TREATMENT OF INSOMNIA IN VETERANS WITH TRAUMA-RELATED DISORDERS: A BRIEF GROUP COGNITIVE-BEHAVIORAL INTERVENTION

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ABSTRACT

Estimates of insomnia prevalence among people with Posttraumatic Stress Disorder (PTSD) range from 40% to 87%. Initial research findings suggest that PTSD treatments, without targeted insomnia interventions, do not appear to address sleep disruption sufficiently. Cognitive behavioral therapy for insomnia (CBT-I) has shown promising effectiveness in PTSD populations. The current study evaluated CBT-I with a brief group treatment approach, which is consistent with the model of care most commonly implemented by Veterans Affairs (VA) Medical Centers.

Participants were veterans with trauma-related disorders recruited from two VA Medical Centers. Random assignment was used to divide participants between a CBT-I group and a treatment-as-usual waitlist control group. Participants in the CBT-I group received four 60-minute weekly group sessions. The CBT-I treatment included stimulus control, sleep hygiene instructions, passive muscle relaxation, and sleep education. Validated measures of sleep and daytime functioning were used to evaluate treatment effects.

Data from 65 participants were evaluated using mixed design repeated measures analyses. The results showed that participants who received the CBT-I intervention had greater improvements in sleep efficiency as measured by a sleep diary than participants in the waitlist control group. Sleep questionnaire data and daytime functioning outcomes did not differ significantly between the treatment and waitlist groups. Problems related to participant attrition and missing data were limitations in this study. Implications for future research and clinical implementation of insomnia treatment with veterans are discussed.

LIST OF ABBREVIATIONS AND SYMBOLS

BAI	Beck Anxiety Index
BDI-II	Beck Depression Index – second edition
CBT-I	Cognitive behavioral therapy for insomnia
$\chi 2$	Chi squared: a test statistic that is calculated as the sum of the squares of observed values minus expected values divided by the expected values
df	Degrees of freedom: number of values free to vary after certain restrictions have been placed on the data
DBAS-16	Dysfunctional Beliefs About Sleep scale
η_p^2	Partial eta squared: a measure of variance calculated as the sums of squares of the effect divided by the sum of the sums of squares of the effect and the error
f	Cohen's f: the square root of variance explained over variance not explained
F	Fisher's F ratio: a ration of two variances
ISI	Insomnia Severity Index
IRT	Imagery rehearsal therapy
Λ	Wilks' Lambda: multivariate tests of mean differences among more than two groups
M	Mean: the sum of a set of measurements divided by the number of measurements in the set
NFQ	Nightmare Frequency Questionnaire
p	Probability associated with the occurrence under the null hypothesis of a value as extreme or more extreme than the observed value
PCL-M	PTSD Checklist – military version

PTSD	Posttraumatic stress disorder
SE	Sleep efficiency
SD	Standard deviation: a measure of dispersion of the data from the mean
SOL	Sleep onset latency
SQR	Sleep quality rating
t	Computed value of *t* test
TWAK	Terminal wake time
WASO	Wake time after sleep onset
%	Percent
<	Less than
=	Equal to

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1. Introduction

Insomnia is a highly prevalent health problem and is associated with increased use of health services, increased medication use, and negative impact on overall perceived health (Simon & VonKorff, 1997). Individuals with psychological disorders have significantly greater prevalence rates of insomnia (Lichstein, 2000), and trauma-related disorders have been shown to produce a particularly detrimental impact on sleep (Ohayon & Shapiro, 2000). Insomnia has been found to persist even after trauma-related disorders are treated, which highlights the importance of perpetuating factors that contribute to insomnia (Zayfert & DeViva, 2004). Emergent research in the field of sleep medicine and recent changes in diagnostic criteria for insomnia have brought increased attention to insomnia among individuals with psychological illness.

Insomnia Definition and Comorbidity

Insomnia is defined by the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5; American Psychiatric Association, 2013a) as a predominant complaint of persistent dissatisfaction with sleep quantity or quality associated with difficulty initiating or maintaining sleep. To qualify for the diagnosis, the disturbance must occur three or more nights per week for at least three months, cause the individual significant distress, and be accompanied by deficits in daytime functioning (American Psychiatric Association, 2013a). Insomnia diagnoses are made based on a subjective complaint. Several markers may be helpful in

determining the insomnia severity, such as time to fall asleep and duration of awakenings, number of nights per week on which the problems occur, and chronicity of the sleep disruption.

Insomnia prevalence estimates in the general population range from 6% to 15.9% (Lichstein, Durrence, Riedel, Taylor, & Bush, 2004; Ohayon 2002). However, insomnia has been shown to be more common among people who have psychiatric illnesses, particularly mood and anxiety disorders (Ford & Kamerow, 1989; Lichstein, 2000). For example, Weyerer and Dilling (1991) found 50% of psychiatric patients with anxiety or depression diagnoses reported moderate to severe insomnia. Additionally, patients who present for clinical services with a chief complaint of insomnia have been found to have rates of psychiatric comorbidity ranging from 35% to 44% (Coleman et al., 1982; Buysse et al., 1994). Buysse and colleagues (1994) reviewed 216 cases of individuals who presented to five sleep centers with an insomnia complaint, and found that 44% of patients received a diagnosis of insomnia related to a psychiatric disorder compared to 20% who were diagnosed as having primary insomnia under the DSM-IV criteria.

The recently published DSM-5 (American Psychiatric Association, 2013a) introduced a major change to the diagnostic criteria for sleep disorders by eliminating the categories of insomnia related to another mental or medical disorder. The diagnoses of primary and comorbid insomnia have been consolidated in the DSM-5 and replaced by the unified term "insomnia disorder." This change was intended to highlight the importance of paying independent clinical attention to insomnia, even when it co-occurs with another medical or psychiatric illness, as well as to underscore the bidirectional relationship between insomnia and coexisting disorders (American Psychiatric Association, 2013b).

The revisions to the DSM-5 insomnia nosology reflect a paradigm shift in the field of sleep medicine, informed by research that has demonstrated a complex interaction between

mental and medical disorders and disturbed sleep, rather than a direct causal relationship. For example, researchers have found that insomnia persisted after the comorbid psychiatric conditions were successfully treated, which suggests that independent perpetuating factors develop and contribute to the maintenance of sleep dysfunction (Belleville, Guay, & Marchand, 2011; Taylor, Walters, Vittengl, Krebaum, & Jarrett, 2010; Zafret & DeViva, 2004). Poor sleep quality has also been shown to mediate the relation between psychological stressors and the development of and recovery from other mental disorders (Koren, Arnon, Lavie, & Klien, 2002; Picchioni et al., 2010).

Posttraumatic Stress and Trauma-Related Disorders

The definition of Posttraumatic Stress Disorder (PTSD) has also undergone significant changes in the DSM-5. PTSD has been relocated out of the anxiety disorders section to a separate class, titled trauma- and stressor-related disorders. New symptoms were added and a restructured four-cluster organization was introduced. The revised definition states that PTSD is a disorder that develops following exposure to a traumatic event, such as actual or threatened death, serious injury, or sexual violence (Criterion A). Criterion 2A included in the DSM-IV-TR definition (i.e., peri-traumatic fear, helplessness, or horror requirement) was eliminated because it was unsupported by research and shown to have poor clinical utility (Friedman, Resick, Bryant, & Brewin, 2011). Symptoms of PTSD are now divided into four clusters, which include intrusion (Criterion B), persistent avoidance (Criterion C), negative alterations in cognitions and mood (Criterion D), and alterations in arousal and reactivity (Criterion E). Criterion B was essentially unchanged from the DSM-IV-TR definition but was renamed from “re-experiencing” to “intrusion” in order to emphasize the intrusive rather than ruminative nature of the symptoms (Miller et al., 2012). Criterion C retains two effortful avoidance symptoms that were also present

in the DSM-IV-TR (American Psychiatric Association, 2000), but other symptoms formerly included in this cluster were moved to Criterion D in order to reflect research which demonstrated a distinction between effortful avoidance and general numbing of responsiveness (Friedman et al., 2011). Criterion D includes seven symptoms, two of which are new and five that were previously included in Criterion C. The newly added symptoms include persistent negative appraisals and pervasive negative moods. The symptom that referred to a "sense of foreshortened future" in the DSM-IV-TR has been expanded to include negative expectations about self, others, and the world in general. Criterion E introduced one new symptom – reckless and self-destructive behavior. Another symptom in this criterion was modified to emphasize aggressive behavior rather than angry feelings, which would now be categorized along with other negative emotions in Criterion D.

In order to meet full diagnostic DSM-5 criteria, an individual must exhibit at least one Criterion B symptom, one Criterion C symptom, and two or more symptoms in Criteria D and E. Symptoms must be present longer than one month and result in significant distress or impairment in social, occupational, or other important area of functioning. Individuals who do not meet full criteria but report trauma-related symptoms and experience marked distress and impairment in important areas of functioning that persists longer than one month after the traumatic event would receive a diagnosis of adjustment disorder according to the DSM-5 nosology.

Several studies have evaluated the incidence of subthreshold PTSD and functional impairments among individuals who do not meet full criteria for PTSD (Bersalau, Lucia, & Davis, 2004; Grubaugh et al., 2005; Weiss et al., 1992). In a study conducted with veterans, Grubaugh and colleagues concluded that individuals with subthreshold PTSD had significantly worse functional status and higher prevalence of other psychiatric disorders compared to those

without PTSD symptoms. Mental healthcare utilization among veterans with subthreshold PTSD was significantly lower compared to those diagnosed with PTSD and not significantly different from those without PTSD symptoms. These findings suggest that individuals who present with subthreshold PTSD would benefit from clinical attention but may be getting overlooked by clinicians and researchers.

Lifetime prevalence rates for PTSD in the general population have been estimated at 5% for males and 10% for females using DSM-IV criteria, with higher rates among at-risk populations such as military personnel (Foa, Keane, & Friedman, 2000). Veterans of the Vietnam War are an extensively studied cohort of individuals with high rates of PTSD. The National Vietnam Veterans Readjustment Study found a 30% lifetime prevalence rate and 15% current prevalence of PTSD among veterans of the Vietnam War (Kulka et al., 1990; Schlenger et al., 1992). An additional 22% of Vietnam veterans were found to have subthreshold PTSD symptoms during their lifetime, and 11% exhibited current symptoms (Weiss et al, 1992). Initial estimates of PTSD prevalence among veterans of the ongoing conflicts in Iraq and Afghanistan suggest 15% to 17% of veterans who participated in Operation Iraqi Freedom (OIF) and 6% to 11% of veterans of Operation Enduring Freedom (OEF) meet criteria for the disorder (Hoge et al., 2004). Among OIF/OEF veterans, PTSD rates were higher for soldiers who had more combat experiences; veterans who were involved in five or more firefights had a rate of 19.3%, whereas those who were not engaged in firefights during their deployment had a PTSD rate of 4.5% (Hoge et al., 2004). Miller and colleagues (2012) evaluated a large community sample and a group of veterans with PTSD using an internet-based survey and found that prevalence rates were 1% to 2% lower using the DSM-5 diagnostic criteria compared to the DSM-IV-TR.

Data from the National Comorbidity Survey suggest that remission of symptoms, without active treatment efforts, is unlikely in cases where the duration of PTSD exceeded one year (Kessler, Sonnega, Bromet, Hughes, & Nelson, 1995). Psychological treatments for PTSD usually include exposure, cognitive restructuring, cognitive processing therapy, anxiety management programs, or a combination of several of these treatments. Meta-analytic findings from 24 studies conducted between 1980 and 2003 suggest that Cognitive Behavior Therapy (CBT), exposure therapy, and Eye Movement and Desensitization Reprocessing are all highly effective in reducing symptom severity, and 40% to 70% of patients who completed treatment no longer met diagnostic criteria for PTSD (Bradley, Greene, Russ, Dutra & Westen, 2005). Pharmacotherapy is also widely used to treat PTSD; however, several randomized clinical trials have shown that the effect sizes for medication treatment of PTSD are small, which has led to recommendations that medications alone not be used as a frontline treatment approach, except in cases where proven efficacious psychotherapy is unavailable (Sullivan & Neria, 2009).

PTSD and Disturbed Sleep

Estimates of insomnia prevalence among individuals with PTSD range from 70% to 87% (Leskin, Woodward, Young, & Sheikh, 2002; Ohayon & Shapiro, 2000) and the DSM-5 retains difficulty falling and staying asleep (Cluster E) and nightmares (Cluster B) in the diagnostic criteria for PTSD. Abundant self-report data reveal that sleep disruption is a common complaint among individuals with PTSD (e.g., Harvey, Jones, & Schmidt, 2003; Roszell, McFall, & Malas, 1991), leading some researchers to refer to sleep problems as the "hallmark of PTSD" (Ross, Ball, Sullivan, & Caroff, 1989).

