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Treatment for Insomnia in Combat-Exposed OEF/OIF/OND Military Veterans: Preliminary Randomized Controlled Trial

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Abstract

Objective—Chronic insomnia is highly prevalent among military personnel returning from Iraq and Afghanistan. We evaluated the effects of a military version of a brief behavioral treatment of insomnia (BBTI-MV) compared to an information only control (IC) condition in combat-exposed Veterans of Operations Enduring/Iraqi Freedom or Operation New Dawn (OEF/OIF/OND) on insomnia, sleep quality, and daytime symptoms of anxiety and depression.

Method—Forty OEF/OIF/OND Veterans (Mean age = 38.4 years old, s.d. = 11.69; 85% men; 77.5% white) were randomized to one of two conditions. BBTI-MV consisted of two in-person sessions and two telephone contacts delivered over four weeks, and included personalized recommendations to reduce insomnia. The IC condition also consisted of 2 in-person sessions two telephone contacts delivered over four weeks, and Veterans were encouraged to read written information about sleep-promoting behaviors. The Insomnia Severity Index, Pittsburgh Sleep Quality Index, PTSD Checklist, and Beck Depression and Anxiety Inventories were completed at baseline, post-treatment, and at the six-month follow-up.

Results—Both interventions were associated with clinically significant improvements in insomnia, although the magnitude of improvements in sleep and rates of treatment response and remission were greater for BBTI-MV compared to IC from pre- to post-treatment.

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Conclusion—Both BBTI-MV and the provision of information were associated with clinically significant improvements in insomnia among Veterans. Despite the preliminary nature of the findings and limitations inherent to small controlled trials, the findings suggest that both approaches may provide viable options in a stepped-care approach to the treatment of insomnia in retuning combat-exposed Veterans. Larger, confirmatory effectiveness trials are required.

Keywords

Military Veterans; insomnia; stimulus control; sleep restriction; education

Introduction

Increased sleep latency, increased duration of wakefulness after sleep onset, short sleep duration, and increased sleep fragmentation are some of the common forms of sleep disturbances endorsed by military personnel during military deployment (Peterson, Goodie, Satterfield, & Brim, 2008; Seelig et al., 2010). Insomnia is one of the most common reasons for referral to mental health services in deployed military personnel (Cozza et al., 2004). After returning home, as many as 70% of Service Members continue to report chronic and clinically significant sleep complaints, including insomnia (Collen, Orr, Lettieri, Carter, & Holley, 2012; McLay, Klam, & Volkert, 2010; Mysliwiec et al., 2013; Seelig et al., 2010; Wright, Adler, Bliese, & Eckford, 2008; Yang et al., 2013). These observations are consistent with prior studies of Vietnam Veterans (Lewis, Creamer, & Failla, 2009; Neylan et al., 1998) and Veterans of the first Gulf War (Kroenke, Koslowe, & Roy, 1998), showing that insomnia does not spontaneously remit over time in deployed and/or combat-exposed Service Members.

Insomnia complaints are strongly associated with the severity of other wounds of war, including posttraumatic stress disorder (PTSD), depression, and chronic mild traumatic brain injury and related headaches (Carlsten, Tarkowski, Holmdahl, & Nilsson, 1990; Lande, 2012; Macera, Aralis, Rauh, & Macgregor, 2013; McLay et al., 2010; van, van, Westenberg, Super, & Vermetten, 2013; Wright et al., 2011). In addition, insomnia is a risk factor for psychiatric disorders that are frequent in combat-exposed troops, including PTSD, alcohol abuse or dependence, depression, and suicidality (Applewhite, Keller, & Borah, 2012; Lande, 2012; McLay et al., 2010; Wright et al., 2011). Thus, the chronicity of insomnia in deployed and returning military personnel combined with the heightened risk of poor psychiatric outcomes suggest that sleep-specific treatments are urgently needed, and may contribute to accelerated recovery and resilience in Service Members. Cognitive-behavioral treatment of insomnia (CBTI) effectively improves sleep quality (Irwin, Cole, & Nicassio, 2006; Morin, Culbert, & Schwartz, 1994; Smith et al., 2002), and has recently been the focus of dissemination efforts in the Department of Veterans Affairs (VA) (Karlin, 2013; Karlin, Trockel, Taylor, Gimeno, & Manber, 2013; Manber et al., 2012). However, CBTI remains scarce in primary and community care settings where a significant number of Service Members and military Veterans seek and receive care (e.g., community-based civilian clinics, support resources at local Veterans of Foreign Wars organizations), and for those who are not eligible for services through VA clinics (e.g., <http://www.gao.gov/assets/590/585745.pdf>; Center for Veterans Analysis and Statistics, 2013 [<http://www.va.gov/>

[vetdata/index.asp](#); retrieved Dec 2, 2013). CBTI typically refers to treatment protocols delivered over five to eight sessions conducted by a licensed psychologist trained in behavioral sleep medicine (Edinger & Carney, 2008; Morin, 1993; Perlis et al., 2000), although the recent roll-out of CBTI in the VA clinics includes training of a significant number (approximately 30%) of masters level clinicians (Trockel, Karlin, Taylor, & Manber, 2014). Nevertheless, these time and personnel resources and high levels of expertise may not be readily available in many medical and community care settings.

A number of studies have now shown that brief behavioral insomnia treatments, i.e., arbitrarily defined as 5 sessions or less based on published CBTI manuals, (Edinger & Carney, 2008; Morin, 1993; Perlis, Aloia, & Kuhn, 2011) can efficaciously improve insomnia in civilian and military samples (e.g., (Buysse et al., 2011; Edinger et al., 2009; Edinger, Wohlgemuth, Radtke, Coffman, & Carney, 2007; Germain, Shear, Hall, & Buysse, 2007; Kyle, Morgan, Spiegelhalter, & Espie, 2011; Swift et al., 2012). Recently, 4-week behavioral insomnia treatment packages have been shown effective in the treatment of primary or comorbid insomnia in civilian and military samples (Buysse et al., 2011; Edinger et al., 2007). These briefer treatments consistently focus on evidence-based techniques grounded in the two-process model of sleep regulation as the underlying rationale for implementing stimulus control and sleep restriction. Typically, the educational background included in BBTI approaches is more focused on the two process model of sleep regulation as the rationale for stimulus control and sleep restriction, and general information about sleep (e.g., sleep and aging, sleep architecture) are not included. Furthermore, cognitive restructuring of dysfunctional beliefs about sleep is not included in BBTI, whereas CBTI approaches include exercises that specifically address cognitive factors that may perpetuate insomnia (Harvey, Tang, & Browning, 2005; Perlis et al., 2011). Lastly, relaxation techniques that are often part of CBTI approaches are not included as part of BBTI. These brief behavioral treatments of insomnia (BBTI) focus on four rules to improve sleep quality, as extensively described elsewhere (Troxel, Germain, & Buysse, 2012). Moderate to large effect sizes detected with BBTI are comparable to those reported with CBTI (Morin et al., 1994; Okajima, Komada, & Inoue, 2011; Smith et al., 2002)

Thus, behavioral treatments that require fewer sessions, that provide military relevant and sleep-focused content, that are evidence-based, and that can be delivered by a wide range of healthcare providers (e.g., social workers, nurses) in non-specialized medical settings may be more easily disseminated to settings where Service Members and Veterans may seek help for insomnia. If such were the case, more specialized resources, as well as the longer CBTI format, may then be dedicated to patients who present with more chronic, complex, and severe insomnia, and /or more significant comorbidities that require multifaceted treatment. The military version of a brief behavioral treatment of insomnia (BBTI-MV) consists of two individual in-person sessions and two telephone contacts delivered over a four-week period, and was developed with the above considerations in mind. The military version of BBTI (BBTI-MV) was informed by a pilot treatment adaptation study with Active Duty Service Members and Veterans who provided feedback on the content and format of traditional BBTI and CBTI. The resulting BBTI-MV differs from civilian BBTI and CBTI treatment packages in several ways. First, the language is culturally adapted to military samples. For instance, the terms “therapy” is replaced by training; “therapist” or “clinician” are replaced

by coach; “psychoeducation” is called briefing; and treatment recommendations are called “sleep tactics”. Second, the BBTI-MV explicitly builds on skills acquired during military experiences, such as applied training to achieve proficiency for given skills (e.g., marksmanship for sleep using sleep efficiency and restorative sleep as metrics of performance). Third, the educational component about healthy sleep, age-specific norms, sleep architecture, and other items that are commonly included in civilian BBTI or CBTI packages is minimal. Rather, only principles of sleep regulation and healthy sleep practices that provide the rationale for stimulus control and sleep restriction are the specific focus of the first segment of the first intervention visit. Fourth, these principles are illustrated by military-relevant examples only (e.g., military- and deployment-specific precipitating or perpetuating factors of insomnia and/or hypervigilance at night). Fifth, the costs and benefits of hypervigilance in different context (i.e., during deployment in high-risk zones vs. in garrison) are also discussed. Finally, the implementation of recommendations includes a personalized plan for safety regarding weapons that participants may keep in their bedroom.

