Klingaman EA, et al. Prevalence, predictors and correlates of insomnia in US army soldiers. *J Sleep Res*. 2018;**27**(3):e12612.
12. Raskind MA, et al. A parallel group placebo controlled study of prazosin for trauma nightmares and sleep disturbance in combat veterans with post-traumatic stress disorder. *Biol Psychiatry*. 2007;**61**(8):928–934.
13. Neylan TC, et al. Fluvoxamine and sleep disturbances in posttraumatic stress disorder. *J Trauma Stress*. 2001;**14**(3):461–467.
14. Neylan TC, et al. The effect of nefazodone on subjective and objective sleep quality in posttraumatic stress disorder. *J Clin Psychiatry*. 2003;**64**(4):445–450.
15. Gunn HE, et al. Brief Behavioral Treatment of Insomnia. *Sleep Med Clin*. 2019;**14**(2):235–243.
16. Phelps AJ, et al. What are effective psychological interventions for veterans with sleep disturbances? A rapid evidence assessment. *Mil Med*. 2017;**182**(1):e1541–e1550.

17. Morin CM, et al. Patients' acceptance of psychological and pharmacological therapies for insomnia. *Sleep*. 1992;15(4):302–305.
18. Vincent N, et al. Treatment preference and patient satisfaction in chronic insomnia. *Sleep*. 2001;24(4):411–417.
19. Schutte-Rodin S, et al. Clinical guideline for the evaluation and management of chronic insomnia in adults. *J Clin Sleep Med*. 2008;4(5):487–504.
20. Qaseem A, et al. Management of chronic insomnia disorder in adults. *Ann Intern Med*. 2016;165(2):125–133.
21. Morin CM, et al. Psychological and behavioral treatment of insomnia: update of the recent evidence (1998–2004). *Sleep*. 2006;29(11):1398–1414.
22. Karlin BE, et al. National dissemination of cognitive behavioral therapy for insomnia in veterans: therapist- and patient-level outcomes. *J Consult Clin Psychol*. 2013;81(5):912–917.
23. Hoge CW, et al. Combat duty in Iraq and Afghanistan, mental health problems, and barriers to care. *N Engl J Med*. 2004;351(1):13–22.
24. Maguen S, et al. Time to treatment among veterans of conflicts in Iraq and Afghanistan with psychiatric diagnoses. *Psychiatr Serv*. 2012;63(12):1206–1212.
25. Epstein DR, et al. Insomnia treatment acceptability and preferences of male Iraq and Afghanistan combat veterans and their healthcare providers. *J Rehabil Res Dev*. 2012;49(6):867–878.
26. Bramoweth AD, et al. Brief behavioral treatment for insomnia vs. cognitive behavioral therapy for insomnia: results of a randomized noninferiority clinical trial among veterans. *Behav Ther*. 2020;51(4):535–547.
27. Buysse DJ, et al. Efficacy of brief behavioral treatment for chronic insomnia in older adults. *Arch Intern Med*. 2011;171(10):887–895.
28. McCrae CS, et al. Efficacy of brief behavioral treatment for insomnia in older adults: examination of sleep, mood, and cognitive outcomes. *Sleep Med*. 2018;51:153–166.
29. McCrae CS, et al. Effects of brief behavioral treatment for insomnia on daily associations between self-reported sleep and objective cognitive performance in older adults. *Behav Sleep Med*. 2019;15:1–12.
30. Germain A, et al. Treatment for insomnia in combat-exposed OEF/OIF/OND military veterans: preliminary randomized controlled trial. *Behav Res Ther*. 2014;61:78–88.
31. Sayer NA, et al. Reintegration problems and treatment interests among Iraq and Afghanistan combat veterans receiving VA medical care. *Psychiatr Serv*. 2010;61(6):589–597.
32. Talbot LS, et al. Cognitive behavioral therapy for insomnia in posttraumatic stress disorder: a randomized controlled trial. *Sleep*. 2014;37(2):327–341.
33. Edinger JD, et al. Cognitive behavioral therapy for treatment of chronic primary insomnia: a randomized controlled trial. *JAMA*. 2001;285(14):1856–1864.
34. Jungquist CR, et al. The efficacy of cognitive behavioral therapy for insomnia in patients with chronic pain. *Sleep Med*. 2010;11(3):302–309.
35. Jungquist CR, et al. The durability of cognitive behavioral therapy for insomnia in patients with chronic pain. *Sleep Disord*. 2012;2012:679648.
36. Ouellet MC, et al. Efficacy of cognitive-behavioral therapy for insomnia associated with traumatic brain injury: a single-case experimental design. *Arch Phys Med Rehabil*. 2007;88(12):1581–1592.
37. Ouellet MC, et al. Cognitive behavioral therapy for insomnia associated with traumatic brain injury: a single-case study. *Arch Phys Med Rehabil*. 2004;85(8):1298–1302.
38. Netzer NC, et al. Using the Berlin Questionnaire to identify patients at risk for the sleep apnea syndrome. *Ann Intern Med*. 1999;131(7):485–491.
39. Senaratna CV, et al. Validity of the Berlin questionnaire in detecting obstructive sleep apnea: a systematic review and meta-analysis. *Sleep Med Rev*. 2017;36:116–124.