Severity of sleep dysfunction and severity of PTSD have been shown to be correlated. Germain, Buysse, Shear, Fayyad, and Austin (2004) divided a sample of 367 outpatients with

PTSD into three groups based on symptom severity, assessed by the Clinician-Administered PTSD Scale (CAPS), and compared their sleep using the Pittsburgh Sleep Quality Index (PSQI). Their findings revealed that individuals classified as having very severe PTSD (CAPS $\geq$ 80) reported higher PSQI global scores, greater sleep latency, shorter sleep duration, more sleep disturbances, and greater daytime dysfunction than the severe (CAPS of 60 to 79) and moderate (CAPS of 50 to 59) PTSD groups. Notably, the PSQI scores in all three groups exceeded the clinical threshold. Other psychiatric comorbidity, PTSD chronicity, and trauma type were not associated with sleep disturbance severity in this sample.

Individuals with combat-related PTSD have also been found to have significantly elevated rates of sleep disruption. Neylan and colleagues (1998) reanalyzed data from the National Vietnam Veterans Survey and found that 44% of veterans with PTSD reported sleep onset difficulty occasionally to very frequently, compared to 6% of veterans without PTSD and 5% of healthy controls. Ninety-one percent of veterans with PTSD, 63% of veterans without PTSD, and 53% of healthy controls reported occasional or frequent difficulty with sleep maintenance.

In addition to occurring in the context of PTSD, insomnia initially associated with PTSD may also persist beyond remission of the stress disorder (Zayfert & DeViva, 2004) and develop into a learned pattern of maladaptive sleep behavior that is not resolved after the initial cause is addressed. This finding is contrary to conceptions of secondary insomnia as a symptom of the underlying disorder. Rather, the persistence of residual insomnia following PTSD remission is consistent with the Spielman model, which suggests that predisposing, precipitating, and perpetuating factors operate in insomnia (Spielman, Caruso, & Glovinsky, 1987). In the case of PTSD, exposure to trauma serves as a precipitating event for sleep disruption, but over time,

perpetuating factors emerge (e.g., poor sleep hygiene, dysfunctional beliefs about sleep) and cause insomnia to become a chronic problem.

Objective measures of sleep quality in individuals with PTSD have produced mixed findings. Polysomnography (PSG) has been used to evaluate sleep among individuals with PTSD. PSG records physiological activity during sleep, such as brain wave activity, eye movements, muscle tone, heart rate, and respiratory activity. These recordings allow researchers to objectively evaluate sleep efficiency, which is defined as the percentage of time spent in bed that an individual is asleep. Measurements of brain activity also provide information about sleep architecture by distinguishing between light sleep (Stage 1 and 2), deep sleep (Stage 3), and rapid eye movement (REM) sleep. Several studies detected differences in sleep architecture among individuals with PTSD. PSG findings in combat veterans with PTSD found reduced sleep efficiency in this group (Glaubman, Mikulincer, Porat, & Wasserman, 1990; Lavie, Hefez, Halperin, & Enoch, 1979; Mellman, Kulik-Bell, Ashlock, & Nolan, 1995). A PSG study of Hurricane Andrew survivors with PTSD did not find reduced sleep efficiency; however, participants exhibited greater frequency of awakenings and more entries into Stage 1 sleep (Mellman, David, Kulik-Bell, Hebding, & Nolan, 1995). Fuller, Waters, and Scott (1994) found that individuals with PTSD had more arousals from sleep during the first half of the sleep period and decreased overall deep sleep compared to control subjects. Other studies have reported no differences in sleep architecture between persons with PTSD and normal controls (Dagan, Zinger, & Lavie, 1997; Engdahl, Eberly, Hurwitz, Mahowald, & Blake, 2000).

Psychological Insomnia Treatment Approaches

The development of cognitive behavioral insomnia treatments has been strongly informed by the "3-P Model" described by Spielman (1986). According to this model, insomnia results as

a function of predisposing, precipitating, and perpetuating factors. Stable biological traits (e.g., hyperarousal) are conceptualized as predisposing characteristics. An acute stressor or illness acts as a precipitant, and self-defeating behavioral responses or compensatory strategies that an individual adopts perpetuate the insomnia. Spielman argued that insomnia differs from many other psychiatric disorders in that perpetuating factors often become functionally autonomous from the initial cause of the sleep disruption and serve to maintain chronic sleep problems even when the initial precipitant is no longer present. Thus he advanced the view that treatment should focus on modifying behaviors that perpetuate insomnia, such as spending excessive time in bed, napping, using caffeine to counteract daytime sleepiness, engaging in non-sleep activities in the bedroom, and excessive worry about sleep.

Cognitive behavioral therapy for insomnia (CBT-I) refers to a range of treatments that aim to address the behavioral and cognitive factors that interfere with sleep initiation and maintenance. Multi-component CBT-I usually includes some combination of the following methods: stimulus control, sleep restriction, relaxation training, sleep hygiene instructions, and interventions specifically targeted at sleep-related cognitions. CBT-I is the most thoroughly researched and validated psychological protocol for treating insomnia. In a review of 37 studies that evaluated psychological treatments for insomnia, Morin and colleagues (2003) concluded that cognitive and behavioral interventions are an effective approach for managing persistent insomnia. The authors report that 70% to 80% of clients who received CBT-I had clinically meaningful improvements in sleep quality. In addition, CBT-I was associated with a 50% reduction in insomnia symptoms, and treatment gains were relatively stable even at extended follow-up. The authors suggested that multi-component therapy is more likely to address the

various factors contributing to sleep disruption; however, they acknowledged that the relative efficacy of each component has not been systematically evaluated.

Treatment of Insomnia Co-Occurring with Psychological Disorders

When psychological approaches for treating insomnia were first introduced, there was a prevalent perspective in the sleep medicine field that insomnia observed in the context of psychiatric illness is a manifestation of the underlying disorder and therefore could be adequately managed by treatment of the psychiatric condition (Belanger, Morin, Langlois, & Ladouceur, 2004; Buysse, et al., 1997). However, in the last 15 years there has been a growing shift away from this view and research has generated a body of literature that supports the effectiveness of insomnia treatment with people who have co-occurring psychological disorders (McCrae & Lichstein, 2001).

Several studies have evaluated CBT-I interventions for individuals with psychiatric illness. Lichstein, Wilson, and Johnson (2000) administered a four-session intervention to older adults with co-occurring anxiety and depression and showed that the treatment led to improved sleep quality; however, depression and anxiety ratings did not improve. Dopke, Leher, and Wells (2004) provided a CBT-I treatment to 10 individuals with serious mental illness and found that the treatment resulted in reduced sleep disruption. Taylor, Lichstein, Weinstock, Sanford, and Temple (2007) administered CBT-I to a group of eight individuals with insomnia and mild depression. Participants in this study had improved sleep and reduced depression severity following the treatment, and these gains were maintained at three-month follow-up. Manber and colleagues (2008) compared treatment response among depressed individuals receiving antidepressant medication combined with CBT-I or a control condition, consisting of a quasi-desensitization therapy for insomnia. This study showed that participants receiving CBT-I had

greater sleep improvement and better depression outcomes compared to individuals in the control condition.

Treatment of Insomnia in PTSD

Clinical trials of psychotherapy for PTSD usually do not specify treatment outcomes on individual symptoms, and evidence for changes in insomnia status following PTSD treatment, absent a targeted sleep intervention, is limited. Zayfert and DeViva (2004) evaluated the effect of CBT for PTSD on sleep outcomes. No targeted interventions for sleep were included in the treatment protocol. At pre-treatment, 88% of individuals with PTSD reported insomnia. Forty-eight percent of patients who no longer met clinical criteria for PTSD following treatment continued to report clinically significant insomnia, and for 30% of study patients, the insomnia was severe. Based on this finding, the authors concluded that insomnia comorbid with PTSD develops into a learned behavior pattern that persists after resolution of the precipitating condition. Spoormaker and Montgomery (2008) conducted a review of published studies that evaluated the effect of PTSD treatments on sleep quality and concluded that sleep disturbances are not reduced by psychological or pharmacological treatments for PTSD. The reviewers emphasized that sleep disruption is not just a secondary symptom but a core feature of PTSD, and recommended that sleep-focused interventions be included in PTSD treatment protocols.

CBT-I as a stand-alone treatment, as well as in combination with treatments designed to address nightmares, has shown promising results for the treatment of sleep disruption among individuals with PTSD. DeViva, Zayfert, Pigeon, and Mellman (2005) administered a five-session CBT-I intervention to five women who had completed PTSD treatment but continued to report sleep disruption. After receiving the treatment, participants reported improved sleep quality and fewer dysfunctional beliefs and preoccupations with sleep; however, scores on the

self-report measures generally remained in the clinical range and no comparison group was included. Owen (2002) found that a six-session group CBT-I treatment, adjunctive to standard inpatient treatment for PTSD, led to improved sleep quality, reduced sleep latency, and greater sleep duration compared to PTSD treatment without a targeted insomnia intervention. However, small final sample size, resulting from high attrition, was a limitation of this study. Gellis and Gehrman (2011) administered five individual sessions of CBT-I to eight veterans. These researchers found that the intervention led to significant improvements in wake time after sleep onset and sleep efficiency as measured by a sleep diary and significantly reduced sleep related distress as measured by the Insomnia Severity Index (ISI). Despite significant improvement, five of the eight participants continued to show sleep patterns consistent with quantitative criteria for insomnia.

Several studies have evaluated treatment protocols that combined CBT-I with imagery rehearsal therapy (IRT), which targets nightmares. Krakow and colleagues (2001) administered a three-session intervention that combined CBT-I and IRT to 62 victims of violent crime. This study showed that the intervention led to reduced nightmare frequency and improved scores on the PSQI; however, scores generally remained in the clinical range. Germain, Shear, Hall, and Buysse (2007), tested a one-session CBT-I intervention with seven victims of violent crime who met diagnostic criteria for PTSD. Participants reported improved sleep and reduced PTSD symptom severity six weeks after receiving the intervention. Ochsner-Margolis (2011) conducted a randomized controlled trial of CBT-I and IRT delivered in four individual sessions to OIF/OEF veterans. Sixteen veterans who completed the intervention were found to have significant improvements in sleep quality compared to fourteen participants who were assigned to a waitlist

control condition. Although preliminary evidence for the efficacy of CBT-I alone and in combination with IRT is promising, further studies are needed.

Nightmares and PTSD

Nightmares are a prevalent sleep-related problem for individuals with PTSD. Unlike insomnia, which is part of the hyperarousal symptom cluster, nightmares are included in the intrusion symptom cluster. Ohayon and Shapiro (2000) found that 19% of people with PTSD in a community sample reported nightmares, compared to 4% of people without PTSD. Among veterans, Neyland and colleagues (1998) found that nightmares were reported by 52% of individuals with PTSD as compared to only 5% of veterans without PTSD and 3% of healthy controls. Increased nightmare frequency among people with PTSD may be linked to changes in REM sleep. A number of studies have shown an increased amount of REM sleep and increased REM density among individuals with PTSD (Engdahl, Eberly, Hurwitz, Mahowald, & Blake, 2000; Mellman, Kulick-Bell, et al., 1995; Ross et al., 1994).

Krakow, Kellner, Pathak, and Lambert (1995) developed IRT to address nightmares in people with PTSD. Patients receiving IRT are instructed to write about the content of their nightmares and then change the story any way they want and rehearse the new story. IRT has been found to be effective in reducing nightmare frequency (Krakow et al., 2000; Krakow, Kellner, Pathak, & Lambert, 1996; Krakow & Zadra, 2006).

In the current study, IRT was not included for several reasons. First, no causal link between nightmares and insomnia has been established. Second, IRT involves a rehearsal component that greatly resembles exposure therapy, which veterans commonly receive as part of standard PTSD treatments. Third, unlike insomnia, which tends to persist following treatment of PTSD, nightmares are among the least frequently reported symptoms following PTSD treatment

(Zayfert & DeViva, 2004), suggesting that nightmares are adequately addressed by traditional PTSD treatments and may not require a targeted intervention. In a review of sleep and PTSD, Maher, Rego, and Asnis (2006) stated that because data from patients receiving prolonged exposure treatment suggest residual insomnia occurs in the absence of nightmares, it is therefore important to test whether stand-alone insomnia treatments are effective for these patients. Considering the above reasons, the current study focused on CBT-I for individuals with PTSD and did not include a targeted intervention for nightmares. However, a measure to evaluate nightmares was included.

Study Goals

Based on the documented effectiveness of CBT-I for treating insomnia comorbid with psychiatric disorders and on the promising preliminary evidence for the effectiveness of CBT-I in PTSD populations, CBT-I represents a logical approach to the treatment of insomnia in veterans with PTSD and other trauma-related disorders and warrants further investigation in this cohort. The current study evaluated a brief group treatment approach, which is consistent with the model of care most commonly implemented by VA medical centers.

The protocol in this study differs from previously published research in several ways. The intervention used in this study focused solely on insomnia symptoms, rather than combining CBT-I with IRT for nightmares. This approach was chosen to evaluate whether CBT-I as a single treatment can result in improved outcomes for veterans with trauma-related disorders and co-occurring sleep disturbances. Previous studies that evaluated the efficacy of insomnia treatment in veterans with PTSD have used restrictive selection criteria, such as excluding individuals with comorbid conditions or only focusing on veterans from a given service era (i.e., Vietnam War, OEF/OIF). The current study was designed to be more inclusive with regard to participant

selection criteria. Participants in this study were veterans from mixed service eras who presented with trauma-related disorders and a variety of medical and psychiatric conditions, making the sample more representative of the veteran population receiving services at VA hospitals. Additionally, the current study used a group treatment, whereas most previous research has evaluated individual treatments. The design of the current study most closely resembles research conducted by Owen (2002), which used a six-session group treatment; however, the current study used an abbreviated four-session protocol.