In this study, we conducted a randomized controlled trial to compare the acute effects of a brief behavioral treatment of insomnia specifically tailored to military Veterans (BBTI-MV) to an information control (IC) condition. An exploratory aim was to monitor sleep improvements over time in a naturalistic six-month follow-up period. The IC condition has been used in a previous randomized trial with civilian older adults (Buysse et al., 2011; Germain et al., 2006), or in combination with placebo treatments (Germain et al., 2012), and was found to have no or negligible benefits on insomnia complaints, overall sleep quality, and daytime symptoms of anxiety and depression. The primary hypothesis was that BBTI-MV would be associated with greater rates of treatment response and remission and greater improvements in insomnia severity compared to the IC post-treatment. Insomnia severity was reassessed after an uncontrolled, six-month follow-up period. Because a reduction in insomnia severity is often associated with improvements in overall sleep quality and daytime symptoms of PTSD, depression, and anxiety, the secondary hypothesis was that improvements in insomnia would be accompanied by improvements in overall sleep quality, and reductions in disruptive nocturnal behaviors (e.g., bad dreams, sleep terrors) and in daytime symptoms of PTSD, depression, and anxiety.

Methods

Overview of study design

The study was a randomized controlled trial, and included a naturalistic, uncontrolled six-month follow-up period. After providing written informed consent, participants completed a series of procedures to determine eligibility. These included self-report and clinician-administered sleep evaluation measures, a physical screening, and a urine drug screen, and one night in the sleep laboratory to rule out the presence of sleep apnea and periodic leg movement disorders. Eligible participants then completed baseline assessments of insomnia severity, sleep quality, and psychiatric symptom severity, and were randomized to one of the two treatment conditions. Prior to their first in-person treatment visits, all participants completed a sleep diary to prospectively assess sleep patterns, as well as health behaviors that may interfere with sleep (e.g., nicotine use, caffeine and alcohol consumption). Both

treatment conditions were delivered over a four-week period, and included 2 in-person visits (weeks 1 and 3), and 2 telephone contacts (weeks 2 and 4). Participants continued to monitor their sleep patterns with the sleep diary throughout the four week intervention period, as well as for 10 consecutive days and night following the last treatment contact. Participants then repeated clinical sleep and psychiatric outcome measures. Finally, participants were contacted monthly for six months, at which point they completed the sleep and psychiatric measures again. The 6 months period was uncontrolled, and conducted to explore whether sleep improvements (or lack thereof) would persist over time.

Participants

The University of Pittsburgh Institutional Review Board approved the present study. Combat-exposed Veterans who served in combat theaters and who were between the ages of 18 and 60 years old were recruited through public television, newspapers, and radio advertisements aired between April 2009 and March 2011. Prior military service was documented by examining the participant's DD Form 214, a form issued by the Department of Defense upon a military service member's separation from active duty. Active Duty Service Members were asked to provide valid military identification. Combat exposure was assessed with the Combat Exposure Scale (CES) (Lund, Foy, Sippelle, & Strachan, 1984). The CES evaluates the frequency of exposure to seven combat-related experiences. Scores range from 0 to 41, and higher scores reflected more intense combat exposures. Other eligibility criteria included 1) having been deployed to or in support of Operations Enduring/Iraqi Freedom or Operation New Dawn (OEF/OIF/OND); 2) onset of insomnia occurred during or after deployment; 3) meeting criteria for primary or comorbid insomnia as defined by the International Classification of Sleep Disorders (American Academy of Sleep Medicine, Hauri, & Sateia, 2005); and 4) endorsing a baseline score equal to or greater than 14 on the Insomnia Severity Index (ISI), (Bastien, Vallieres, & Morin, 2001; Morin, 1993) which indicates moderate insomnia. Participants using psychotropic or hypnotic medications were eligible if the medication and dose was stable for 3 weeks prior to study entry, and no changes were expected over the course of the acute treatment phase. Exclusion criteria included 1) presence of diagnosed or suspected sleep breathing disorder; 2) presence of another sleep disorder requiring treatments other than behavioral insomnia treatments (e.g., restless leg syndrome); 3) severe and/or untreated psychiatric disorder with markedly impaired functioning and requiring immediate clinical attention; 4) lifetime history of bipolar or psychotic disorder; 5) unstable or untreated major medical condition; and 6) current alcohol/substance abuse or dependence (past three months).

Eligibility assessment: Screening procedures and measures

After providing written, informed consent, participants first completed three clinical interviews, a battery of self-report measures, and a medical screening. The Structured Clinical Interview for DSM-IV (First, Spitzer, Gibbon, & Williams, 1995) was used to assess past and current psychiatric history. The Structured Clinical Interview for DSM-IV Sleep Disorders was developed locally to evaluate symptoms of DSM-IV sleep disorders including insomnia, sleep-disordered breathing, restless legs syndrome and other sleep-related movement disorders, and parasomnias. This instrument, like the SCID, assesses the presence of core symptoms of these sleep disorders as defined by the International

Classification of Sleep Disorders (American Academy of Sleep Medicine et al., 2005) and DSM-IV.

The Clinician Administered PTSD Scale (Blake et al., 1995), the gold standard for the assessment of PTSD, was used to evaluate the presence and severity of past and current PTSD symptom severity. Finally, participants completed a medical screening to verify the absence of unstable medical conditions that would result in exclusion, and which included a urine toxicology screen to rule out drug use. The Epworth Sleepiness Scale (Johns, 1991; Johns, 1992) was also completed during this visit to evaluate for the presence and severity of excessive daytime sleepiness. A score greater than 9 indicates clinically significant daytime sleepiness. Participants who remained eligible after the first visit returned to the laboratory for an overnight polysomnographic (sleep) study to evaluate for sleep disordered breathing. Participants who were found to have an apnea-hypopnea index greater than 15 events per hour were excluded, and referred to their primary care physician or sleep clinic for further evaluation and treatment. This AHI cut-off represents the lower limit of moderate obstructive sleep apnea, and the level that is used to justify treatment (independent range of symptoms) in many settings (Adult Obstructive Sleep Apnea task Force of the American Academy of Sleep Medicine et al., 2009),

Baseline and post-treatment assessments and outcome measures

Participants who were deemed eligible after completing all of the above eligibility procedures were then invited to complete the baseline assessment visit. During this visit, participants completed the Insomnia Severity Index (refs), as well as other self-report measures of sleep quality and psychiatric distress. The ISI was used as the primary sleep outcome measure. The ISI is a 7-item self-report questionnaire that assesses subjective severity of insomnia symptoms, degree of satisfaction with sleep, nature and noticeability of daytime impairments, and concerns caused by the sleep difficulties. Each item is rated on a 0 to 4 point scale. An ISI score ≥ 14 reflects clinically significant insomnia. In addition, overall sleep quality was assessed using the Pittsburgh Sleep Quality (PSQI), (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989), and the PSQI-Addendum for PTSD (PSQI-A), (Germain, Hall, Krakow, Katherine Shear, & Buysse, 2005; Insana, Hall, Buysse, & Germain, 2013). The PSQI is a 18-item self-report measure that assesses different component of sleep quality. Scores range from 0 to 21, with higher scores indicating poorer sleep quality. A cut-off of 5 has been shown to discriminate between good sleepers and sleep disordered samples (Buysse et al., 1989). The PSQI-A assesses the severity of seven disruptive nocturnal behaviors that are commonly endorsed by trauma-exposed individuals (Germain et al., 2005; Insana et al., 2013). Scores range from 1 to 21, with higher scores reflecting more severe disturbances.

Given the relationships between sleep disturbances and daytime symptoms of psychiatric distress in civilian and military samples (see Bramoweth & Germain, 2013 for review), participants also completed the PTSD Checklist – Civilian version (PCL-C), (Blanchard, Jones-Alexander, Buckley, & Forneris, 1996) the Beck Depression Inventory (BDI), (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961) and the Beck Anxiety Inventory (BAI), (Beck, Epstein, Brown, & Steer, 1988) to assess symptoms of PTSD, depression, and anxiety,

respectively. The PCL-C is a 17-item self-report measures that have been widely used in military and civilian population to assess the severity of PTSD symptoms (see (Terhakopian, Sinaii, Engel, Schnurr, & Hoge, 2008; Wilkins, Lang, & Norman, 2011) for review). The BDI and BAI each include 21 items that assess the severity of somatic and cognitive symptoms of depression and anxiety, respectively.