40. Bastien CH, et al. Validation of the Insomnia Severity Index as an outcome measure for insomnia research. *Sleep Med*. 2001;2(4):297–307.
41. First MB, et al. *Structured Clinical Interview for DSM-5-Research Version (SCID-5-RV, version 1.0.0)*. Arlington, VA: American Psychiatric Association; 2015.
42. Weathers FW, et al. The Clinician-Administered PTSD Scale for DSM-5 (CAPS-5): development and initial psychometric evaluation in military Veterans. *Psychol Assess*. 2018;30:383–395.
43. Corrigan JD, et al. Initial reliability and validity of the Ohio State University TBI Identification Method. *J Head Trauma Rehabil*. 2007;22(6):318–329.
44. Bogner J, et al. Reliability and predictive validity of the Ohio State University TBI identification method with prisoners. *J Head Trauma Rehabil*. 2009;24(4):279–291.
45. Mundt JC, et al. The Work and Social Adjustment Scale: a simple measure of impairment in functioning. *Br J Psychiatry*. 2002;180:461–464.
46. Leger D, et al. HD-16: a new quality of life instrument specifically designed for insomnia. *Sleep Med*. 2005;6(3):191–198.
47. Johns MW. Reliability and factor analysis of the Epworth Sleepiness Scale. *Sleep*. 1992;15(4):376–381.
48. Buysse DJ, et al. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry Res*. 1989;28(2):193–213.
49. Mollaveya T, et al. The Pittsburgh sleep quality index as a screening tool for sleep dysfunction in clinical and non-clinical samples: A systematic review and meta-analysis. *Sleep Med Rev*. 2016;25:52–73.
50. Seidenberg M, et al. Development and validation of a Multiple Ability Self-Report Questionnaire. *J Clin Exp Neuropsychol*. 1994;16(1):93–104.
51. Blevins CA, et al. The Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5): Development and Initial Psychometric Evaluation. *J Trauma Stress*. 2015;28(6):489–498.
52. Wortmann JH, et al. Psychometric analysis of the PTSD Checklist-5 (PCL-5) among treatment-seeking military service members. *Psychol Assess*. 2016;28(11):1392–1403.
53. Beck AT, Steer RA. *Manual for the Beck Depression Inventory*. San Antonio, TX: Psychological Corp.; 1993.
54. Beck AT, et al. Psychometric properties of the Beck Depression Inventory: twenty-five years of evaluation. *Clin Psychol Rev*. 1988;8:77–100.
55. Cella D, et al. Initial adult health item banks and first wave testing of the Patient-Reported Outcomes Measurement Information System (PROMIS™) Network: 2005–2008. *J Clin Epidemiol*. 2010;63(11): 1179–1194.
56. Amtmann D, et al. Development of a PROMIS item bank to measure pain interference. *Pain*. 2010;150(1):173–182.
57. Morin CM. *Insomnia: Psychological Assessment and Management*. New York, NY: Guilford Press; 1993.
58. Buysse DJ, et al. Recommendations for a standard research assessment of insomnia. *Sleep*. 2006;29(9):1155–1173.
59. Ascher LM, et al. Paradoxical intention and insomnia: an experimental investigation. *Behav Res Ther*. 1979;17(4):408–411.
60. Espie CA, et al. A controlled comparative investigation of psychological treatments for chronic sleep-onset insomnia. *Behav Res Ther*. 1989;27(1):79–88.

61. Lichstein KL, et al. Relaxation and sleep compression for late-life insomnia: a placebo-controlled trial. *J Consult Clin Psychol*. 2001;**69**(2):227–239.
62. Lichstein KL, et al. Psychological treatment of secondary insomnia. *Psychol Aging*. 2000;**15**(2):232–240.
63. Morin CM, et al. Nonpharmacological interventions for insomnia: a meta-analysis of treatment efficacy. *Am J Psychiatry*. 1994;**151**(8):1172–1180.
64. Turner RM, et al. Controlled comparison of progressive relaxation, stimulus control, and paradoxical intention therapies for insomnia. *J Consult Clin Psychol*. 1979;**47**(3):500–508.
65. Bernstein DA, et al. *New Directions in Progressive Relaxation Training: A Guidebook for Helping Professionals*. Westport, CT: Praeger Publishers; 2000.
66. Austin PC, et al. A substantial and confusing variation exists in handling of baseline covariates in randomized controlled trials: a review of trials published in leading medical journals. *J Clin Epidemiol*. 2010;**63**(2):142–153.
67. Stata Statistical Software: Release 15. College Station, TX: StataCorp LLC; 2017.
68. Tyagi S, et al. Behavioral treatment of chronic insomnia in older adults: does nocturia matter? *Sleep*. 2014;**37**(4):681–687.
69. Troxel WM, et al. Predictors of treatment response to brief behavioral treatment of insomnia (BBTI) in older adults. *J Clin Sleep Med*. 2013;**9**(12):1281–1289.
70. Okajima I, et al. Effects of a tailored brief behavioral therapy application on insomnia severity and social disabilities among workers with insomnia in Japan: a randomized clinical trial. *JAMA Netw Open*. 2020;**3**(4):e202775.
71. Reilly ED, et al. Mobile app use for insomnia self-management: pilot findings on sleep outcomes in veterans. *Interact J Med Res*. 2019;**8**(3):e12408.