The three main treatment components included in this study were relaxation training, stimulus control, and sleep hygiene. These treatments were chosen based on empirical support for their effectiveness for treating insomnia that co-occurs with other psychological illnesses (Taylor et al., 2007; Johnson & Robertson, 2013), and their suitability for delivery in a time-limited group format. Additionally, psychoeducation regarding sleep mechanisms and individual differences in sleep requirements was presented in order to address participants' unrealistic expectations and unhelpful worry about sleep. Because each group member received the same information and recommendations, this treatment was well suited to didactic presentation by a therapist to multiple participants at once, and group discussion could be used for problem solving to address common barriers to adherence.

Hypotheses

The primary hypotheses of the current study were that participants who received the CBT-I intervention would have greater changes than participants assigned to the waitlist condition from baseline to post-treatment in the following domains: (1) improved sleep parameters, as measured by the sleep diary, (2) reduced sleep-related distress, as measured by the Insomnia Severity Index (ISI), (3) fewer dysfunctional beliefs about sleep, as measured by

Dysfunctional Beliefs and Attitudes about Sleep Scale (DBAS-16), and (4) improved daytime functioning, as measured by the PTSD Checklist, Military Version (PCL-M), Beck Depression Inventory, Second Edition (BDI-II) and Beck Anxiety Inventory (BAI).

2. Method

Participant Recruitment

Participants were recruited at two VA medical centers, the Tuscaloosa Veterans Administration Medical Center (TVAMC) and the Veterans Administration Maine Healthcare System – Togus campus (VAMHCS). The research program was initiated at TVAMC and later relocated to VAMHCS when the lead researcher transitioned to this VA site to complete internship training. The treatment programs already in place for PTSD and trauma-related disorders at the two hospitals differed. TVAMC uses a model that emphasizes residential treatment programs in which veterans are housed at the VA while receiving therapy and medication management. At VAMHCS, PTSD and trauma-related disorders treatment is offered only on an outpatient basis.

Veterans at TVAMC were recruited from three residential treatment programs: Domiciliary Residential Rehabilitation Treatment Program (DRRTP), PTSD Residential Rehabilitation Program (PRRP), and Substance Abuse Residential Rehabilitation Treatment Program (SARRTP). The DRRTP provides housing and treatment for homeless veterans, some of whom have a diagnosis of PTSD or trauma-related disorder; average duration of stay on this unit is greater than 100 days. The PRRP offers similar treatment options but does not provide homelessness assistance; average duration of participation in this program is around 60 days. The SARRTP offers treatment for PTSD and substance abuse; average duration of stay is around 90 days. The majority of treatment is conducted in a group therapy format, and veterans are offered

a catalog of groups and classes focusing on PTSD, substance abuse, and interpersonal relationships. In most cases, veterans also receive individual therapy and pharmacotherapy.

Veterans at VAMHCS were recruited from outpatient programs that offer individual and group treatment. One such program is the PTSD Clinical Team, which offers individual cognitive processing therapy and prolonged exposure treatments, cognitive processing therapy groups, psychoeducational treatment groups, and anger management classes. Another program from which participants were recruited was the PTSD Intensive Outpatient Program, which offers acceptance and commitment therapy based group treatment and individual services. Many of the veterans at VAMHCS also receive pharmacotherapy.

At both VA sites, several methods were used to identify and recruit potential participants. Flyers were posted in areas of the hospitals where veterans with PTSD and trauma-related disorders receive care, such as the residential units at TVAMC and the mental health clinic at VAMHCS. The lead researcher also attended mental health treatment groups to present information about the study and invite veterans to participate. Additionally, researchers distributed information about the study to VA treatment teams and individual providers and encouraged them to refer veterans who endorsed sleep problems. Veterans who self-referred for the study or were recommended by a VA provider were contacted by the lead researcher, who explained the study procedures in detail and scheduled veterans who expressed interest in participating for an in-person informed consent and eligibility screening appointment.

Inclusion and Exclusion Criteria

Individuals who consented to participate in the study were screened for inclusion by conducting a review of the computerized medical record and administration of pre-treatment study questionnaires. The goal of the study was to evaluate the effectiveness of CBT-I adjunctive

to other psychological and medical care already provided at the VA medical centers. In order to ensure a representative sample of veterans with trauma-related disorders receiving treatment at VA hospitals, the exclusionary criteria for this study were minimal.

In order to qualify for the study, participants had to endorse exposure to a traumatic event and report current problems associated with this trauma, including sleep disruption. Participants with PTSD in partial remission or partially controlled with medication, as well as veterans with trauma-related symptoms that did not meet full diagnostic criteria, were allowed to participate as long as they met the suggested clinical cutoff of 45 or greater on the PCL-M.

Participants were screened for the presence of sleep disruption using two methods. A three-item questionnaire designed by the experimenter was used to establish an insomnia diagnosis under the DSM-IV-TR criteria. In order to be included in the study, participants had to endorse difficulty falling or staying asleep that had persisted for greater than one month and was associated with impaired daytime functioning. In addition, participants were screened for inclusion using the Insomnia Severity Index (ISI), and had to endorse a score above the suggested clinical cutoff of eight or greater to qualify.

Veterans 19 years of age or older were eligible to participate in the research (i.e., the age of majority in Alabama, where the research was initiated). The broad age requirement resulted in a heterogeneous sample of veterans from different service eras. Both male and female veterans were invited to participate; however, the majority of participants were male, which is consistent with the demographic characteristics of the VA patient population.

Because of high rates of comorbidity in the target sample, screening participants for inclusion was a significant challenge. Three major domains were considered in the screening process: substance abuse, medical problems, and psychiatric comorbidity. Participants were

considered eligible if they reported a sustained abstinence from alcohol and recreational drugs for at least one week prior to the initial screening. Participants were not excluded based on the presence of comorbid medical diagnoses, with the exception of life threatening or severe medical problems (e.g., stage III to IV malignancy, chronic obstructive pulmonary disease, coronary artery disease) that would limit the veteran's ability to participate in treatment. Veterans with comorbid psychiatric diagnoses were included in the study if they did not present an acute risk of self-harm or harm to others and did not manifest acute psychosis.

Individuals with other sleep disorders, with the exception of nightmares and treated sleep apnea, were excluded from the study. A brief screening interview was used to exclude participants who endorsed symptoms of restless leg syndrome, or periodic limb movements during sleep. Participants were not excluded based on nightmare disorder. Participants diagnosed with sleep apnea were allowed to participate if they reported that they were complying with their prescribed treatment. To maximize the inclusivity of the study, individuals taking a medication for sleep were allowed to participate if they continued to experience significant sleep disturbances despite using the medication.

Treatment Outcome Measures

The following measures and evaluations were collected twice for both study groups. The CBT-I group completed the assessments at baseline and post-treatment. Participants in the waitlist group completed the assessments at time intervals matched to the CBT-I group, at baseline and five weeks after baseline.

Sleep diary. Participants' sleep was assessed using nightly sleep diaries (Lichstein et al., 2004, p. 52). Sleep diaries measured the following parameters: sleep onset latency (SOL), wake time after sleep onset (WASO), terminal wake time (TWAK), total sleep time (TST), total time

in bed (TIB), and sleep efficiency (SE), which is a percentage calculated by dividing TST by TIB and multiplying by 100. Participants were also asked to make sleep quality ratings (SQR) for each night on a five-point scale, ranging from "very poor" to "excellent". Participants in both groups filled out a sleep diary for two separate one-week intervals, at baseline and post-treatment.

Insomnia Severity Index (ISI). The ISI (Morin, 1993) is a seven-item self-report measure that assesses disturbed sleep and daytime dysfunction. The ISI allows for assessment of insomnia symptom severity, has been shown to be a valid and sensitive measure for insomnia screening, and can be used to detect changes in perceived sleep disruption over the course of treatment (Bastien, Vallieres, & Morin, 2001). A cutoff score of greater than or equal to eight indicates clinically significant impairment.

Dysfunctional Beliefs and Attitudes about Sleep (DBAS-16). The DBAS-16 is a 16-item self-report measure designed to assess participants' sleep related cognitions, such as faulty beliefs and appraisals, unrealistic expectations, and attentional biases. The scale has been shown to be reliable (Cronbach's alphas = 0.77 to 0.79) and has adequate temporal stability (r = 0.83; Morin, Vallières, & Ivers, 2007). Research has shown that CBT-I successfully reduced dysfunctional beliefs about sleep, and these reductions were correlated with reduced insomnia symptomatology (Edinger, Wohlgemuth, Radtke, Marsh, & Quillian, 2001).

PTSD Checklist Military Version (PCL-M). The PCL-M is a 17-item scale designed to assess symptoms that correspond to the DSM-IV criteria for PTSD. Participants rate how much they have been bothered by each symptom using a 5-point anchored scale. The PCL-M has high test-retest reliability, good internal consistency, and correlates highly with other PTSD measures (Weathers, Litz, Herman, Huska, & Keane, 1993). The PCL was shown to be strongly correlated

with the CAPS, which is considered the gold standard for PTSD assessment (Blanchard, Jones-Alexander, Buckley, & Forneris, 1996). For the analyses of treatment effects, PCL-M scores were recomputed excluding item 13, which refers to trouble falling or staying asleep.

Beck Depression Inventory, Second Edition (BDI-II). The Beck Depression Inventory, Second Edition (BDI-II; Beck, Steer, & Brown, 1996) is a 21-item self-report instrument intended to assess the existence and severity of symptoms of depression. The BDI-II is a revised version of the original BDI (Beck, Rial & Rickles, 1974) that was modified to conform to changes in the diagnostic criteria for depression in the DSM-IV. The BDI-II is composed of 21 questions scored on a four-point scale from zero to three. On two items (16 and 18), there are seven options to indicate either an increase or decrease of appetite and sleep. Clinical interpretations range from minimal depressive symptoms (zero to 13), to mild symptoms (14 to 19), moderate symptoms (20 to 28), and severe symptoms (29 to 63). Among individuals with insomnia, Cronbach's alphas for depressed versus non-depressed participants were .89 and .82, respectively (Carney, Ulmer, Edinger, Krystal, & Knauss, 2009). Alternative cutoffs for clinically significant depression have been suggested for individuals with insomnia ($\geq$ 17 versus $\geq$14), resulting in better specificity (79% versus 66%), and lower but acceptable sensitivity (81% versus 91%; Carney et al., 2009).

Beck Anxiety Inventory (BAI). The BAI (Beck, Epstein, Brown, & Steer, 1988) is a 21-item scale developed for measuring severity of anxiety in a psychiatric population. Items are rated on a four-point scale from zero to three, with higher scores indicating greater impairment. The BAI has shown high internal consistency (Cronbach's alpha = .92) and adequate test-retest reliability over one week (r = .75; Beck et al., 1988).

Treatment Adherence

Three investigator-developed logs were used to measure adherence with the treatment components: relaxation, sleep hygiene, and stimulus control. Participants were asked to record each instance of practicing the treatment components outside of the CBT-I session on a daily basis. These measures were collected in the CBT-I group during the course of treatment in order to evaluate the relation between participants' adherence to the treatment recommendations and their sleep related outcomes.

Additional Measures

The following measures and evaluations were collected once at baseline for both groups. These measures were used for inclusion screening and evaluated for inclusion as covariates in the analyses of treatment effects.

Medical record review. The VA uses a sophisticated computerized patient record system (CPRS) to log and store information regarding all aspects of patient treatment. A review of the CPRS medical record was used to gather the following information: participant demographics, history of medical or psychiatric conditions, current medications, and military service history. Accuracy of information gathered through CPRS review was verified with the participant. If any of the aforementioned information was not available in the medical record, the lead researcher attempted to collect it directly from the participant.

Nightmare Frequency Questionnaire (NFQ). The NFQ is a two-question retrospective survey that assesses number of nights per week with nightmares and count of the number of nightmares that occur during the week (Krakow et al., 2000). This measure has been found to have high test-retest reliabilities and is correlated with measures of nightmare-related distress (Krakow et al., 2002).

Procedures

Veterans interested in the sleep treatment group completed an informed consent at the beginning of the initial screening session. Following the informed consent procedures, participants filled out a battery of self-report questionnaires (ISI, DBAS-16, BDI-II, BAI, PCL-M, and NFQ). Participants were also given a sleep diary to fill out for one week and asked to return it to the researcher once it was completed. The data collected at the initial interview were used both for inclusion screening and as baseline data for participants who qualified. Participants enrolled in the study were randomized to either receive four 60-minute weekly group treatment sessions (CBT-I group) or be assigned to a five-week treatment as usual waitlist control group. Both CBT-I and TAU participants continued to receive standard VA care during the course of the study. Group randomization was used to assign participants to treatment condition in groups of four. This approach was used in order to facilitate formation of treatment groups and reduce delays between participant enrollment and treatment initiation.