After completing the baseline assessment visit, all participants were asked to prospectively track their sleep/wake patterns using the Pittsburgh Sleep Diary (PghSD) (Monk et al., 1994) for the seven to 10 consecutive days and nights that immediately preceded their first treatment visit. The PghSD includes items on the time at which the participant went to bed, attempted to fall asleep, the number, cause, and duration of nocturnal awakenings, final time out of bed, and total estimated time spent asleep. The PghSD provided weekly averages of sleep latency (or time to fall asleep), total sleep time, sleep efficiency (defined as the ratio of total sleep time / total time spent in bed), wake time after sleep onset, total sleep time, and nightly nightmare frequency. Data derived from the sleep diary was used to individualize sleep prescriptions for participants randomized to BBTI-MV.

All self-report measures as well as the sleep diary were repeated 10 to 14 days after the last treatment visit, and again at the end of the six-month follow-up period.

Randomization and treatment conditions

Participants who completed all screening procedures and were found to be eligible were randomized in a 1:1 manner to BBTI-MV and IC. A permuted block design randomization was stratified by use of an antidepressant (yes/no) and age group (18–36, > 37 years old).

BBTI-MV was adapted from a manualized behavioral treatment that was initially developed for chronic insomnia in older adults as described elsewhere (Buysse et al., 2011; Germain et al., 2006; Troxel et al., 2012). BBTI-MV is delivered over four consecutive weeks, and includes one individual in-person visit (45 minutes) at Week 1, a booster in-person visit at Week 3 (< 30 minutes), and brief telephone appointments during Weeks 2 and 4 (< 20 minutes each). The booster session and telephone contacts serve three purposes: 1) to promptly address difficulties that may have arisen in the prior week while applying the techniques suggested for those in BBTI-MV; 2) to closely monitor and reinforce adherence to treatment for those in BBTI-MV or to answer questions regarding the brochures for those in the IC condition, (see details below); and 3) to assess potential side effects. Combat or traumatic experiences were not discussed during any of the intervention contacts, nor were coping strategies to manage symptoms of PTSD, depression, anxiety, or other health, interpersonal, or marital difficulties.

The content of the first BBTI-MV session focused on providing accurate and concise information about military specific factors that adversely affect sleep before and during deployment, and about behaviors that contribute to the persistence of insomnia post-deployment. The two-process model of sleep regulation (Borbely, 1982) was then presented. Additionally, the rationale for stimulus control (Bootzin & Nicassio, 1978) and sleep restriction (Spielman, Saskin, & Thorpy, 1987) was presented. Individualized “sleep prescriptions”, or recommended bed time and rise times were determined based on data

gathered from the baseline sleep diary. The procedures followed to individualize sleep prescriptions have been extensively detailed elsewhere (Troxel et al., 2012). Briefly, the average total sleep time reported on the sleep diary was first computed for each participant. Following the principles of sleep restriction (Spielman et al., 1987), 30 minutes were added to the average total sleep time, in order to provide the total of time allowed in bed for the next two weeks. The participant and the therapist then first identified the rise time to be implemented, then worked backwards to identify the earliest bed time allowed for the next two weeks. Instructions for stimulus control were then provided, and combined with the newly prescribed sleep schedule. Finally, instructions on how to avoid napping and how to manage the transient and expected increase in sleepiness and fatigue were discussed. Specific strategies to promote adherence to the recommended bed time and rise time were tailored to each participant in BBTI-MV. At the end of the session, participants received a new 14-day sleep/wake diary to track adherence and progress until the following in-person visit.

The second in-person visit (Week 3) was used to review adherence to the prescribed sleep-wake schedule, and to determine whether changes in the prescribed time in bed were required. Specifically, participants who showed a diary-based average sleep latency and average duration of wake-time after sleep onset of less than 30 minutes, with an average sleep efficiency greater than 85% on the previous week's sleep diary were allowed to increase the total time spent in bed by 15 minutes for the subsequent three or four nights, by either advancing bedtime by 15 minutes or delaying the rise time by 15 minutes. If sleep consolidation was maintained over these nights, they were instructed to extend their allotted time in bed by another 15 minutes, and so on. However, if sleep latency and the duration of wake time after sleep onset exceeded 30 minutes, or if sleep efficiency was less than 85%, they are instructed to restrict their time in bed by 15 minutes.

The IC condition was also delivered over four consecutive weeks, and included one individual in-person visit (approximately 30 minutes) at Week 1, a booster in-person visit at Week 3 (< 20 minutes), and brief telephone appointments during Weeks 2 and 4 (< 20 minutes each). Veterans randomized to the IC condition received two brochures created by the American Academy of Sleep Medicine (AASM) on insomnia and healthy sleep practices on Week 1. Participants were told that the content of the brochures had been approved by the AASM, which is the professional association of American sleep specialists. The same brochures have been used in a previous trial of BBTI (Buysse et al., 2011). They were instructed to review the content of the brochures in the following weeks, and were informed that the therapist would follow up with them over the following weeks to determine if they had read the materials, and if they had any questions or comments on the content of the brochures. The content of the AASM brochures was not discussed or reviewed during this session. The AASM brochures also included information regarding sleep-promoting behaviors (e.g., do not go to or stay in bed unless sleeping; limit time in bed to sleep time, limit light and noise in your sleep environment, limit caffeine and alcohol intake). However, no specific or individually tailored recommendations were offered to alter sleep-related behaviors. Rather, the therapist encouraged the veteran to read these brochures for potentially helpful strategies. Combat or traumatic experiences, or strategies to manage psychiatric symptoms or other types of difficulties, were not discussed in the IC condition.

Veterans randomized to the IC condition returned for an in-person on Week 3 to review information collected from the sleep diary, and address any question they may have had. As in the BBTI-MV conditions, telephone contacts were scheduled on Weeks 2 and 4 to monitor side effects and address questions.

After completing the post-treatment evaluation, Veterans randomized to the IC conditions were offered BBTI-MV, and completed the follow-up period and assessments.

Therapist training and competence

Both interventions were delivered by a masters' level clinical social worker (RJR) with 10 years of prior clinical experience in cognitive-behavioral treatments of mood and anxiety disorders. She first completed a three-day intensive training program in behavioral sleep medicine for the treatment of insomnia, and underwent additional supervised training at the University of Pittsburgh. The training procedures included didactic readings and continuing education sessions on diagnostic and evaluation issues relevant to sleep complaints and sleep disorders. The therapist met with the principal investigator on a weekly basis for supervision and discussion regarding conceptualization and strategies to implement BBTI-MV with study participants, to review specific tactics to be utilized and adapted during intervention sessions, and to identify tailored individual recommendations for reducing insomnia. All sessions were audiotaped and reviewed for adherence to the manual content. Because BBTI-MV is a manualized intervention and because a script was provided to the therapist to present the brochures in the IC condition, treatment integrity was assessed and revealed no deviation from either treatment protocol (i.e., BBTI-MV and IC).

Definition of treatment response and remission

Treatment response was defined as a reduction of 8 points or more on the ISI (Morin, Belleville, Belanger, & Ivers, 2011). Remission was defined as 1) meeting criteria for treatment response, and 2) achieving a post-treatment ISI score below the clinical threshold of 7 for the post-treatment and 6-month follow-up.

Post-treatment disposition and naturalistic six-month follow-up

After the post-treatment evaluation, participants randomized to BBTI-MV were contacted monthly to remind them of the date of their six-month follow-up appointment, and Veterans randomized to the IC conditions were offered BBTI-MV. After completing the four-week BBTI-MV treatment phase, these Veterans were contacted monthly to remind them of the date of their six-month follow-up appointment to re-assess changes in insomnia, sleep quality, and daytime symptoms.

Statistical analyses

Distributions were first examined to assess normality and check for outliers. PCL scores were not normally distributed, and a natural log (ln) transformation was used in the analyses. All continuous variables were described in original units using means and standard deviations while frequencies and percentages were used to describe all categorical variables. Student *t*-tests and Chi-squared tests were conducted to compare randomized samples on clinical variables.

Primary and secondary outcomes of interest were tested using planned contrasts in mixed effects models modeling 3 time points (pre, post-treatment and 6-month follow-up). We followed the intention-to-treat principle: all randomized participants who completed the outcomes of interest at least one of the time points were included in the analyses and groups were analyzed according to the original randomized treatment. The planned contrasts first examined BBTI-MV vs. IC differences in the changes from pre- to post-treatment. Secondly, the planned contrasts examined changes separately within the BBTI-MV group and in the group of Veterans first randomized to the IC group. For the post- to follow-up within group comparisons, only four veterans first randomized to the IC conditioned declined BBTI-MV between the post-treatment and six-month follow-up; therefore, their follow-up assessment was treated as missing in the analyses. Specifically, only veterans randomized to the IC condition who then completed BBTI-MV contribute follow-up scores in this post to follow-up planned contrast. Sensitivity analyses were thus conducted to assess whether the exclusion of the four veterans who declined BBTI-MV after completing the IC conditions altered the effects seen for the IC group. The sensitivity analysis (using all subjects, dropping follow-up scores for those IC subjects who later declined BBTI-MV) yield similar findings.

Treatment response rates (defined as reduction of 8 points on the ISI), and remission rates (defined as meeting criteria for treatment response and post-treatment ISI scores equal to or below the clinical cut-off scores of 7) were assessed post-treatment and at the six-month follow-up, and were compared using Chi-squared tests at post-treatment.

Results

Sample characteristics

The participant flow is provided in Figure 1. To highlight the typical challenges in recruiting military samples for research studies, the total number of initial inquiries received by phone and telephone screens completed prior to the in-person consent visit. Reasons for exclusion before and after the consent visits are included in the flowchart. A total of 697 individuals contacted the research program to inquire about the study and initiated brief telephone screening. Two-hundred-forty-eight individuals (35.6%) declined further participation (i.e., lost contact with research team, no showed after at least three rescheduled appointments, or were no longer interested or able to participate); 181(26%) were excluded because they did not meet the inclusion criteria regarding military service; 58 were excluded due to the presence of another sleep disorder (8%); and 28 (4%) were excluded due to the presence of concurrent unstable or untreated medical or psychiatric disorders. Seventy-six Veterans provided written informed consent (65 men, 11 women; Mean age = 39.00 years, *s.d.* = 12.59 years; range: 21 to 65 years old). Thirty-six participants were excluded after providing written consent. Loss of interest or ability to continue participation (*n* = 17) and exclusionary sleep, psychiatric, or medical conditions (*n* = 14) were the most common reasons for withdrawal after consent. The remaining 40 Veterans (34 men, Mean age = 38.36, *s.d.* = 11.69 years) were randomized to BBTI-MV or the IC condition. Of the 20 Veterans randomized to BBTI-MV, all initiated the treatment, 17 completed all sessions and the post-treatment assessments, and 15 completed the six-month follow-up assessments. Of

the 20 Veterans randomized to IC, one declined the randomization to the IC condition and withdrew prior to the first intervention session, 19 initiated the treatment, 16 completed all sessions and the post-treatment assessments, and 10 completed the six-month follow-up. These 10 Veterans included four who declined BBTI-MV after completing the four-week trial, and six who elected to complete the four-week course of BBTI-MV.

Demographic and military service information and the apnea-hypopnea index obtained at baseline for the two treatment groups are provided in Table 1. Of the 40 randomized participants, 28 completed their military service in the Army. The sample included 34 (85%) men, and 31 Caucasians (77.5% white), which are consistent with the demographics of living Military Veterans registered with the VHA as of September 2013 (http://www.va.gov/vetdata/Veteran_Population.asp). Eight met diagnostic criteria for current PTSD (four in each treatment group), nine met diagnostic criteria for a current mood or anxiety disorder (three randomized to BBTI-MV) and five continued use of psychotropic or hypnotic medication during the course of the study (four randomized to BBTI-MV). Military branch, use of medications, or current or past psychiatric history did not differ between the two groups.

Response and remission rates post-treatment and at the six-month follow-up

Thirteen of the 17 Veterans (76.47%) who completed BBTI-MV met criteria for treatment response compared to eight of the 16 Veterans (50%) who completed the IC, but the two groups did not differ ($\chi^2 = 2.50, p > 0.05$). Closer examination of sleep dairies and of weekly clinical notes revealed that all eight IC responders implemented changes consistent with stimulus control (i.e., elected to wake up at the same time every day of the week; did not go to bed unless they were sleepy and did not stay in bed unless they were asleep) after reading the brochures and receiving bibliotherapy from the therapist (RJR). None of the eight IC non-responders made changes to their sleep schedule or sleep habits over the course of the interventions. The four BBTI-MV non-responders were all unable to adhere to the prescribed sleep-wake schedule during the four-week intervention due to: unanticipated orders for field training ($n = 1$); unanticipated changes in work schedule ($n = 2$); and premature birth of a child ($n = 1$). All 13 responders to BBTI-MV closely adhered to the prescribed sleep wake schedule, and did not deviate by more than 30 minutes from the prescribed wake time over the course of treatment. Nine of the 17 who completed BBTI-MV (52.94%) and five of the 16 who completed the IC condition (31.25%) met the criterion for remission post-treatment, and the two groups did not significantly differ on this criterion ($\chi^2 = 1.59, p > 0.05$).

Twenty-five Veterans were reached and completed the 6-month follow-up assessment, including 15 who were first randomized to BBTI-MV, six who completed BBTI-MV after completing the IC condition, and four who declined BBTI-MV after completing the IC condition. Among the 15 randomized to BBTI-MV, seven remained in remission and one new remission occurred, one maintained the response status and one new response occurred, one participant maintained the response status and one more met the response criterion; two remained non-responders, and two participants relapsed (one from remission to non-response, and the other from response to non-response). The ISI score was missing for the

last participant. Among the six participants who were randomized to the IC condition and elected to receive BBTI-MV, three participants met the criterion for remission, two maintained their response status, and one met the criterion for treatment response. Finally, of the four participants who were randomized to the IC condition, declined BBTI-MV, and completed the six-month follow-up, one achieved remission, one remained in remission, one remained a responder, and one achieved response.

Changes in sleep and daytime symptom measures over time

Mean scores pre- and post-treatment for the sleep and daytime symptom measures, planned contrasts, and effect sizes with 95% confidence intervals are summarized in Table 2. Pre- to post-treatment improvements in insomnia severity and sleep quality were significantly greater in BBTI-MV compared to the IC condition. However, the two groups did not differ significantly on disruptive nocturnal behaviors or on any of the daytime symptom measures pre-to post-treatment.

Within-group planned contrasts across time points for the BBTI-MV group and for the IC condition are presented in Table 3. Veterans randomized to BBTI-MV significant reductions in insomnia severity, improvements in sleep quality, and reduction in depression severity pre- to post-treatment, and maintained these gains at the six-month follow-up. No significant improvements in disruptive nocturnal behaviors or daytime symptoms of PTSD or anxiety detected over time in the BBTI-MV group.

Participants who were initially randomized to the IC condition also showed reductions in insomnia severity and improvements in sleep quality pre- to post-treatment. IC followed by BBTI-MV was associated with further reductions in insomnia severity at the six month-follow-up. This group of Veterans also showed reductions in the severity of anxiety and PTSD symptoms pre- to post-IC. IC followed by BBTI-MV was associated with further improvements in PTSD symptom severity at the six month follow-up.

Discussion

The goal of this preliminary randomized controlled trial was to evaluate the effects of the military version of a brief behavioral treatment of insomnia in combat-exposed Service Members and Veterans on insomnia severity compared to an information only control condition. Consistent with previous studies conducted in civilians (Buysse et al., 2011; Edinger & Sampson, 2003; Germain et al., 2006; Smith, Huang, & Manber, 2005), the military version of a brief behavioral treatment of insomnia was shown to be feasible, safe, and associated with clinically significant improvements in insomnia and overall sleep quality. BBTI-MV was associated with high rates of response and remission at post-treatment and improvements were maintained over the 6-month open follow-up period. The results suggest that BBTI-MV represents a potential new format to deliver evidence-based behavioral treatments for insomnia (i.e., stimulus control and sleep restriction) in returning military personnel who present with primary or comorbid insomnia in a variety of care settings where CBTI and/or sleep specialists are unavailable. While this preliminary trial is promising, the results should nevertheless be interpreted with caution. Confirmatory trials

are required in order to fully assess the efficacy and effectiveness of BBTI-MV among Veterans and Service Members.

While rates of treatment response (77%) and remission (53%) were greater in those who received BBTI-MV, the provision of educational materials that contain behavioral strategies to improve insomnia in combination with the therapist encouragement to read and consider the recommendations listed in the materials yielded unexpectedly high rates of treatment response (50%) and remission (32%) in this sample of combat-exposed Veterans and Service Members. A previous trial that employed the same comparison condition (Buysse et al., 2011; Germain et al., 2006; Germain et al., 2012) found response rates of approximately 25% and remission rates of less than 5% in individuals who received information only. In contrast to earlier studies, the examination of sleep diaries completed by Veterans randomized to the IC conditions revealed that all IC responders and remitters implemented behavioral changes consistent with stimulus control. Thus, the present findings suggest that the provision of educational materials with minimal interventions from a therapist may provide a viable strategy in a stepped-care model for the treatment of insomnia in returning Service Members and Veterans. It is possible that military training and experiences may facilitate adherence to behavioral changes recommended described in the information materials for sleep restriction and stimulus control and increase tolerance to transient increases in sleepiness and fatigue, thereby, facilitating sleep improvements. Thus, it is possible that the IC condition was not an inert intervention, but appears to be similar to bibliotherapy with minimal therapist's supervision. Insomnia trials with self-help or bibliotherapy interventions, with or without therapist's supervision, have in reported moderate to large improvements for adults with insomnia (Jernelov et al., 2012; Lancee, van den Bout, van, & Spoormaker, 2012; Mimeault & Morin, 1999; Morgan, Gregory, Tomeny, David, & Gascoigne, 2012). Thus, bibliotherapy with minimal therapist's supervision may constitute an efficacious intervention for military Veterans with relatively low levels of psychiatric comorbidities. The latter possibility can be empirically investigated. Nevertheless, and while preliminary, the present observations suggest that bibliotherapy, in the right context and with the right patient, can be included in personalized medicine/stepped-care approaches to treating insomnia. Larger confirmatory randomized trials and/or preference based trials are necessary to identify individual characteristics that may predict better outcomes following educational recommendations or individualized treatment recommendations.