Participants in the CBT-I group completed a sleep diary prior to the first session and after the last treatment session. Participants assigned to waitlist group completed sleep diaries at baseline and five weeks after baseline. Participants receiving CBT-I treatment completed a second assessment battery one week after the last session and those assigned to the waitlist condition completed an assessment battery at five weeks after initial intake. Waitlist participants were offered participation in the CBT-I group upon completion of the five-week assessment.

Treatment adherence measures were administered to the participants in the CBT-I group. Participants were asked to complete these measures daily starting with the session in which the treatment component was introduced, and to continue filling out the questionnaires through the post-treatment assessment.

Treatment Delivery

Treatment groups were facilitated by Yuriy Ustinov, M.A., who was supervised by licensed clinical psychologists. Between three and eight participants took part in the group cohorts. Sessions were held in group therapy rooms in the mental health departments of the VA hospitals. Rooms were set up with chairs either spaced out in a semi-circle or around a large table. Participants were given a treatment folder at the beginning of the first session containing a summary of relaxation instructions and a log for tracking relaxation practice. Blank paper, a writing utensil, and a writing surface were also supplied for participants in case they elected to take notes. Additional handouts and logs for stimulus control and sleep hygiene were handed out in later sessions. Information about sleep mechanisms was illustrated with a simple graph that the therapist drew on a dry-erase board. Additionally, the therapist used the dry-erase board to illustrate correct procedures for filling out the treatment logs. When the in-session relaxation practices were conducted, the therapist encouraged participants to move to a seat in the room where they could have ample space and felt comfortable.

Treatment Protocol

Session 1. The goals of the first session were to provide participants with information about sleep mechanisms and architecture, discuss the relation between sleep disruption and trauma-related disorders, and introduce the first treatment technique, relaxation. The therapist provided participants with accurate information about processes of sleep, individual differences in sleep requirements, and consequences of sleep disruption. Participants were also informed about the relation between trauma-related disorders and sleep disruption, such as the impact of hyperarousal on sleep initiation and maintenance. This portion of the intervention was intended to address unhelpful beliefs that are commonly present among people with insomnia, such as

exaggerated concerns about the negative consequences of poor sleep, misconceptions about sleep requirements, and sleep-related preoccupations. In addition, the information provided to participants was used as justification for the relaxation, sleep hygiene, and stimulus control treatments. Participants were encouraged to ask questions about the information presented and the therapist reserved 15 to 20 minutes of each session for group discussion.

Relaxation training was presented in the second half of the first session. Participants were taught deep breathing and passive muscle relaxation techniques. In this relaxation protocol, participants were instructed to focus on regions of the body, relax the muscles in that area, and focus on comfortable sensations in that body region. Passive relaxation has comparable effectiveness compared to progressive relaxation for the treatment of insomnia, and may be more suitable for elderly or physically ill individuals for whom muscle tensing may be difficult (Lichstein, 2000a). A therapist-guided relaxation was performed during the session and participants were encouraged to practice relaxation twice daily as homework, once during the day and again at bedtime. The relaxation protocol used in this study is based on the one suggested by Lichstein (2000a). A handout summarizing the relaxation protocol, along with a daily log for tracking adherence, was provided to the participants.

Session 2. This session began with a review of relaxation homework. The therapist then presented and explained sleep hygiene and stimulus control instructions. Sleep hygiene involves a set of lifestyle adjustments by which the patients can reduce sleep-disruptive behaviors and increase sleep-promoting behaviors. The following recommendations are included: (1) sleep only as much as you need to feel refreshed during the following day, (2) make sure your bedroom is a comfortable temperature and free from noise and light, (3) eat regular meals and do not go to bed hungry, (4) avoid excessive liquids in the evening, (5) reduce caffeine intake, especially in the

afternoon and evening, (6) avoid alcohol, especially in the evening, (7) avoid tobacco products close to bedtime, and (8) avoid naps longer that 30 minutes (Riedel, 2000). Stimulus control instructions included a set of recommendations intended to strengthen the association between the bedroom and sleep. Participants were encouraged to avoid going to bed unless they felt sleepy, to leave the bed if they are unable to fall asleep within 15 to 20 minutes, and to return to bed only when they felt sleepy again. The same procedure was recommended for nighttime awakening if the participant was unable to fall back asleep within 15 to 20 minutes. Participants were also encouraged to avoid sleeping outside the bedroom and to keep a fixed rising time seven days per week (Morin, 1993).

Participants received handouts that outline the instructions for these treatment components. A simplified graphic that described biological drives that regulate sleep and wake was illustrated on the dry-erase board and was used to provide justification for keeping a regular schedule and avoiding daytime naps. The therapist provided a rationale for behavior change by explaining how each component of sleep hygiene and stimulus control practices address different aspects of insomnia. For example, to help participants understand the stimulus control instructions, the therapist highlighted the importance of establishing positive associations between the bedroom and sleep by using relevant examples of associations that individuals may experience in other areas of their lives.

Sleep hygiene instructions were also reviewed in detail and participants were encouraged to discuss obstacles to adopting sleep promoting practices (i.e., eating regular meals, avoiding daytime naps, and limiting caffeine intake) and creating a sleep-promoting bedroom environment (i.e., reducing disruption from noise and light during the night). The therapist tried to assist participants in developing a strategy to overcome these obstacles. Participants were encouraged

to practice these techniques as homework, to continue to practice relaxation twice daily, and were provided with logs to assess adherence. A guided relaxation was performed at the conclusion of the session.

Session 3. The session began with a review of the homework using the relaxation, stimulus control, and sleep hygiene logs. Justification for the procedures was reviewed and particular attention was devoted to discussing obstacles for adopting the new behavioral changes. The therapist attempted to help participants to problem solve and develop plans for behavior change. In addition, the therapist emphasized the importance of consistent practice for gaining positive outcomes. The goal of this session was to increase participants' self-efficacy and improve adherence. As with previous sessions, a therapist-led relaxation was conducted.

Session 4. The focus of the final session was on maintenance of behavior change. The therapist explained that sleep is likely to continue to improve if participants adhere to the recommendations. However, sleep quality is also likely to fluctuate, and the therapist discussed the natural variability of sleep in order to address participants' attitudes and beliefs about occasional sleep problems. The major treatment components were briefly reviewed and guided relaxation was performed. Participants were asked to continue to complete daily adherence logs until the post-treatment assessment, which was conducted one week after the last session.

Make-up session. Participants who missed a session due to a conflicting appointment, family emergency, medical emergency, etcetera, were given the opportunity to make-up one session. The therapist met with the participant individually to complete the make-up session after which the participant was invited to rejoin the group.

3. Results

Participant Characteristics

Participants were recruited at the TVAMC between February 2011 and May 2012. Recruitment at VAMHCS was conducted between February and June of 2013. One-hundred and four veterans expressed interest in the study and met with the researcher to discuss participation and review the consent form during the enrollment periods. Seventy-five veterans elected to enroll in the study and gave consent to participate in the research program. Examples of veterans' stated reasons for declining to participate included having insufficient time or resources (e.g., transportation) to attend the treatment groups, not wanting to take part in group treatment, not being eligible for the study due to meeting exclusion criteria (e.g., untreated sleep apnea, active substance abuse), and feeling uncomfortable with participating in research or filling out questionnaires.

Seventy-five participants consented to take part in the research program; 40 were randomized to the CBT-I group and 35 were randomized to the waitlist group. The last group of four participants enrolled in the study was randomized to the treatment group. Data from five participants enrolled at TVAMC, four from the waitlist group, and one from the CBT-I group, were excluded from the database because these participants could not be reached for re-consent as required by the TVAMC IRB following a modification to the study protocol. Thus, the addition of four extra participants to the treatment group and the removal of five participants

from the database resulted in an imbalance in the number of participants assigned to each condition.

Data from 70 participants who were randomized to either the treatment or waitlist group were included in the analyses, 32 at TVAMC and 38 at VAMHC. Participants ranged in age from 26 to 76 years old. The mean age of participants was 53.60 years (*SD*=10.76). The sample was composed primarily of Caucasian (60.0%) and African American (38.6%) individuals; one participant reported his race as Native American. The majority of participants were men (92.9%). All participants endorsed exposure to one or more traumatic events and experiencing current symptoms related to the trauma, and 87.1% had a diagnosis of PTSD documented in their VA medical record. The majority of participants (70.0%) had more than one psychiatric diagnosis, including anxiety disorders other than PTSD (67.1%), major depression (25.7%), bipolar disorder (11.4%), and other mood disorders (34.3%). A large portion of participants also had diagnosed medical comorbidities, including hypertension and other cardiovascular disorders (54.3%), diabetes (15.7%), sleep apnea (18.6%), and pain conditions (51.4%).

The majority of participants had a prescription for a psychiatric medication. Selective serotonin reuptake inhibitors (SSRI) were the most commonly prescribed class of medications, with 65.0% of subjects taking one or more SSRI medications. Additionally, 15.7% of participants received an atypical antipsychotic, 14.3% were prescribed a benzodiazepine, and 15.7% were prescribed other psychotropic medications (e.g., tricyclic antidepressants, lithium, anticonvulsants). Non-benzodiazepine hypnotics are not included in the VA formulary; however, four participants received either zolpiden or eszopiclone from a non-VA provider. Other medications that have sedative/hypnotic effects were also tracked in the research database.

Gabapentin was prescribed to 17.1% of participants, 8.6% of participants received an opioid medication, and 7.1% were taking an antihistamine prescribed as an anxiolytic or sleep aid.

Chi-square and independent samples t-tests were used to evaluate participant differences in demographics between the two VA sites. The average age and gender distribution did not differ significantly between the sites. There was a significant difference between the sites in racial composition of the samples, $\chi^2(2, N = 70) = 39.03$, $p < .001$. Twenty-two percent of TVAMC participants and 98% of VAMHCS participants self-identified as Caucasian. Between subjects t-tests were used to evaluate baseline differences between the two sites for sleep diary variables (SOL, WASO, TST, TWAK, SE), daytime functioning measures (PCL-M, BDI-II, BAI), and sleep related measures (ISI, DBAS-16). Participants did not differ significantly on baseline sleep diary variables (see Table 1). Sleep-related questionnaire scores were also not significantly different between the sites. Due to the small sample size, non-significant differences in participant characteristics between the sites had low statistical power and should be interpreted with caution. Differences on two baseline measures of daytime functioning were significant. Participants at TVAMC had significantly lower scores on the PCL-M, $t(64) = 5.63$, $p < .001$, and higher scores on the BAI, $t(64) = 2.41$, $p = .018$ (see Table 2).

Table 1

Baseline Sleep Diary Variables by Research Site: TVAMC (n = 24) and VAMHCS (n = 29)

Variable	TVAMC *M* (SD)	VAMHCS *M* (SD)	*t*	*p*
SE (percentage)	69.7 (11.4)	68.7 (14.7)	0.27	.786
SOL (minutes)	53.0 (29.6)	58.3 (40.6)	0.53	.595
WASO (minutes)	62.3 (34.6)	57.6 (41.1)	0.46	.645
TWAK (minutes)	31.8 (38.4)	28.9 (29.2)	0.32	.753
TST (minutes)	350.7 (106.5)	325.2 (103.3)	0.88	.383

Table 2

Baseline Questionnaires by Research Site: TVAMC (n = 28) and VAMHCS (n = 38)

Variable	TVAMC *M* (SD)	VAMHCS *M* (SD)	*t*	*p*
ISI	19.0 (3.5)	20.4(4.0)	1.46	.149
DBAS-16	108.4 (26.5)	100.5 (24.6)	1.29	.220
PCL-M	49.1 (9.8)	62.3 (9.1)	5.64	< .001
BDI-II	30.5 (10.8)	27.0 (9.3)	1.40	.165
BAI	29.7 (12.3)	23.0 (9.9)	2.43	.018

Several significant site-specific differences were observed in prevalence of psychiatric and medical diagnoses and type of medications prescribed. A larger portion of the TVAMC participants had a diagnosis of PTSD, $\chi^2(1, N = 70) = 4.98$, $p = .03$, whereas more VAMHCS participants were diagnosed with anxiety disorders other than PTSD, $\chi^2(1, N = 70) = 14.73$, $p < .001$. Additionally, a greater portion of TVAMC participants had diagnoses of hypertension and cardiovascular illness, $\chi^2(1, N = 70) = 7.34$, $p < .01$. Participants at VAMHCS were more likely to be prescribed an SSRI, $\chi^2(1, N = 70) = 9.11$, $p < .01$.

Attrition

Of the 70 participants included in the study, 36 completed both the baseline and post-intervention assessment. Among those assigned to the treatment-as-usual waitlist condition, 17 of 31 completed the post-waitlist assessment. Ten waitlist participants crossed over to the treatment group and completed at least one session, eight completed all four sessions, and six returned post-treatment measures. In the treatment condition, 19 of 39 completed the post-treatment assessment. Among the participants assigned to the treatment group who did not return

completed post-treatment measures, 12 did not present for the treatment, six attended at least one treatment session, and two completed all four sessions (see Figure 1).

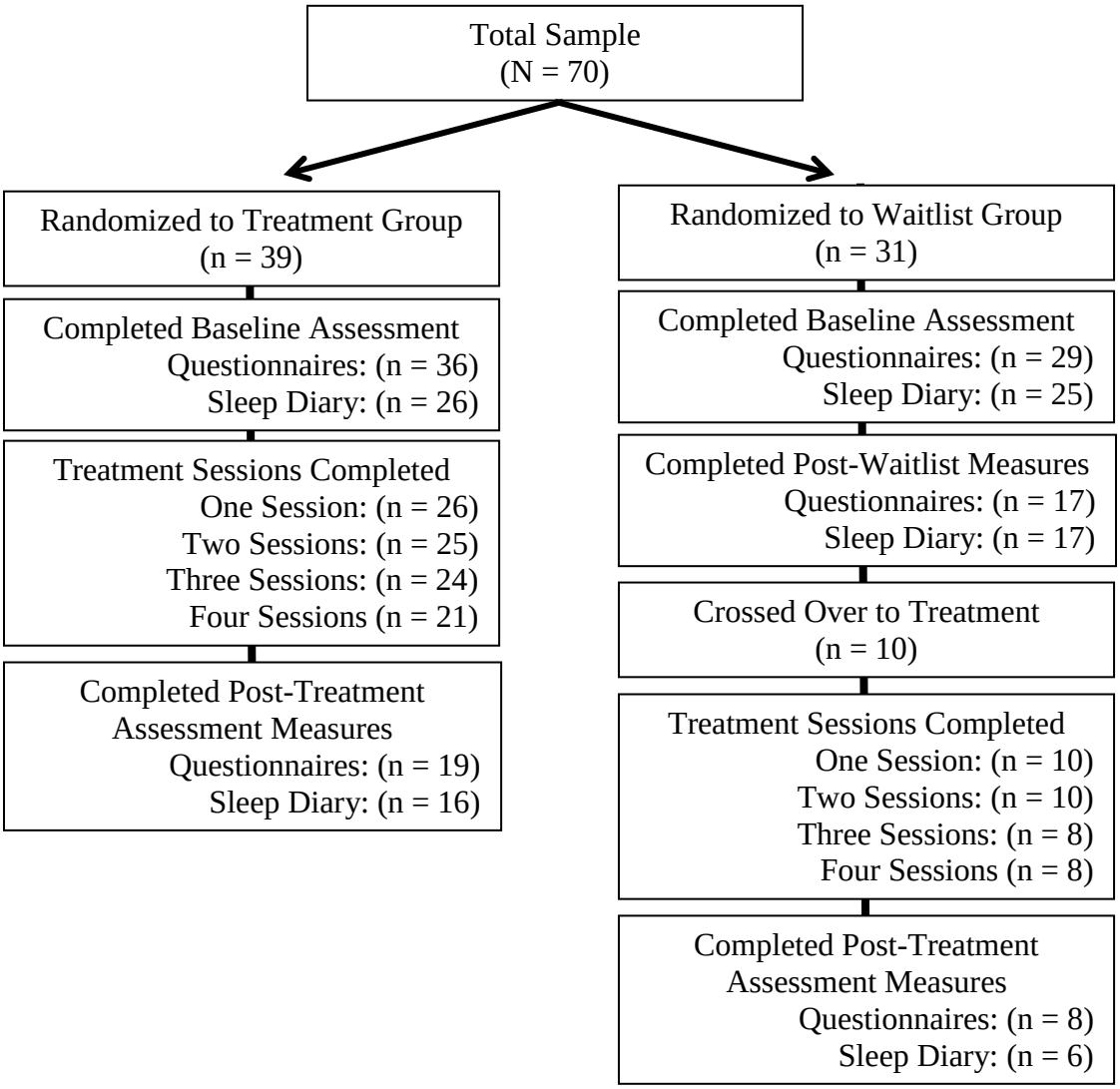

Figure 1. Flow chart of participants through study.

Chi-square and independent samples t-tests were used to explore differences in demographics and baseline measures between participants who completed the second assessment and those who did not. Baseline sleep diaries were returned by 35 completers and 18 non-completers, and baseline questionnaires were returned by 36 completers and 30 non-completers.

Baseline sleep diary variables were not significantly different for completers and non-completers (see Table 3). Similarly, there were no significant differences in scores on the baseline sleep-related questionnaires and daytime functioning measures (see Table 4). Participants' age and race were not significantly related to completion status. Due to the small sample size, tests of group equivalence may not have had sufficient power to detect participant differences. The only significant difference that was identified between the completers and non-completers was related to research site, $\chi^2(1, N = 70) = 4.58$, $p = .03$. At TVAMC, 37.5% of participants completed the second assessment, compared to 63.2% at VAMHCS.

Table 3

Baseline Sleep Variables for Participants who Completed Baseline and Post-Intervention Sleep Diaries (n = 35) and Participants who Completed Baseline Only (n = 18)

Variable	Completed Both Assessments *M* (SD)	Completed Baseline Only *M* (SD)	*t*	*p*
SE (percentage)	70.5(11.1)	66.7 (16.6)	1.00	.322
SOL (minutes)	52.6 (32.6)	62.3 (41.6)	0.93	.357
WASO (minutes)	61.5 (37.2)	56.0 (40.4)	0.46	.645
TWAK (minutes)	27.4 (26.4)	35.7 (44.3)	0.73	.472
TST (minutes)	334.3 (84.1)	341.6 (138.6)	0.21	.839

Table 4

Baseline Questionnaires for Participants who Completed Baseline and Post-Intervention Questionnaires (n = 36) and Participants who Completed Baseline Only (n = 30)

Variable	Completed Both Assessments *M* (SD)	Completed Baseline Only *M* (SD)	*t*	*p*
ISI	20.2 (3.6)	19.0 (4.1)	0.84	.407
DBAS-16	106.0 (21.8)	101.4 (29.6)	0.72	.476
PCL-M	58.8 (10.6)	54.2 (12.0)	1.67	.100
BDI-II	28.4 (9.5)	28.6 (10.9)	0.09	.929
BAI	26.5 (11.5)	25.1 (11.4)	0.48	.630

Randomization

Chi-square and independent samples t-tests were used to explore differences in demographics and baseline measures between participants who were assigned to the treatment group and those assigned to the waitlist group in order to evaluate the success of randomization. Participants' age and race were not significantly related to treatment group. Differences in sleep diary measures were also non-significant (see Table 5). The waitlist group was found to have significantly greater baseline PTSD severity as measured by the PCL-M, and significantly higher scores on the DBAS-16 (see Table 6).

Table 5

Baseline Sleep Diary Variables by Condition: Treatment (n = 26) and Waitlist (n = 25)

Variable	Treatment *M* (SD)	Waitlist *M* (SD)	*t*	*p*
SE (percentage)	70.4 (11.8)	67.8 (14.7)	0.71	.477
SOL (minutes)	49.3 (34.9)	63.3 (35.9)	1.43	.157
WASO (minutes)	64.0 (40.8)	54.7 (34.7)	0.89	.379
TWAK (minutes)	29.0 (29.6)	31.6 (37.7)	0.28	.781
TST (minutes)	333.7 (81.9)	340.1 (126.8)	0.22	.827

Table 6

Baseline Questionnaires by Treatment Condition: Treatment (n = 36) and Waitlist (n = 29)

Variable	Treatment *M* (SD)	Waitlist *M* (SD)	*t*	*p*
ISI	19.3 (3.6)	20.5(3.1)	1.35	.181
DBAS-16	97.2 (24.6)	112.4 (24.5)	2.49	.015
PCL-M	53.5 (11.5)	60.8 (10.1)	2.68	.009
BDI-II	26.8 (9.6)	31.6 (10.3)	1.55	.126
BAI	23.7 (10.9)	28.6 (11.6)	1.78	.080

Correlations between Baseline Variables and Treatment Outcome

Bivariate correlations between participants' pre-intervention characteristics and change scores in the treatment outcome variables were evaluated in order to identify plausible covariates that merited inclusion in the tests of treatment effects. Correlations were evaluated for both treatment conditions together and for the waitlist and treatment groups separately. No significant correlations were observed; therefore, covariates were not included in the analyses of treatment effects.

Data Screening and Tests of Statistical Assumptions

Normal distribution of the dependent variables was evaluated using visual inspection of histograms and univariate Shapiro-Wilks tests. All of the dependent measures, with the exception of TWAK, were found to be normally distributed for both conditions and for the combined sample. The distribution of TWAK was bi-modal due to a significant number of participants reporting that they arose from bed immediately upon awaking, thereby registering a zero on this variable. No outlier values greater than two standard-deviations from the mean were observed in any of the dependent measures. For multivariate models, homogeneity of covariance matrices was tested using the Box's M tests. Due to the conservative nature of this test and the fact that MANOVA is robust to violations of the homogeneity of covariance assumption when cell sizes are relatively equal, the Box's M was interpreted with a significance criterion of $p < .001$ to reject the null hypothesis. No violations of the assumption of homogeneity of covariance matrices of the dependent variables were observed in the models. Levene's tests were used to assess the equality of variances in the univariate tests, and no violations were observed in the models.

Approach to Analysis of Treatment Effects

Repeated measures analyses were used to evaluate the intervention effects on the dependent variables (i.e., sleep diary measures, self-report questionnaires of sleep, and daytime functioning measures). A mixed design was used with time of assessment entered as a within subjects independent variable and treatment group entered as a between subjects independent variable. The tests of the Time x Group interaction effects were of primary interest for comparisons of outcome between the CBT-I and waitlist groups. Partial eta squared (η_p^2) was used to evaluate the magnitude of observed effects using interpretive guidelines for small

(.0099), medium (.0588), and large (.1379) effect sizes recommended by Richardson (2011) to correspond with Cohen's (1969) guidelines for interpretation of *f* values.

Three datasets were constructed in order to analyze the data. First, the analyses of intervention effects were executed for all participants who enrolled in the study and completed the baseline assessment, hereafter referred to as the "total sample." For participants with missing post-intervention data, baseline values were carried forward to post-intervention. The second dataset included only those participants who provided both pre- and post-intervention data, hereafter referred to as "intervention completers." Finally, data from all of the participants who received treatment and completed a post-treatment assessment, including those who crossed over from the waitlist, were analyzed, hereafter referred to as "treatment recipients." For the waitlist group participants included in the third dataset, data provided at the completion of the waitlist period were used as the pre-treatment comparison point for evaluation of post-treatment effects.

Analyses of Treatment Effects – Total Sample

Sleep diary. Sleep diary data from 25 waitlist and 26 treatment group participants were included in the analyses, with Time entered as the within subjects factor and Group entered as the between subjects factor. Because SE is computed based on other sleep diary variables, it was evaluated using a separate model in order to avoid suppression effects resulting from multicolinearity between dependent variables.

A mixed design ANOVA for SE showed a significant main effect of Time, $F(1,49) = 8.30$, $p = .006$, $\eta_p^2 = .145$. The main effect of Group was not significant, $F(1,49) = 2.67$, $p = .110$, $\eta_p^2 = .051$. The Time x Group interaction was significant and had a medium effect size, $F(1,49) = 4.31$, $p = .043$, $\eta_p^2 = .081$ (see Figure 2). Post-hoc simple effects test showed that baseline SE did not differ significantly between the treatment groups, $F(1,49) = 0.58$, $p = .459$, $\eta_p^2 = .011$. At

post-intervention, SE was significantly higher in the CBT-I group compared to the waitlist group, $F(1,49) = 4.97$, $p = .030$, $\eta_p^2 = .092$. The change in SE from baseline to post-intervention in the treatment group was significant and showed a large effect size, $F(1,49) = 12.53$, $p = .001$, $\eta_p^2 = .204$. Pre- to post-intervention change in SE in the waitlist group was not significant, $F(1,49) = 0.32$, $p = .576$, $\eta_p^2 = .006$.

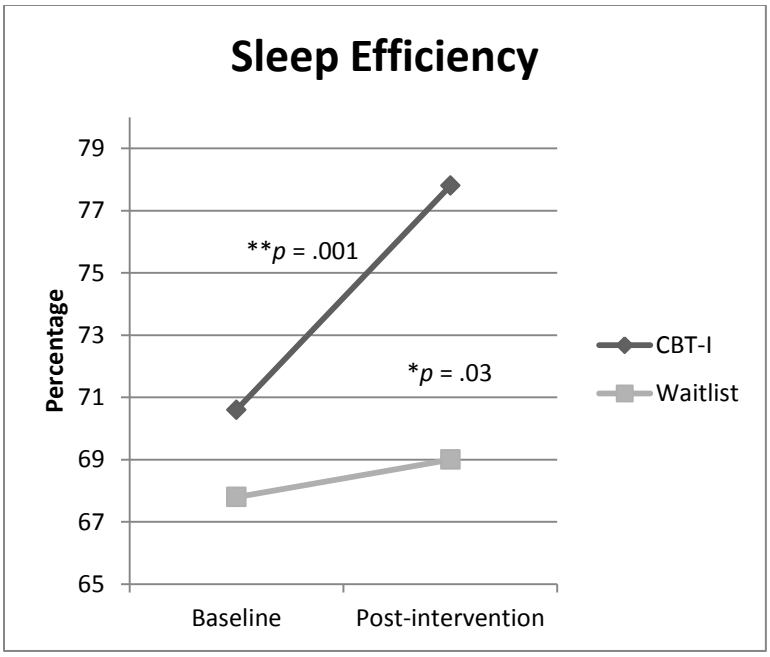

Figure 2. Sleep efficiency at baseline and post-intervention for the treatment and waitlist groups for the total sample.
** Indicates a significant difference between CBT-I and waitlist groups at post-intervention.*
*** Indicates a significant pre- to post-intervention change.*

A mixed design MANOVA was used to evaluate changes in TST, SOL, WASO, and TWAK. The omnibus tests for Time, Wilks' $\Lambda = .833$, $F(4,46) = 2.31$, $p = .072$, $\eta_p^2 = .167$, and Group, Wilks' $\Lambda = .869$, $F(4,46) = 1.74$, $p = .158$, $\eta_p^2 = .131$, were not significant. The Time x Group interaction was also not significant, Wilks' $\Lambda = .850$, $F(4,46) = 2.02$, $p = .107$, $\eta_p^2 = .150$. No univariate testing was conducted.