Contrary to our hypothesis, improvements in insomnia and overall sleep quality were not paralleled by marked improvements in symptoms of PTSD, depression, and anxiety. Rather, BBTI-MV was associated with modest improvements in depression, whereas the IC condition was associated with modest improvements in PTSD and anxiety symptoms. The absence of marked improvements in daytime symptoms is likely due to the overall low baseline severity of PTSD, depression, and anxiety symptoms endorsed by this sample. The latter likely reflects our recruitment strategies, which were independent from VA-based recruitment, and in turn, may have contributed to the enrollment of Veterans (and Active Duty Service Members) who are less severely and chronically ill relative to treatment-seeking VA samples. Nevertheless, the results provide preliminary support for the use of BBTI-MV in Veterans and Service Members who endorse clinically significant insomnia.

While the present findings suggest that BBTI-MV and therapist's assisted bibliotherapy can be associated with marked improvements in sleep quality, replications in larger military samples with more severe psychiatric symptoms or active psychiatric affective or substance disorders are necessary to evaluate the effects of reducing insomnia on daytime symptoms of PTSD, depression, and anxiety.

The present study has a number of limitations. The determination of the sample size for this preliminary trial was based on effect sizes reported in other controlled trials of brief behavioral sleep treatments and information only controls in civilian samples. However, the present findings showed that larger samples were needed to detect significant group differences on response and remission rates. Despite efforts to minimize exclusion criteria, the presence of comorbid unstable or severe untreated psychiatric, medical, and sleep disorders constituted a primary reason for exclusion (after no-shows for visit or inability to continue participation in the study). This observation highlights the frequency of insomnia complaints comorbid with severe psychiatric, medical, or sleep disorders in this sample, and points to the limited generalizability of the present findings to more severely ill military Veterans and Service Members. As previously noted, larger randomized trials in more heterogeneous samples are required to draw more definitive conclusions regarding the potential effectiveness of BBTI-MV and IC. Special attention should be dedicated to testing the effects of insomnia treatments in Veterans with comorbid alcohol or substance use disorders and PTSD and/or depression. The use of a single therapist (RJR) with extensive experience in cognitive-behavioral treatments of anxiety disorders is also a limitation of this preliminary trial. Whether the magnitude of the improvements in insomnia would be comparable with less experienced therapists is yet to be determined. Delivering BBTI-MV, although several trials have shown that non-doctoral level clinicians delivering CBTI in civilian samples leads to significant decreases in insomnia severity (Buysse et al., 2011; Espie et al., 2007; Trockel et al., 2014). Nevertheless, the manualization of BBTI-MV is likely to facilitate the dissemination of this military-relevant treatment to practitioners with different levels of training in evidence-based psychotherapies and behavioral sleep medicine. In summary, a number of limitations need to be carefully considered in the interpretation of implications for these preliminary findings. Despite these limitations, findings from this preliminary randomized controlled trial suggest that larger clinical trials or comparative effectiveness trials are warranted to fully evaluate and compare the effects of bibliotherapy, BBTI-MV, and CBTI on insomnia and daytime symptoms of depression and anxiety in military samples. Larger trials are also necessary to determine which treatment best matches patients' characteristics and to determine treatment strategies to optimize outcomes. The results of this study also suggest that information-based or self-help treatment strategies and BBTI-MV may both be valuable components of a cost-effective, stepped-care approach for Veterans who present with complaints of insomnia. In other words, while the longer CBTI formats (5–8 sessions) are effective for a majority of participants who receive the treatment, bibliotherapy and BBTI-MV are likely to be complementary treatments and help to deliver and disseminate behavioral insomnia treatments more broadly, especially in contexts where available resources and expertise may limit access to care. The current preliminary findings suggest that brochures that include recommendations for behavioral changes that are consistent with stimulus control and/or

sleep restriction may yield significant improvements in Veterans who present with low psychiatric and medical comorbidities. The present findings also suggest that the combination of brochures followed by BBTI may yield clinically meaningful improvements in sleep in this sample. In turn, both AASM brochures and BBTI-MV may be considered “lower dose” interventions that may be effective in those with mild to moderate levels of comorbidity. Of note, briefer, “lower dose” intervention strategies may be well-suited for mobile health technologies. More intensive treatments and the often limited resources and expertise could, thus, be made available for individuals who present with more severe or complex psychiatric and/or medical comorbidities. Specific guidelines to personalize the treatment of insomnia, including the identification of its optimal “dose,” are currently lacking, but are essential in the development of cost-effective treatment strategies for insomnia in military Veterans and Service Members. In addition to examining the “dose” of intervention required for different levels of severity and complexity of insomnia, it may be useful to examine the levels of clinical expertise and training required to effectively deliver insomnia treatment in a stepped model of care.

In a related manner, longitudinal studies are necessary to evaluate whether BBTI-MV and other treatments can prevent the occurrence and recurrence of psychiatric conditions for which insomnia is an established predictor, including PTSD and other anxiety disorders, depression, heightened suicidality, and addictive disorders (Baglioni et al., 2011; Breslau, Roth, Rosenthal, & Andreski, 1996; Bryant, Creamer, O'Donnell, Silove, & McFarlane, 2010; Ribeiro et al., 2012; Seelig et al., 2010).

Focusing on insomnia as a primary treatment target in post-deployment populations offers several advantages. From a clinical perspective, sleep disturbances are highly prevalent, expected, and perceived as socially acceptable during and after military deployment (Ogle, Bradley, Santiago, & Reynolds, 2012; Wright et al., 2008). The perceived stigma for seeking help for insomnia may be low compared to the perceived stigma associated with seeking mental health treatment for PTSD, depression, anxiety, or addictive behaviors (Milliken, Auchterlonie, & Hoge, 2007; Warner et al., 2011). Hoge and colleagues have shown that military personnel are reluctant to seek psychiatric treatment (Hoge et al., 2004). However, PTSD, depression, anxiety, and addictive disorders are all characterized by insomnia and other sleep disturbances. Thus, offering sleep-focused treatments may provide a symptom-focused, non-stigmatizing portal of entry into behavioral health care; essentially a “gateway” mental health treatment. In a similar manner, addressing insomnia prior to initiating treatment for comorbid psychiatric issues may provide military personnel, who often avoid talking about military-related experiences to civilians, an opportunity to build trust and rapport with clinicians. In turn, rapid improvements in insomnia may provide positive reinforcement for help seeking, and thus, enhance engagement in treatment for comorbid psychiatric disorders and other post-deployment challenges such as marital difficulties. Finally, the brevity of the four-week course of BBTI-MV allows for early consideration of alternative treatment approaches in the event of non-response. All of these possibilities are easily amenable to empirical testing.