A mixed design ANOVA was used to evaluate changes in SQR. The main effect of Time was significant, $F(1,49) = 5.46$, $p = .024$, $\eta_p^2 = .100$. SQR increased from baseline to post-

intervention across groups, *M(SD)* pre-intervention = 2.3(0.6), *M(SD)* post-intervention = 2.8(1.6). The main effect of Group, $F(1,49) = 0.39$, $p = .537$, $\eta_p^2 = .008$, and the Time x Group interaction, $F(1,49) = 0.01$, $p = .937$, $\eta_p^2 < .001$, were not significant.

Sleep questionnaires. Sleep questionnaire data from 29 waitlist and 36 treatment group participants were included in the analyses, with Time entered as the within subjects factor and Group entered as the between subjects factor.

Mixed design ANOVAs were used to evaluate changes in ISI and DBAS-16. For ISI, the main effect of Time was significant, $F(1,63) = 25.43$, $p < .001$, $\eta_p^2 < .288$. ISI scores indicated less distress at post-intervention across groups, *M(SD)* pre-intervention = 19.8(3.9), *M(SD)* post-intervention = 17.9(4.6). The main effect of Group, $F(1,63) = 1.68$, $p = .200$, $\eta_p^2 = .026$, and the Group x Time interaction, $F(1,63) = 0.03$, $p = .858$, $\eta_p^2 = .001$, were not significant. For the DBAS-16, both main effects of Time, $F(1,63) = 5.69$, $p = .020$, $\eta_p^2 = .084$, and Group, $F(1,63) = 6.03$, $p = .017$, $\eta_p^2 = .089$, were significant. Scores on the DBAS-16 were higher in the waitlist group across the measurement points, *M(SD)* waitlist group = 109.8(25.5), *M(SD)* treatment group = 95.8(24.3), and mean scores on this measure decreased from pre- to post-intervention in the overall sample, *M(SD)* pre-intervention = 105.6(24.6), *M(SD)* post-intervention = 99.1(26.6). The Time x Group interaction for the DBAS-16 was not significant, $F(1,63) = 0.09$, $p = .766$, $\eta_p^2 = .001$.

Daytime functioning questionnaires. A mixed design MANOVA was used to evaluate treatment effects on BDI-II, BAI, and PCL-M scores with data from 36 treatment group participants and 29 waitlist participants. The omnibus test for the main effect of Time was significant, Wilks' $\Lambda = .827$, $F(1,61) = 4.26$, $p = .008$, $\eta_p^2 = .173$. Post-hoc univariate tests revealed significant findings for BDI-II, $F(1,63) = 10.79$, $p = .002$, $\eta_p^2 = .146$, and PCL-M

scores, $F(1,63) = 10.00$, $p = .002$, $\eta_p^2 = .137$. BDI-II scores were lower at the post-intervention assessment across the groups, *M(SD)* pre-intervention = 28.4(10.0), *M(SD)* post-intervention = 25.4(11.0). Similarly, scores on the PCL-M decreased from pre- to post-intervention across groups, *M(SD)* pre-intervention = 49.8(9.8), *M(SD)* post-intervention = 47.3(11.0). The main effect of Group, Wilks' $\Lambda = .897$, $F(1,61) = 2.32$, $p = .084$, $\eta_p^2 = .103$, and the Group x Time interaction, Wilks' $\Lambda = .914$, $F(3,61) = 1.90$, $p = .139$, $\eta_p^2 = .086$, were not significant.

Analyses of Treatment Effects – Intervention Completers

The analyses of treatment effects were repeated using data from participants who completed measures at both assessment points. The overall findings were consistent with those from the total sample. The only observed significant Group x Time interaction was for SE.

Sleep diary. Sleep diary data from 17 waitlist and 16 treatment group participants who completed both pre- and post-intervention assessments were analyzed using a mixed design ANOVA to evaluate changes in SE from pre- to post-intervention. The main effect of Time was significant, $F(1,31) = 10.43$, $p = .003$, $\eta_p^2 = .252$, indicating greater SE at post-intervention across groups. The main effect of Group was not significant, $F(1,31) = 4.15$, $p = .050$, $\eta_p^2 = .118$. The test of the Group x Time interaction was significant, $F(1,31) = 5.77$, $p = .022$, $\eta_p^2 = .157$ (see Figure 3). Post-hoc simple effects tests showed that baseline SE did not differ significantly between the groups, $F(1,31) = 0.195$, $p = .662$, $\eta_p^2 = .006$; however, at post-intervention the treatment group had significantly greater sleep efficiency compared to the waitlist group, $F(1,30) = 9.40$, $p = .004$, $\eta_p^2 = .233$. Pre- to post-intervention changes were significant for the treatment group and showed a large effect size, $F(1,31) = 15.39$, $p < .001$, $\eta_p^2 = .332$. Changes in SE for the waitlist group were not significant, $F(1,31) = 0.35$, $p = .557$, $\eta_p^2 = .011$.

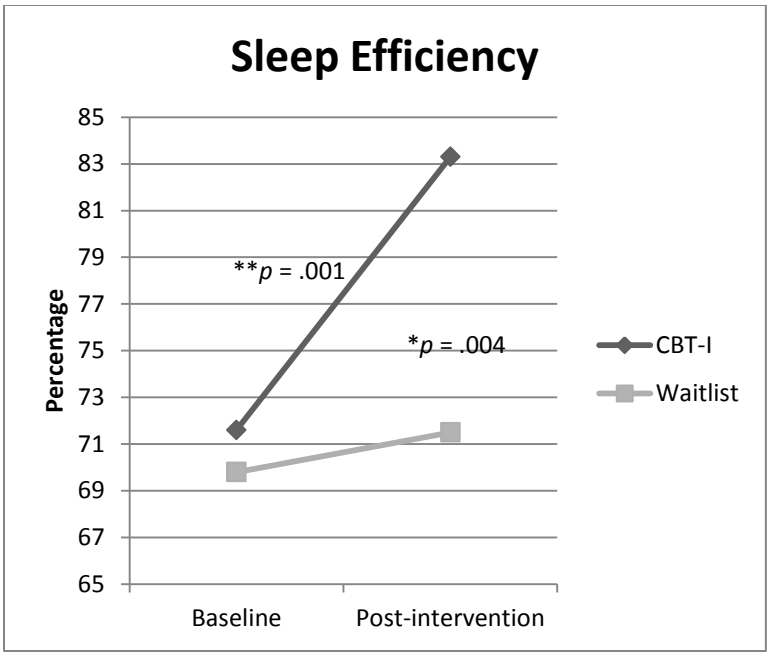

Figure 3. Sleep efficiency at baseline and post-intervention for the treatment and waitlist groups for intervention completers.
** Indicates a significant difference between CBT-I and waitlist groups at post-intervention.*
*** Indicates a significant pre- to post-intervention change.*

A mixed design MANOVA was used to evaluate changes in SOL, WASO, TWAK, and TST. No significant main effects were observed for Time, Wilks' $\Lambda = .720$, $F(4,28) = 2.72$, $p = .050$, $\eta_p^2 = .280$, or Group, Wilks' $\Lambda = .808$, $F(4,28) = 1.67$, $p = .186$, $\eta_p^2 = .192$. The interaction effect of Group x Time was also not significant, Wilks' $\Lambda = .746$, $F(4,28) = 2.38$, $p = .076$, $\eta_p^2 = .254$.

A mixed design ANOVA was used to evaluate changes in participants' SQR. A significant main effect of Time was observed, $F(1,31) = 5.75$, $p = .023$, $\eta_p^2 = .156$. SQR improved from the baseline to post-intervention across groups, *M(SD)* pre-intervention = 2.3(0.6), *M(SD)* post-intervention = 3.1(1.8). The effect of Group, $F(1,31) < 0.01$, $p = .975$, $\eta_p^2 < .001$, and the Group x Time interaction, $F(1,31) = 0.04$, $p = .842$, $\eta_p^2 = .001$, were not significant.

Sleep questionnaires. A mixed design ANOVA was used to evaluate changes in ISI. The main effects of Time, $F(1,34) = 37.61$, $p < .001$, $\eta_p^2 = .525$, and Group, $F(1,34) = 5.98$, $p = .020$,

η_p^2 = .149, were significant. ISI scores decreased significantly across groups, *M(SD)* pre-intervention = 20.2(3.6), *M(SD)* post-intervention = 16.7(4.7), and were significantly higher in the waitlist group across time points, *M(SD)* waitlist group = 20.0(4.2), *M(SD)* treatment group = 17.1(3.3). The test of Group x Time interaction was not significant, $F(1,34) = 0.291$, $p = .593$, $\eta_p^2 = .008$.

Treatment effects for DBAS-16 scores were also evaluated using a mixed ANOVA design. The main effect of Time was significant, $F(1,33) = 6.16$, $p = .018$, $\eta_p^2 = .157$. There was a significant reduction in DBAS-16 scores from baseline to post-intervention across groups, *M(SD)* pre-intervention = 106.5(21.9), *M(SD)* post-intervention = 95.6(25.3). The main effect of Group, $F(1,33) = 2.58$, $p = .118$, $\eta_p^2 = .037$, as well as the Group x Time interaction, $F(1,31) = 0.22$, $p = .642$, $\eta_p^2 = .007$, were not significant.

Daytime functioning measures. Treatment effects on daytime functioning were evaluated using a mixed design MANOVA with BDI-II, BAI, and PCL-M entered as dependent variables. The omnibus effect of Time was significant, Wilks' $\Lambda = .688$, $F(3,32) = 4.84$, $p = .007$, $\eta_p^2 = .312$. Follow-up univariate tests for the effect of Time were significant for PCL-M scores, $F(1,34) = 10.73$, $p = .002$, $\eta_p^2 = .240$, and BDI-II scores, $F(1,34) = 12.91$, $p = .001$, $\eta_p^2 = .275$. Results indicated that participants had reduced scores on both the PCL-M, *M(SD)* pre-intervention = 51.3(9.7), *M(SD)* post-intervention = 46.6(11.9), and BDI-II, *M(SD)* pre-intervention = 28.4(9.5), *M(SD)* post-intervention = 22.8(10.6). Changes in BAI scores from pre- to post-intervention were not significant, $F(1,31) = 3.04$, $p = .090$, $\eta_p^2 = .082$. The omnibus main effect of Group was not significant, Wilks' $\Lambda = .801$, $F(3,32) = 2.64$, $p = .066$, $\eta_p^2 = .199$. Similarly, the omnibus test of the Group x Time interaction was not significant, Wilks' $\Lambda = .846$, $F(3,32) = 1.94$, $p = .144$, $\eta_p^2 = .154$.

Analyses of Treatment Effects - Treatment Recipients

Analyses of treatment effects were evaluated for participants assigned to the treatment group who completed post-intervention measures and participants assigned to the waitlist group who then crossed over to treatment and returned the post-treatment assessment measures. Time was entered as a within subjects variable and Group to which participants were initially randomized (i.e., treatment versus waitlist) was entered as a between subjects variable in the models. The main effects of Time were interpreted to determine the impact of the treatment in the aggregate sample. The Time x Group interactions were evaluated to determine whether treatment response differed between participants who were randomized to CBT-I and participants who crossed over from the waitlist group.

Sleep Diary. Sleep diary data from 16 treatment group participants and six waitlist participants were evaluated. In a mixed design ANOVA with SE entered as the dependent variable, a significant main effect of Time was observed, $F(1,20) = 18.79$, $p < .001$, $\eta_p^2 = .484$, and SE increased in the overall sample. The main effect of Group, $F(1,20) = 0.03$, $p = .860$, $\eta_p^2 = .002$, and the Time x Group interaction, $F(1,20) = 0.28$, $p = .605$, $\eta_p^2 = .014$, were not significant. Similarly, a mixed design MANOVA for SOL, WASO, TWAK, and TST showed a significant main effect of Time, Wilks' $\Lambda = .566$, $F(4,17) = 3.25$, $p = .037$, $\eta_p^2 = .434$. Univariate post-hoc tests showed that participants had increased TST and reduced SOL and WASO at post-treatment. The main effect of Group, Wilks' $\Lambda = .908$, $F(4,17) = 0.43$, $p = .783$, $\eta_p^2 = .092$, as well as the Group x Time interaction, Wilks' $\Lambda = ..896$, $F(4,17) = 1.94$, $p = .740$, $\eta_p^2 = .104$, were not significant.