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Reference List

- Epstein LJ, Kristo D, Strollo PJ, Friedman N, Malhotra A, et al. Adult Obstructive Sleep Apnea task Force of the American Academy of Sleep Medicine. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *Journal of Clinical Sleep Medicine*. 2009; 5(3):263–276. [PubMed: 19960649]
- Hauri PJ, Sateia MJ. American Academy of Sleep Medicine. The International Classification of Sleep Disorders, Second Edition (ICSD-2): Diagnostic and Coding Manual. 2005
- Applewhite L, Keller N, Borah A. Mental health care use by soldiers conducting counterinsurgency operations. *Military Medicine*. 2012; 177(5):501–506. Retrieved from PM:22645874. [PubMed: 22645874]
- Baglioni C, Battagliese G, Feige B, Spiegelhalder K, Nissen C, Voderholzer U, et al. Insomnia as a predictor of depression: a meta-analytic evaluation of longitudinal epidemiological studies. *Journal of Affective Disorders*. 2011; 135(1–3):10–19. doi:S0165-0327(11)00029-2 [pii];10.1016/j.jad.2011.01.011 [doi]. Retrieved from PM:21300408. [PubMed: 21300408]
- Bastien CH, Vallieres A, Morin CM. Validation of the Insomnia Severity Index as an outcome measure for insomnia research. *Sleep Medicine*. 2001; 2(4):297–307. Retrieved from http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=11438246. [PubMed: 11438246]
- Beck AT, Epstein N, Brown G, Steer RA. An inventory for measuring clinical anxiety: psychometric properties. *Journal of Consulting and Clinical Psychology*. 1988; 56(6):893–897. [PubMed: 3204199]
- Beck AT, Ward CH, Mendelson M, Mock J, Erbaugh J. An inventory for measuring depression. *Archives of General Psychiatry*. 1961; 4:561–571. Retrieved from PM:13688369. [PubMed: 13688369]
- Blake DD, Weathers FW, Nagy LM, Kaloupek DG, Gusman FD, Charney DS, et al. The development of a Clinician-Administered PTSD Scale. *Journal of Traumatic Stress*. 1995; 8(1):75–90. Retrieved from PM:7712061. [PubMed: 7712061]
- Blanchard EB, Jones-Alexander J, Buckley TC, Forneris CA. Psychometric properties of the PTSD Checklist (PCL). *Behaviour Research and Therapy*. 1996; 34(8):669–673. Retrieved from PM: 8870294. [PubMed: 8870294]
- Bootzin, RR.; Nicassio, PM. Behavioral treatments of insomnia. In: Hersen, M.; Eisler, RE.; Miller, PM., editors. *Progress in behavior modification*. Vol. 6. New York: Academic Press; 1978. p. 1-45.
- Borbely AA. A two process model of sleep regulation. *Human Neurobiology*. 1982; 1(3):195–204. Retrieved from PM:7185792. [PubMed: 7185792]
- Bramoweth AD, Germain A. Deployment-related insomnia in military personnel and veterans. *Curr.Psychiatry Rep*. 2013; 15(10):401. [doi]. Retrieved from PM:24005883. [PubMed: 24005883]
- Breslau N, Roth T, Rosenthal L, Andreski P. Sleep disturbance and psychiatric disorders: a longitudinal epidemiological study of young adults. *Biological Psychiatry*. 1996; 39(6):411–418. [PubMed: 8679786]

- Bryant RA, Creamer M, O'Donnell M, Silove D, McFarlane AC. Sleep disturbance immediately prior to trauma predicts subsequent psychiatric disorder. *Sleep*. 2010; 33(1):69–74. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/20120622>. [PubMed: 20120622]
- Buyse DJ, Germain A, Moul DE, Franzen PL, Brar LK, Fletcher ME, et al. Efficacy of brief behavioral treatment for chronic insomnia in older adults. *Archives of Internal Medicine*. 2011; 171(10):887–895. Retrieved from PM:21263078. [PubMed: 21263078]
- Buyse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: A new instrument for psychiatric practice and research. *Psychiatry Research*. 1989; 28(2):193–213. Retrieved from PM:2748771. [PubMed: 2748771]
- Carlsten H, Tarkowski A, Holmdahl R, Nilsson LA. Oestrogen is a potent disease accelerator in SLE-prone MRL lpr/lpr mice. *Clinical & Experimental Immunology*. 1990; 80(3):467–473. Retrieved from PM:2372993. [PubMed: 2372993]
- Collen J, Orr N, Lettieri CJ, Carter K, Holley AB. Sleep disturbances among soldiers with combat-related traumatic brain injury. *Chest*. 2012; 142(3):622–630. doi:chest.11-1603 [pii];10.1378/chest.11-1603 [doi]. Retrieved from PM:22459784. [PubMed: 22459784]
- Cozza, SJ.; Benedek, DM.; Bradley, JC.; Grieger, TA.; Nam, TS.; Waldrep, DA. Topics specific to the psychiatric treatment of military personnel. In: Schnurr, PP.; Cozza, SJ., editors. *The Iraq War Clinician Guide*. 2nd ed.. National Center for PTSD and Department of Defense; 2004.
- Edinger, JD.; Carney, CE. *Overcoming Insomnia: A Cognitive-Behavioral Therapy Approach Therapist Guide (Treatments That Work)*. 1st edition ed.. Oxford University Press, Inc.; 2008.
- Edinger JD, Olsen MK, Stechuchak KM, Means MK, Lineberger MD, Kirby A, et al. Cognitive behavioral therapy for patients with primary insomnia or insomnia associated predominantly with mixed psychiatric disorders: a randomized clinical trial. *Sleep*. 2009; 32(4):499–510. Retrieved from PM:19413144. [PubMed: 19413144]
- Edinger JD, Sampson WS. A primary care "friendly" cognitive behavior insomnia therapy. *Sleep*. 2003; 26(2):177–182. [PubMed: 12683477]
- Edinger JD, Wohlgemuth WK, Radtke RA, Coffman CJ, Carney CE. Dose-response effects of cognitive-behavioral insomnia therapy: a randomized clinical trial. *Sleep*. 2007; 30(2):203–212. Retrieved from PM:17326546. [PubMed: 17326546]
- Espie CA, Macmahon KM, Kelly HL, Broomfield NM, Douglas NJ, Engleman HM, et al. Randomized clinical effectiveness trial of nurse-administered small-group cognitive behavior therapy for persistent insomnia in general practice. *Sleep*. 2007; 30(5):574–584. Retrieved from PM:17552372. [PubMed: 17552372]
- First, M.; Spitzer, RL.; Gibbon, M.; Williams, JBW. *Structured Clinical Interview for DSM-IV Axis I Disorders-Patient Edition (SCID-I/P) (Version 2.0 ed.)*. New York: New York State Psychiatric Institute; 1995.
- Germain A, Hall M, Krakow B, Katherine Shear M, Buysse DJ. A brief sleep scale for Posttraumatic Stress Disorder: Pittsburgh Sleep Quality Index Addendum for PTSD. *Journal of Anxiety Disorders*. 2005; 19(2):233–244. Retrieved from http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15533706. [PubMed: 15533706]
- Germain A, Moul DE, Franzen PL, Miewald JM, Reynolds CF, Monk TH, et al. Effects of a brief behavioral treatment for late-life insomnia: Preliminary findings. *Journal of Clinical Sleep Medicine*. 2006; 2(4):403–406. Retrieved from PM:17557467. [PubMed: 17557467]
- Germain A, Richardson R, Moul DE, Mammen O, Haas G, Forman SD, et al. Placebo-controlled comparison of prazosin and cognitive-behavioral treatments for sleep disturbances in US Military Veterans. *Journal of Psychosomatic Research*. 2012; 72(2):89–96. doi:S0022-3999(11)00283-2 [pii];10.1016/j.jpsychores.2011.11.010 [doi]. Retrieved from PM:22281448. [PubMed: 22281448]
- Germain A, Shear MK, Hall M, Buysse DJ. Effects of a brief behavioral treatment for PTSD-related sleep disturbances: A pilot study. *Behaviour Research and Therapy*. 2007; 45:627–632. Retrieved from PM:16777060. [PubMed: 16777060]
- Harvey AG, Tang NK, Browning L. Cognitive approaches to insomnia. *Clinical Psychology Review*. 2005; 25(5):593–611. Retrieved from PM:15979771.