Sleep Questionnaires. Sleep questionnaire data from 19 treatment group participants and eight waitlist participants were evaluated. Mixed design ANOVAs for ISI and DBAS-16

revealed a pattern of results similar to those for the sleep diary measures. Main effects of Time were significant for both the ISI, $F(1,25) = 15.97$, $p < .001$, $\eta_p^2 = .390$, and the DBAS-16, $F(1,25) = 6.15$, $p = .021$, $\eta_p^2 = .204$. Participants showed improvement from pre- to post-treatment on both measures. The main effects of Group were not significant for either the ISI, $F(1,25) = 0.12$, $p = .736$, $\eta_p^2 = .005$, or the DBAS-16, $F(1,25) = 1.64$, $p = .213$, $\eta_p^2 = .064$. The Group x Time interactions for the ISI, $F(1,25) = 0.09$, $p = .762$, $\eta_p^2 = .004$, and DBAS-16, $F(1,25) = 0.07$, $p = .796$, $\eta_p^2 = .069$, were also not significant.

Daytime Functioning Measures. A mixed design MANOVA was used to evaluate treatment effects on PCL-M, BDI-II, and BAI data from 19 treatment group participants and eight waitlist participants. The omnibus test for the main effect of Time was significant, Wilks' $\Lambda = .623$, $F(3,23) = 4.63$, $p = .011$, $\eta_p^2 = .377$. Post-hoc univariate tests showed significant improvements on all of the daytime functioning measures. The main effect of Group, Wilks' $\Lambda = .831$, $F(3,23) = 1.56$, $p = .225$, $\eta_p^2 = .169$, and the Group x Time interaction, Wilks' $\Lambda = .799$, $F(3,23) = 2.17$, $p = .119$, $\eta_p^2 = .221$, were not significant.

Adherence and Treatment Outcome

In order to evaluate the relation between treatment adherence and treatment outcome, regression analyses were used to predict change scores in the treatment outcome measures using adherence scores for the three treatment components. Three scores were created using logs completed by the treatment group participants, represented as percentage of adherence with relaxation, sleep hygiene, and stimulus control recommendations. Multivariate regression models were constructed for sleep diary variables, sleep questionnaires, and daytime functioning measures. The only significant relation identified was between adherence and change scores on the ISI, $F(3,18) = 7.15$, $p = .002$. Univariate post-hoc tests revealed that the relation between

relaxation adherence and ISI changes was significant, $F(1,21) = 6.87$, $p = .017$, and that participants who reported higher compliance with relaxation practice had greater reductions in ISI scores.

4. Discussion

Participants who received the CBT-I intervention had significantly greater improvements in sleep efficiency compared to participants in the waitlist condition. A large treatment effect was detected even when data from participants who did not complete the study were included, suggesting that the improvements in sleep efficiency were particularly robust. For those participants who completed the CBT-I intervention, the improvements were clinically meaningful. The average increase in sleep efficiency in the treatment group was over 12%, and the post-treatment mean approached the recommended benchmark for normal sleep efficiency of 85% (Morin, 1993). Treatment effects on the individual sleep diary variables trended in the hypothesized direction, but the interaction of time of measurement and treatment condition was not statistically significant. Thus, the first hypothesis was partially supported by the findings.

The second hypothesis was not supported by the data. Participants in both groups reported significantly less sleep-related distress at post-intervention, as measured by ISI scores, and the interaction effect between time of measurement and treatment condition was not statistically significant, indicating the absence of a treatment effect. It is unclear whether the observed changes across groups were related to participation in the study, resulted from elements unrelated to the research program that occurred in the interim between assessments, or were produced by regression toward the mean. Average reduction in ISI scores across the groups was less than two points. Although statistically significant, these changes do not suggest a clinically meaningful improvement based on suggested interpretations for this measure (Morin, Belleville,

Bélanger, and Ivers, 2011), and the mean values on the ISI at post-intervention continued to exceed the suggested clinical cutoff (Bastien et al., 2001).

One potential explanation for the disparity between the sleep diary and ISI findings may be related to the timeframe that participants were asked to consider in making their ratings. When completing the sleep diary, participants were asked to rate their sleep for one night at a time over a seven-day period. Conversely, the ISI prompted participants to base their rating on their overall sleep quality over the past two weeks. Thus, the ISI captured more global appraisals of sleep quality, which may be more susceptible to attention biases, such as focusing on isolated bad nights that negatively valence perceptions of sleep quality as a whole. Additionally, because participants completed the post-intervention assessment shortly after the last session, the newly gained improvements in sleep quality that were captured by the sleep diary may not have been represented in their ISI responses.

Another perspective that may help to explain the discrepancy between sleep diary and ISI findings is to consider the cognitive factors that influenced participants' beliefs about the impact of sleep on other life domains. Unlike the sleep diary, the ISI solicited participants' ratings of the degree to which sleep difficulties interfered with their daytime performance. Thus, perceived deficits in daytime alertness, performance on daily tasks, and overall mood were also captured by the ISI. The cognitive model of insomnia suggests that individuals with chronic sleep problems are prone to excessive monitoring for sleep-related daytime deficits and excessive worry about the consequences of not sleeping well (Harvey, 2002). Therefore, the lack of a therapeutic effect on the ISI scores may reflect a lack of change in cognitions about sleep, rather than absence of sleep improvement. Previous research has highlighted the relation between global appraisals of

sleep quality and perceived daytime functioning deficits, which are separate from quantitative aspects of sleep quality, such as those captured by sleep diaries (Ustinov et al., 2010).

The third hypothesis was also not supported by the data. Scores on the DBAS-16 did not show a significant change for either group, suggesting the CBT-I intervention did not address participants' unhelpful beliefs about sleep, such as excessive worry about the consequences of insomnia and perceived lack of control over sleep. Due to the brevity of this treatment protocol, the amount of attention devoted to identifying and challenging unhelpful beliefs about sleep may not have been sufficient. The cognitive component of the intervention was largely psychoeducational, such as informing participants about individual differences in sleep requirements to reduce unrealistic expectations about the amount of sleep that is necessary to function well during the day. These concepts were discussed in the first session and reviewed briefly in the second. However, the bulk of the intervention focused on encouraging behavioral changes, such as adherence to stimulus control, sleep hygiene, and regular relaxation practice.

The effects on dysfunctional beliefs about sleep observed in the current study differ from those reported by a group of researchers who found significant reduction in DBAS-16 scores following four sessions of a strictly behavioral intervention that included stimulus control and sleep restriction (Roane, Dolan, Bramwoeth, Rosenthal, & Taylor, 2012). The authors suggested that behavioral treatment components provided participants with opportunities for behavioral experiments that led to reduced dysfunctional beliefs. The discrepancy between the current findings and those of Roane and colleagues may be related to the populations that were studied. Whereas the current study focused on veterans with trauma-related disorders, Roane and colleagues recruited a community sample of individuals who presented to a sleep disorders center. It is possible that individuals with trauma-related disorders have more ingrained

dysfunctional beliefs about sleep. For example, these individuals may attribute trauma-related symptoms, such as intrusive thoughts that interfere with concentration, irritability, and depressed mood, to poor sleep quality. Other dysfunctional beliefs, such as fear of letting down one's guard when sleeping, may also be unique to individuals with trauma-related disorders.

When considered together, results for the sleep diary, ISI, and DBAS-16 suggest that the CBT-I intervention in the current study helped participants improve their quantitative sleep parameters but failed to modify their global appraisals and beliefs about sleep. Therefore, interventions that target the cognitive dimensions of insomnia through role plays and behavioral experiments, such as those described by Harvey, Sharpley, Ree, Stinson, and Clark (2007), could be a valuable addition to the current protocol and warrant investigation with individuals who have insomnia that co-occurs with trauma-related disorders.

The fourth hypothesis was not supported by the data because participants' self-report of trauma-related symptoms, anxiety, and depression did not show greater improvement in the treatment condition. Similar findings have been reported in other studies that found successful treatments for insomnia did not result in corresponding improvements in measures of depression and anxiety (Lichstein, 2000b; Owen, 2002). The baseline mean values for participants in the current study indicated that for both groups, BDI-II, BAI, and PCL-M scores were all in the "moderate" to "severe" range and generally remained stable at post-treatment. This finding is concerning, considering that in addition to the study intervention, veterans in this sample were receiving other mental health services, and a majority were taking prescription psychotropic medications. These data highlight the significant burden that mental health problems present for veterans with histories of trauma and the refractory nature of their symptoms. Considering the current study only captured symptom reports over a five-week period, the lack of significant

findings may also reflect a need for longer term treatment to sufficiently address these areas of functioning.

Study Limitations

Several important limitations of the current study need to be considered when interpreting these results. Sleep quality was assessed only through self-report, and no objective measures were included. Therefore, it is not possible to conclude whether changes in sleep parameters were due to actual improvements in sleep quality or changes in how participants perceived their sleep. Inclusion of non-obtrusive objective measures, such as actigraphy, would have been a valuable adjunct to self-report data, but was not available for this study due to prohibitive cost. Another drawback is that treatment was administered by a single therapist, which limits the generalizability of the findings. Additionally, the results reported in this study are from baseline and post-treatment measures and do not include follow-up assessments. Therefore, it is not known whether observed gains were maintained over time or if additional treatment effects emerged after participants left treatment. The use of a treatment-as-usual control group rather than a placebo condition also limits the interpretation of the observed treatment effects.

Another major limitation of the current study resulted from the high attrition rates. Complete data from less than 50% of participants who were enrolled in the study were available for analysis. Comparable attrition rates have been reported in similar CBT-I group treatment studies with veterans (Owen, 2002). Therefore, interpretations of treatment effects need to take into account that the participants who completed the intervention may have differed in important ways from those who enrolled in the program but were lost to follow-up. Differences between study completers and non-completers were evaluated by testing for significant differences between these groups in baseline data. However, none of the demographic or symptom severity

measures revealed significant differences. Factors not captured by the assessment measures included in this study likely impacted participant drop out. For example, some veterans reported financial limitations that prevented them from accessing care. Thus, socioeconomic status may be a predictor of treatment completion. Because of the potential for systematic differences not measured in this study, I chose to account for attrition by carrying baseline values forward to post-treatment for participants with missing post-intervention data. Unlike statistical data imputation techniques, this approach does not make an assumption that data were missing completely at random.

The only factor that was significantly related to attrition and differentiated completers and non-completers was the research site, with participants at TVAMC being less likely to complete the study. This difference may have resulted in part from the type of treatment programs from which participants were recruited. I had anticipated that because TVAMC participants were residing at the VA while receiving treatment, there would be fewer obstacles for them to attend the treatment sessions and study related appointments. However, this did not prove to be the case. Frequently, participants reported that they were unable to attend the treatment sessions because they had conflicting healthcare appointments, or because they felt overburdened by the large number of other treatment groups in which they were taking part as a component of their residential placement. Additionally, if participants were discharged from the residential program during the course of the study, it became difficult for them to attend the treatment groups and respond to follow-up assessments. In contrast, outpatient participants at VAMHCS reported fewer obstacles to attending treatment sessions and study related appointments. Most were used to commuting to the VA to take part in treatment and had existing arrangements for transportation and time availability.

Additionally, the observed difference in attrition rates at the two sites was probably influenced by procedural adaptations I made as the study progressed in order to improve participant retention. When I relocated the data collection to VAMHCS, I increased the frequency with which I contacted enrolled participants to remind them about the research. I telephoned participants who were working on sleep diaries on the third day of the assessment period to make sure they were remembering to record their sleep each morning and again at the end of the seven-day period to encourage them to return the completed form. For participants who were enrolled in the treatment group, I telephoned them on the day before each session to remind them to attend. These procedures differed from the standard clinical scheduling practices, in which veterans are expected to keep track of appointments themselves or use a secure online portal to check for upcoming appointments. I was concerned that participants may find the telephone calls intrusive; however, the unanimous response from veterans was appreciative. For the current study, waitlist participants were contacted at the midpoint of the waitlist period to remind them about the study and discuss the upcoming post-waitlist assessment and crossover to treatment. Treatment session times were made available on different days of the week and times of the day to try to accommodate participants' schedules. I also helped veterans connect with service organizations that could provide transportation assistance if getting to the VA was a barrier for them.

Implications for Treatment Implementation and Future Research

I chose to discuss these mundane details of participant tracking and scheduling because they have significant implications for developing programs for veterans with trauma-related disorders. Although the high attrition rates observed in this study are problematic for assessment of treatment efficacy, they may provide valuable information about clinical effectiveness and

feasibility of insomnia treatment approaches in the VA setting. The veterans who participated in the current study had many competing demands on their time and situational barriers that prevented them from taking advantage of the treatment. Unstable housing, changes in employment, lack of transportation or money for fuel, childcare responsibilities, conflicting medical and mental health appointments, and increases in trauma-related symptom severity are examples of reasons that participants provided for dropping out of the study. Thus, improving access to CBT-I services for this population entails more than just making these services available at VA hospitals, but also structuring them in a way that will promote utilization.