- Hoge CW, Castro CA, Messer SC, McGurk D, Cotting DI, Koffman RL. Combat duty in Iraq and Afghanistan, mental health problems, and barriers to care. *New England Journal of Medicine*. 2004; 351(1):13–22. Retrieved from PM:15229303. [PubMed: 15229303]
- Insana SP, Hall M, Buysse DJ, Germain A. Validation of the Pittsburgh Sleep Quality Index Addendum for Posttraumatic Stress Disorder (PSQI-A) in U.S. Male Military Veterans. *Journal of Traumatic Stress*. 2013; 26(2):192–200. [doi]. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/23512653>. [PubMed: 23512653]
- Irwin MR, Cole JC, Nicassio PM. Comparative meta-analysis of behavioral interventions for insomnia and their efficacy in middle-aged adults and in older adults 55+ years of age. *Health Psychology*. 2006; 25(1):3–14. Retrieved from PM:16448292. [PubMed: 16448292]
- Jernelov S, Lekander M, Blom K, Rydh S, Ljotsson B, Axelsson J, et al. Efficacy of a behavioral self-help treatment with or without therapist guidance for co-morbid and primary insomnia—a randomized controlled trial. *BMC Psychiatry*. 2012; 12:5. doi:1471-244X-12-5 [pii]; 10.1186/1471-244X-12-5 [doi]. Retrieved from PM:22264332. [PubMed: 22264332]
- Johns MW. A new method for measuring daytime sleepiness: the Epworth sleepiness scale. *Sleep*. 1991; 14(6):540–545. [PubMed: 1798888]
- Johns MW. Reliability and factor analysis of the Epworth Sleepiness Scale. *Sleep*. 1992; 15(4):376–381. [PubMed: 1519015]
- Karlin BE. National dissemination of cognitive behavioral therapy for insomnia in veterans: Therapist- and patient-level outcomes. 2013
- Karlin BE, Trockel M, Taylor CB, Gimeno J, Manber R. National Dissemination of Cognitive Behavioral Therapy for Insomnia in Veterans: Therapist- and Patient-Level Outcomes. *Journal of Consulting and Clinical Psychology*. 2013 doi:2013-13036-001 [pii];10.1037/a0032554 [doi], Retrieved from PM:23586730.
- Kroenke K, Koslowe P, Roy M. Symptoms in 18,495 Persian Gulf War veterans. Latency of onset and lack of association with self-reported exposures. *Journal of Occupational and Environmental Medicine*. 1998; 40(6):520–528. Retrieved from PM:9636932. [PubMed: 9636932]
- Kyle SD, Morgan K, Spiegelhalter K, Espie CA. No pain, no gain: an exploratory within-subjects mixed-methods evaluation of the patient experience of sleep restriction therapy (SRT) for insomnia. *Sleep Medicine*. 2011; 12(8):735–747. doi:S1389-9457(11)00206-1 [pii];10.1016/j.sleep.2011.03.016 [doi]. Retrieved from PM:21907616. [PubMed: 21907616]
- Lancee J, van den Bout J, van SA, Spoormaker VI. Internet-delivered or mailed self-help treatment for insomnia?: a randomized waiting-list controlled trial. *Behav. Res. Ther.* 2012; 50(1):22–29. doi:S0005-7967(11)00224-5. [pii];10.1016/j.brat.2011.09.012 [doi]. Retrieved from PM: 22055281. [PubMed: 22055281]
- Lande RG. Troublesome triad: trauma, insomnia, and alcohol. *Journal of Addictive Diseases*. 2012; 31(4):376–381. [doi]. Retrieved from PM:23244556. [PubMed: 23244556]
- Lewis V, Creamer M, Failla S. Is poor sleep in veterans a function of posttraumatic stress disorder? *Military Medicine*. 2009; 174(9):948–951. Retrieved from http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=19780370. [PubMed: 19780370]
- Lund M, Foy D, Sippelle C, Strachan A. The Combat Exposure Scale: a systematic assessment of trauma in the Vietnam War. *Journal of Clinical Psychology*. 1984; 40(6):1323–1328. Retrieved from PM:6511942. [PubMed: 6511942]
- Macera CA, Aralis HJ, Rauh MJ, Macgregor AJ. Do sleep problems mediate the relationship between traumatic brain injury and development of mental health symptoms after deployment? *Sleep*. 2013; 36(1):83–90. [doi]. Retrieved from PM:23288974. [PubMed: 23288974]
- Manber R, Carney C, Edinger J, Epstein D, Friedman L, Haynes PL, et al. Dissemination of CBTI to the non-sleep specialist: protocol development and training issues. *Journal of Clinical Sleep Medicine*. 2012; 8(2):209–218. [doi]. Retrieved from PM:22505869. [PubMed: 22505869]
- McLay RN, Klam WP, Volkert SL. Insomnia is the most commonly reported symptom and predicts other symptoms of post-traumatic stress disorder in U.S. service members returning from military deployments. *Military Medicine*. 2010; 175(10):759–762. Retrieved from PM:20968266. [PubMed: 20968266]

- Milliken CS, Auchterlonie JL, Hoge CW. Longitudinal assessment of mental health problems among active and reserve component soldiers returning from the Iraq war. *Journal of the American Medical Association*. 2007; 298(18):2141–2148. Retrieved from PM:18000197. [PubMed: 18000197]
- Mimeault V, Morin CM. Self-help treatment for insomnia: bibliotherapy with and without professional guidance. *J. Consult Clin. Psychol.* 1999; 67(4):511–519. Retrieved from PM:10450621. [PubMed: 10450621]
- Monk TH, Reynolds CF, Kupfer DJ, Buysse DJ, Coble PA, Hayes AJ, et al. The Pittsburgh Sleep Diary. *Journal of Sleep Research*. 1994; 3(2):111–120. Retrieved from PM:10607115; PM: 11537903.
- Morgan K, Gregory P, Tomeny M, David BM, Gascoigne C. Self-help treatment for insomnia symptoms associated with chronic conditions in older adults: a randomized controlled trial. *J. Am. Geriatr. Soc.* 2012; 60(10):1803–1810. [doi]. Retrieved from PM:23035962. [PubMed: 23035962]
- Morin, CM. *Treatment Manuals for Practitioners*. New York-London: The Guilford Press; 1993. *Insomnia: Psychological Assessment and Management*.
- Morin CM, Belleville G, Belanger L, Ivers H. The Insomnia Severity Index: psychometric indicators to detect insomnia cases and evaluate treatment response. *Sleep*. 2011; 34(5):601–608. Retrieved from PM:21532953. [PubMed: 21532953]
- Morin CM, Culbert JP, Schwartz SM. Nonpharmacological interventions for insomnia: a meta-analysis of treatment efficacy. *American Journal of Psychiatry*. 1994; 151(8):1172–1180. Retrieved from PM:8037252. [PubMed: 8037252]
- Mysliwiec V, McGraw L, Pierce R, Smith P, Trapp B, Roth BJ. Sleep disorders and associated medical comorbidities in active duty military personnel. *Sleep*. 2013; 36(2):167–174. [doi]. Retrieved from PM:23372263. [PubMed: 23372263]
- Neylan TC, Marmar CR, Metzler TJ, Weiss DS, Zatzick DF, Delucchi KL, et al. Sleep disturbances in the Vietnam generation: findings from a nationally representative sample of male Vietnam veterans. *American Journal of Psychiatry*. 1998; 155(7):929–933. Retrieved from PM: 0009659859. [PubMed: 9659859]
- Ogle AD, Bradley D, Santiago P, Reynolds D. Description of combat and operational stress control in Regional Command East, Afghanistan. *Military Medicine*. 2012; 177(11):1279–1286. Retrieved from PM:23198502. [PubMed: 23198502]
- Okajima I, Komada Y, Inoue Y. A meta-analysis on the treatment effectiveness of cognitive behavioral therapy for primary insomnia. *Sleep and Biological Rhythms*. 2011; 9(1):24–34. Retrieved from <http://dx.doi.org/10.1111/j.1479-8425.2010.00481.x>.
- Perlis ML, Aloia M, Millikan A, Boehmler J, Smith M, Greenblatt D, et al. Behavioral treatment of insomnia: A clinical case series study. *J. Behav. Med.* 2000; 23(2):149–161. [PubMed: 10833677]
- Perlis, ML.; Aloia, MS.; Kuhn, BR. *Behavioral Treatments for Sleep Disorders: A Comprehensive Primer of Behavioral Sleep Medicine Treatment Protocols*. London, England: Elsevier Inc.; 2011.
- Peterson AL, Goodie JL, Satterfield WA, Brim WL. Sleep disturbance during military deployment. *Military Medicine*. 2008; 173(3):230–235. Retrieved from PM:18419023. [PubMed: 18419023]
- Ribeiro JD, Pease JL, Gutierrez PM, Silva C, Bernert RA, Rudd MD, et al. Sleep problems outperform depression and hopelessness as cross-sectional and longitudinal predictors of suicidal ideation and behavior in young adults in the military. *Journal of Affective Disorders*. 2012; 136(3):743–750. doi:S0165-0327(11)00575-1 [pii];10.1016/j.jad.2011.09.049 [doi]. Retrieved from PM:22032872. [PubMed: 22032872]
- Seelig AD, Jacobson IG, Smith B, Hooper TI, Boyko EJ, Gackstetter GD, et al. Sleep patterns before, during, and after deployment to Iraq and Afghanistan. *Sleep*. 2010; 33(12):1615–1622. Retrieved from http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=21120123; PMID:21120123. [PubMed: 21120123]
- Smith MT, Huang MI, Manber R. Cognitive behavior therapy for chronic insomnia occurring within the context of medical and psychiatric disorders. *Clinical Psychology Review*. 2005; 25(5):559–592. Retrieved from PM:15970367. [PubMed: 15970367]

- Smith MT, Perlis ML, Park A, Smith MS, Pennington J, Giles DE, et al. Comparative meta-analysis of pharmacotherapy and behavior therapy for persistent insomnia. *American Journal of Psychiatry*. 2002; 159(1):5–11. Retrieved from PM:11772681. [PubMed: 11772681]
- Spielman AJ, Saskin P, Thorpy MJ. Treatment of chronic insomnia by restriction of time in bed. *Sleep*. 1987; 10(1):45–56. Retrieved from PM:3563247. [PubMed: 3563247]
- Swift N, Stewart R, Andiappan M, Smith A, Espie CA, Brown JS. The effectiveness of community day-long CBT-I workshops for participants with insomnia symptoms: a randomised controlled trial. *Journal of Sleep Research*. 2012; 21(3):270–280. [doi]. Retrieved from PM:21848573. [PubMed: 21848573]
- Terhakopian A, Sinaii N, Engel CC, Schnurr PP, Hoge CW. Estimating population prevalence of posttraumatic stress disorder: an example using the PTSD checklist. *J. Trauma Stress*. 2008; 21(3): 290–300. [doi]. Retrieved from PM:18553416. [PubMed: 18553416]
- Trockel M, Karlin BE, Taylor CB, Manber R. Cognitive Behavioral Therapy for insomnia with Veterans: evaluation of effectiveness and correlates of treatment outcomes. *Behav. Res. Ther*. 2014; 53:41–46. doi:S0005-7967(13)00197-6 [pii];10.1016/j.brat.2013.11.006 [doi]. Retrieved from PM:24412462. [PubMed: 24412462]
- Troxel WM, Germain A, Buysse DJ. Clinical management of insomnia with brief behavioral treatment (BBTI). *Behav. Sleep Med*. 2012; 10(4):266–279. [doi]. Retrieved from PM:22946736. [PubMed: 22946736]
- van LS, van ZM, Westenberg H, Super A, Vermetten E. Impact of impaired sleep on the development of PTSD symptoms in combat veterans: a prospective longitudinal cohort study. *Depression and Anxiety*. 2013; 30(5):469–474. [doi]. Retrieved from PM:23389990. [PubMed: 23389990]
- Warner CH, Appenzeller GN, Grieger T, Belenkiy S, Breitbach J, Parker J, et al. Importance of anonymity to encourage honest reporting in mental health screening after combat deployment. *Archives of General Psychiatry*. 2011; 68(10):1065–1071. doi:68/10/1065 [pii];10.1001/archgenpsychiatry.2011.112 [doi]. Retrieved from PM:21969463. [PubMed: 21969463]
- Wilkins KC, Lang AJ, Norman SB. Synthesis of the psychometric properties of the PTSD checklist (PCL) military, civilian, and specific versions. *Depress. Anxiety*. 2011; 28(7):596–606. [doi]. Retrieved from PM:21681864. [PubMed: 21681864]
- Wright KM, Adler AB, Bliese PD, Eckford RD. Structured clinical interview guide for postdeployment psychological screening programs. *Military Medicine*. 2008; 173(5):411–421. Retrieved from http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=18543560. [PubMed: 18543560]
- Wright KM, Britt TW, Bliese PD, Adler AB, Picchioni D, Moore D. Insomnia as predictor versus outcome of PTSD and depression among Iraq combat veterans. *Journal of Clinical Psychology*. 2011; 67(12):1240–1258. [doi]. Retrieved from PM:22065464. [PubMed: 22065464]
- Yang SL, Mu YM, Tang KQ, Jiang XK, Bai WK, Shen E, et al. Enhancement of recombinant adeno-associated virus mediated transgene expression by targeted echo-contrast agent. *Genetics and Molecular Research*. 2013; 12(2):1318–1326. doi:gmr2292 [pii];10.4238/2013.April.25.3 [doi]. Retrieved from PM: 23661455. [PubMed: 23661455]

Highlights

- BBTI-MV is associated with marked improvement in insomnia.
- Psychoeducation is also associated with improvements in insomnia.
- Both approaches provide strategies to manage insomnia in post-9/11 personnel.

Figure 1.
Recruitment flow chart

Table 1

Demographic, military, and clinical information for the two treatment groups.

	BBTI-MV (N = 20)	IC (N = 20)	Statistical Comparison
Mean Age (SD)	40.9 (12.0)	35.9 (11.2)	$t(38) = 1.37, n.s.$
% Men (n)	75 (15)	95 (19)	$\chi^2 = 3.14, n.s.$
% Caucasian (n)	70 (14)	85 (17)	$\chi^2 = 1.29, n.s.$
% Army (n)	60% (12)	80% (16)	$\chi^2 = 0.44, n.s.$
Mean Combat Exposure Scale (SD)	13.0 (10.1)	15.9 (11.7)	$t(38) = 0.83, n.s.$
% Use of psychotropics (n)	25% (5)	0% (0)	* $\chi^2 = 3.66, n.s.$
% current PTSD (n)	25% (4)	25% (4)	$\chi^2 = 0.00, n.s.$
% current mood /anxiety disorder	10% (2)	15% (3)	* $\chi^2 = 0.00, n.s.$
Mean apnea-hypopnea index	2.9 ± 4.4	2.8 ± 3.9	$t(38) = 0.05, n.s.$
Mean Epworth Sleepiness Scale	7.3 ± 4.5	7.1 ± 3.6	$t(38) = 0.88, n.s.$

* With continuity correction.

Table 2

Mean scores, planned contrasts, and effect sizes with 95% confidence intervals [95% C.I.] for between-group comparisons pre- to post-treatment including randomized participants.

Variable	BBTL-MV (N = 20)		IC (n = 16)		Group Differences Planned Contrasts		Effect Sizes	
	Pre	Post	Pre	Post	Estimates (SE)	t-statistics (df)	p	[95% C.I.]
	M (SD)	M (SD)	M (SD)	M (SD)				
Insomnia Severity Index	16.30 (3.92)	7.82 (4.71)	14.95 (3.58)	10.00 (4.50)	3.71 (1.67)	2.22 (47)	0.03	0.72 [0.06 – 1.38]
Pittsburgh Sleep Quality Index (PSQI)	11.25 (3.54)	6.00 (3.16)	9.88 (3.43)	7.13 (3.46)	2.80 (1.20)	2.34 (45)	0.02	0.76 [0.10 – 1.42]
PSQI Addendum for PTSD	2.15 (2.91)	1.76 (2.28)	3.33 (3.14)	2.38 (2.78)	-0.39 (0.80)	-0.48 (46)	n.s.	0.16 [-0.48 – 0.79]
PTSD checklist*	24.60 (7.83)	22.88 (9.00)	28.16 (8.32)	23.88 (5.15)	-0.05 (0.09)**	-0.50 (49)	n.s.	0.16 [-0.48 – 0.80]
Beck Depression Inventory*	6.00 (4.89)	3.12 (3.35)	5.00 (4.93)	3.31 (4.19)	2.00 (1.39)	1.44 (49)	n.s.	0.47 [-0.18 – 1.11]
Beck Anxiety Inventory	4.25 (4.52)	3.71 (3.80)	5.35 (5.91)	3.20 (4.92)	-1.67 (1.20)	-1.39 (47)	n.s.	0.45 [-0.19 – 1.10]

* Total score minus sleep item.

† Ln scale used for analyses. Raw mean scores and standard deviations are presented.

Table 3

Within-group[‡] mean scores change (standard error) across time points.

Variable	Pre-to post- Mean score changes		Post-to 6 months treatment contrasts		
	Estimates (SE)	t-statistics (df)	p	Estimates (SE)	t-statistics (df)
Insomnia Severity Index					
BBTI-MV	8.52 (1.16)	7.36 (47)	< 0.001	0.18 (1.30)	0.14 (47)
IC [‡]	4.81 (1.20)	4.00 (47)	< 0.001	4.01 (1.78)	2.25 (47)
Pittsburgh Sleep Quality Index					
BBTI-MV	5.40 (0.81)	6.64 (45)	< 0.001	-0.87 (0.95)	-0.92 (45)
IC [‡]	2.60 (0.88)	2.96 (45)	0.005	0.40 (1.28)	0.31 (45)
PSQI Addendum for PTSD					
BBTI-MV	0.55 (0.54)	1.01 (46)	n.s.	0.10 (0.62)	0.17 (46)
IC [‡]	0.94 (0.59)	1.60 (46)	n.s.	1.17 (0.87)	1.35 (46)
(ln) PTSD checklist [*]					
BBTI-MV	0.10 (0.06)	1.62 (49)	n.s.	0.02 (0.07)	0.33 (49)
IC [‡]	0.15 (0.07)	2.24 (49)	0.03	0.22 (0.09)	2.35 (49)
Beck Depression Inventory [*]					
BBTI-MV	3.15 (0.96)	3.28 (49)	0.002	-0.06 (1.05)	-0.06 (49)
IC [‡]	1.15 (1.01)	1.14 (49)	n.s.	0.78 (1.42)	0.55 (49)
Beck Anxiety Inventory					
BBTI-MV	0.66 (0.83)	0.80 (47)	n.s.	-0.24 (0.94)	-0.26 (47)
IC [‡]	2.34 (0.87)	2.69 (47)	0.01	-0.34 (1.40)	-0.25 (47)

[‡] Planned contrasts examined within-group changes from post-treatment to follow-up assessments separately in the BBTI-MV group and in the group of Veterans first randomized to the IC group who then completed BBTI-MV after the post-treatment assessments.

^{*} Ln scale used for analyses.

^{*} Total score minus sleep item.