Two initiatives that are currently being implemented by the Veterans Healthcare Administration in an effort to improve clients' access to mental health services could be utilized to better disseminate CBT-I interventions. The first such initiative is making telehealth services more available to veterans in rural communities. Adapting CBT-I protocols for delivery via telehealth technology would reduce the burden of travel for individuals who do not have a CBT-I provider in their area. No published data on the effectiveness of CBT-I delivered via telehealth are yet available. However, five studies currently in progress which are evaluating telehealth delivery of CBT-I to civilians and veterans are registered with ClinicalTrials.gov (U.S. National Institutes of Health, 2013). A second initiative that could aid in dissemination of CBT-I to veterans is to increase the presence of mental health services in the context of primary care, such as through Integrated Primary Care and Primary Care Mental Health Integration clinics. Providing insomnia services in primary care settings could decrease the stigma related to seeking mental health services that may act as a barrier for some veterans. This is particularly true for the treatment of insomnia, which is a ubiquitous complaint among veterans that is likely to arise at an appointment with a general practitioner.

Additionally, increasing the number of providers who are trained to administer CBT-I interventions would also improve access. Research has already demonstrated that CBT-I delivered by trained nurses produced favorable clinical outcomes that were comparable to services provided by mental health professionals (Espie et al., 2007; Järnefelt, Lagerstedt, Kajaste, Sallinen, Savolainen, & Hublin, 2012). However, further research is needed to determine if CBT-I intervention delivered by nurses or other frontline medical staff are feasible and effective in the VA setting.

5. Conclusion

The results of the current study were mixed. The impact of the CBT-I intervention on veterans' sleep efficiency was favorable and large effect sizes suggested that participants who received the treatment had clinically meaningful improvements in sleep quality. However, the treatment did not lead to significant improvements in sleep-related distress or dysfunctional beliefs, which suggests that greater focus on cognitive aspects of insomnia is warranted when working with this population. The CBT-I treatment also did not have a significant impact on veterans' daytime functioning, which highlights the importance of providing concurrent treatments that target daytime mood and trauma-related symptoms. Numerous challenges related to implementation of the treatment program were encountered in this project, and future research should focus on development of CBT-I delivery models that reduce structural barriers and increase veterans' access to these service.

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APPENDIX A
PARTICIPANT HANDOUTS

Relaxation Procedure

1) Close your eyes and find a comfortable position.

2) Take 5 deep breaths and hold each one for about 5 seconds before exhaling.

3) Focus on and relax the muscles in your body. Concentrate on each of the following areas of your body for about 45 seconds, let go of the tension in each area, and focus on feelings of relaxation.
    a. right leg
    b. left leg
    c. back, abdomen, and chest
    d. right arm
    e. left arm
    f. face and neck

4) Repeat the following phrase to yourself for about a minute: “I am at peace, my arms and legs are heavy and warm.” Try to feel these sensations.

5) Continue to concentrate on feelings of relaxation.

Sleep Hygiene Instructions

1) Eat regular meals and do not go to bed hungry. Hunger can disrupt sleep, so a light snack at bedtime may help sleep. However, you should avoid large meals or greasy or heavy foods.

2) Limit your use of caffeine products. Caffeine is a stimulant and can cause difficulty falling and staying asleep. Avoid caffeinated beverages (coffee, tea, sodas) and chocolate after 12 pm.

3) Avoid nicotine close to bedtime. Like caffeine, nicotine is a stimulant and can disrupt sleep. Avoid smoking or using tobacco products within 1 hour of bedtime and do not use tobacco at night when not able to sleep.

4) Avoid alcohol, especially in the evening. Although alcohol helps some people fall asleep more easily, it caused awakenings during the night and leads to poor sleep quality.

5) Avoid excessive liquids in the evening. Limiting the amount of liquids you drink close to bedtime will minimize the need for nighttime trips to the bathroom.

6) Maintain a regular exercise routine. Exercise can make falling asleep easier and deepen sleep, but avoid exercise within 3 hours of bedtime. Exercising too close to bedtime can make falling asleep difficult.

7) Avoid long naps. Napping during the day can disrupt your nighttime sleep. If you must take a nap, make sure you sleep less than 30 minutes and not after 3 pm.

8) Do not take your problems to bed. Set aside some time earlier in the evening for working on your problems or planning for the next day. Worry at bedtime can lead to difficulty falling asleep and lead to shallow sleep.

Stimulus Control Instructions

Following these recommendations will strengthen the association between getting into bed and going to sleep:

1) Go to bed only when you feel sleepy.

2) If you do not fall asleep within 15-20 minutes, get out of bed and do something in another room. Return to the bed only when you feel sleepy.

3) If you wake during the night and are unable to fall asleep within 15-20 minutes, get up and do something in another room. Return to the bed only when you feel sleepy.

4) Keep a fixed rising time seven days a week. Avoid sleeping late on weekends.

5) Use the bed only for sleep (or sex). Do not read, watch TV or do other activities in the bed.

6) Sleep only in your bed.

APPENDIX B
ADHERENCE LOGS

RELAXATION LOG

ID _____

DAY 1 Date _____

	RELAXATION RATING		
TIME	Before	After	DURATION OF RELAXATION
1			
2			

DAY 2 Date _____

	RELAXATION RATING		
TIME	Before	After	DURATION OF RELAXATION
1			
2			

DAY 3 Date _____

	RELAXATION RATING		
TIME	Before	After	DURATION OF RELAXATION
1			
2			

DAY 4 Date _____

	RELAXATION RATING		
TIME	Before	After	DURATION OF RELAXATION
1			
2			

DAY 5 Date _____

	RELAXATION RATING		
TIME	Before	After	DURATION OF RELAXATION
1			
2			

DAY 6 Date _____

	RELAXATION RATING		
TIME	Before	After	DURATION OF RELAXATION
1			
2			

DAY 7 Date _____

	RELAXATION RATING		
TIME	Before	After	DURATION OF RELAXATION
1			
2			

RELAXATION RATING:

very aroused and upset — normal calm — completely and deeply relaxed

1	2	3	4	5	6	7	8	9	10

Sleep Hygiene Checklist

Please check the box if you followed the recommendation, leave the box blank if you did not follow recommendation.

	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
Ate regular meals and not go to bed hungry.							
Avoided caffeine after 12 pm.							
Avoid nicotine within 1hr of bedtime.							
Avoid alcohol in the evening.							
Avoided excessive liquids in the evening.							
Avoided naps >30 min.							

Stimulus Control Checklist

Please check the box if you followed the recommendation, leave the box blank if you did not follow the recommendation.

		DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	Went to bed only when you felt sleepy.							
2a	Fell asleep within 15-20 minutes of going to bed.							
2b	Got out of bed when unable to fall asleep within 15-20 minutes.							
3a	Did not have nighttime awakenings longer than 15-20 minutes.							
3b	Got out of bed when awake at night for more than 15-20 minutes.							
4	Got up within 30 minutes of normal rising time.							
5	Used your bed only for sleep.							
6	Slept only in your bed.							

APPENDIX C
IRB APPROVALS

Office for Research

Institutional Review Board for the Protection of Human Subjects

November 11, 2010

THE UNIVERSITY OF ALABAMA RESEARCH

Yuriy Ustinov
Department of Psychology
College of Arts & Sciences
The University of Alabama

Re: IRB Protocol # 10-008-ME
"Treatment of Insomnia in Combat Veterans with Posttraumatic Stress Disorder: A Brief Group Cognitive Behavioral Intervention"

Mr. Ustinov:

The University of Alabama Medical IRB has received the revisions requested by the full board on 4/9/10. The board has reviewed the revisions and your protocol is now approved for a one year period. Please be advised that your protocol will expire one year from the date of approval, March 11, 2010.

Should you need to submit any further correspondence regarding this proposal, please include the assigned IRB application number. Please use reproductions of the IRB approved informed consent form to obtain consent from your participants.

Good luck with your research.

Sincerely,

John C. Higginbotham, Ph.D., MPH
Medical IRB Chair
The University of Alabama

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Office for Research

Institutional Review Board for the
Protection of Human Subjects

THE UNIVERSITY OF
ALABAMA
RESEARCH

February 15, 2013

Yuriy Ustinov, M.A.
Department of Psychology
College of Arts & Sciences
The University of Alabama

Re: IRB Protocol # 13-004-ME
"Cognitive Behavioral Insomnia Treatment Group for Veterans"

Mr. Ustinov:

The University of Alabama Medical IRB has granted initial approval of the above application for a one-year period. Please be advised that your protocol will expire one year from the date of approval, 2/14/13.

If your research will continue beyond this date, complete the Renewal Application Form. If you need to modify the study, please submit the Modification of An Approved Protocol Form. Changes in this study cannot be initiated without IRB approval, except when necessary to eliminate apparent immediate hazards to participants. When the study closes, please complete the Request for Study Closure Form.

Should you need to submit any further correspondence regarding this proposal, please include the assigned IRB application number. Please use reproductions of the IRB approved stamped consent/assent forms to obtain consent from your participants.

Good luck with your research.

Sincerely,

John C. Higginbotham, Ph.D., MPH
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COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

Howard Hughes, PhD, Chair CPHS A
Daniel O'Rourke, MD, Chair CPHS B and D
Jack van Hoff, MD, Chair CPHS C

63 South Main Street • HB 6254 • Hanover, NH 03755
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Date:	03/07/13	**Submission:**	Initial Application
To:	Erica England	**Action:**	Approved
Department:	Psychiatry	**Action Date:**	02/28/13
From:	The Committee for the Protection of Human Subjects	**Expiration Date:**	02/27/14
CPHS #:	23923	**Review Type:**	Full Committee
Study:	Cognitive Behavioral Insomnia Treatment Group for Veterans		

Comments:
- Sponsor Protocol dated 1/31/2013
- CPHS Study Plan v. 2/18/2013
- VA Consent form v. 1/10/2013, stamped with CPHS approval date 2/28/2013
- VA Authorization form v. 2/13/2013

The Committee determined future renewals of this study qualify for expedited review under:
- Category #5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
- Category #7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Thank you for providing study materials for review by the Committee for Protection of Human Subjects (CPHS). The Committee for the Protection of Human Subjects (CPHS) **approves** this **new study**, consent form(s) and other submitted materials. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized.

Please be reminded that informed consent is a process beginning with a description of the research and including an evaluation of comprehension by the researcher. Once the consent form has been signed, each participant should receive a copy. Assessment of each participant's consent by the researcher should continue throughout a research study.

Date Stamped CPHS Consent Form:
The CPHS "date stamps" final approved consent form(s). The stamped approved consent form accompanies this approval letter. Please photocopy and use only the CPHS date stamped consent form for this project.

Any revision to previously approved materials must be approved by the CPHS prior to initiation. Please use the Revisions or Addition Review form for this procedure.

Unanticipated problems involving risks to subjects or others as well as certain adverse drug events and medical device effects should be promptly reported to the CPHS. Please refer to the information and forms to make these reports on the CPHS web site at www.Dartmouth.edu/~cphs. In addition, please promptly report to the CPHS office any known instances of noncompliance and complaints made by subjects in connection with this study.

Based on the risks, this project requires Continuing Review by the CPHS on an annual basis.

If you have any questions, please direct them to CPHS.Tasks@Dartmouth.edu.

Sincerely,

Document Version APP 2006-03-07 14:00:07

Research & Development (R&D) Committee
Department of Veterans Affairs
VA Medical Center, Tuscaloosa, Alabama 35404
(679/151)

APPROVAL - Initial Review

Date: October 27, 2010
From: Andrea Lynn Snow, Ph.D, Chairperson
Investigator: Yuriy Ustinov, MA
Protocol: Treatment of Insomnia in Combat Veterans with Posttraumatic Stress Disorder: A Brief Group Cognitive Behavioral Intervention
ID: 00149 Prom#: 0001 Protocol#: 10-10

The following items were reviewed and approved at the 10/25/2010 meeting:

- Abstract (08/20/2010; APPROVED 08/25/2010)
- Advertisement (08/16/2010; APPROVED 08/25/2010)
- Protocol (08/16/2010; APPROVED 08/25/2010)
- TVAMC Assessment of Clinical Impact Form (07/21/2010)
- VA Research HIPAA Authorization (08/18/2010; APPROVED 08/25/2010)
- VA Research Consent Form (VA Form 10-1086) (08/16/2010; APPROVED 08/25/2010)
- TVAMC Data Security Checklist for Principal Invest (07/22/2010)
- TVAMC Investigator Financial Disclosure and Confli - PI & Co-investigators (06/25/2010)

Your research project has been approved by all applicable R&D Committee subcommittees; therefore, your research project can be initiated.

11/1/2010

LORI L. DAVIS, M.D., Associate Chief of Staff, Research and Development (ACOS, R&D) Date
(or) Chief of Staff, if ACOS, R&D, has a conflict of interest.

Should you need to submit any further correspondence regarding this proposal, please include the assigned IRB ID number. Please use reproductions of the IRB approved informed consent form (if applicable) to obtain consent from your participants.

Approval by each of the following is required prior to study initiation (unless Exempt):
Subcommittee on Human Studies (IRB) [Approval Granted 08/05/2010]
Research & Development (R&D) Committee

10/29/2010