



Placebo-controlled comparison of prazosin and cognitive-behavioral treatments for sleep disturbances in US Military Veterans

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ABSTRACT

Objective: Pharmacological and cognitive-behavioral treatments targeting insomnia and nightmares have been shown to be effective in the treatment of military veterans with sleep complaints comorbid with symptoms of stress-related disorders, including Post-Traumatic Stress Disorder (PTSD), but the two approaches have not been directly compared. This randomized controlled trial compared the effects of prazosin vs. a behavioral sleep intervention (BSI), targeting nightmares and insomnia against a placebo pill control condition on sleep and daytime symptoms.

Methods: Fifty United States military veterans (mean age 40.9 years, SD = 13.2 years) with chronic sleep disturbances were randomized to prazosin ($n = 18$), BSI ($n = 17$), or placebo ($n = 15$). Each intervention lasted 8 weeks. Participants completed self-report measures of insomnia severity, sleep quality, and sleep disturbances. All kept a sleep diary throughout the intervention period. Polysomnographic studies were conducted pre- and post-intervention.

Results: Both active treatment groups showed greater reductions in insomnia severity and daytime PTSD symptom severity. Sleep improvements were found in 61.9% of those who completed the active treatments and 25% of those randomized to placebo.

Conclusion: BSI and prazosin were both associated with significant sleep improvements and reductions in daytime PTSD symptoms in this sample of military veterans. Sleep-focused treatments may enhance the benefits of first-line PTSD treatments.

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Introduction

Sleep disturbances are highly prevalent in combat-exposed military veterans, including recent cohorts of military personnel serving in Iraq and Afghanistan [1,2]. These observations are consistent with previous findings among other military cohorts [3–6]. Three studies have found that sleep disturbances are strongly correlated with PTSD symptom severity and other poor psychological outcomes in military personnel deployed to combat theaters [7–9]. In light of the growing recognition that sleep disturbances are a risk factor for poor psychological and physical health outcomes [e.g., 10,11], there is a pressing need to identify effective treatments targeting veterans' chronic stress-related sleep complaints.

Prazosin, an alpha-1 antagonist, and cognitive-behavioral techniques have been shown to be effective for the treatment of nightmares, non-nightmare distressed awakenings, and insomnia among adults with PTSD, including military veterans [12–17]. Improvements in sleep seen with prazosin are accompanied by significant improvements in daytime symptoms of PTSD [12–16]. Prazosin may attenuate central noradrenergic tone during sleep and especially during Rapid Eye Movement (REM) sleep [13,18] to reduce nightmares and complaints of insomnia comorbid with PTSD. Non-pharmacological sleep-focused interventions are also effective in reducing nightmares and insomnia. For nightmares, Imagery Rehearsal Therapy (IRT) is a technique in which trauma-related or non-trauma related nightmares are rescripted into non-distressing dream scenarios [19–24], which are then mentally rehearsed daily. Nightmares are significantly reduced within 6 weeks and improvements are maintained over time [20,25]. For the treatment of insomnia, techniques known as stimulus control [26] and sleep restriction [27] have been shown to be highly effective in young, middle-age, and older adults with primary insomnia or insomnia comorbid with other psychiatric or medical conditions, including

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military veterans [28–32]. The behavioral sleep intervention in the present study (BSI) integrated each of these approaches.

The effectiveness of prazosin and BSI for nightmares and insomnia has not been directly compared in veterans who have chronic sleep complaints comorbid with PTSD, subthreshold PTSD symptoms, or other psychiatric and medical comorbidities commonly seen in this population. Therefore, the aim of this 8-week randomized clinical trial was to compare the effects of prazosin, BSI, and a placebo conditioning on sleep, nightmares, and daytime psychiatric symptoms in military veterans with a primary sleep complaint comorbid with stress-related psychiatric symptoms. We hypothesized that both prazosin and BSI would show greater improvements in all domains relative to a placebo pill condition. Also, a 4-month follow-up was conducted under naturalistic conditions to explore the sustainability of acute treatment effects.

Methods

This study was approved by the University of Pittsburgh Institutional Review Board (IRB), the VA Pittsburgh Healthcare System IRB, and the Department of Defense Human Research Protection Office.

Participants

Recruitment was conducted between October 2006 and March 2010, using television, radio, and newspapers advertisements, recruitment flyers posted in public areas, and referrals and mass mailing conducted by the VAPHS. One hundred forty-four US military veterans who were 18 years old and older provided written, informed consent (Fig. 1). The primary inclusion criteria were having served or serving in the US military and current sleep complaints. DD Form 214 documentation of prior military service, a form issued by the Department of Defense upon a military service member's separation from active-duty military, was obtained from all participants to verify military service.

Participants completed an extensive physical and psychiatric evaluation that included a detailed physical examination, a series of self-report questionnaires, and clinician-administered interviews to assess PTSD [33], psychiatric history [34], and sleep disorders using a locally developed structured interview previously used in clinical studies (e.g., [28,35,36]).

A screening polysomnogram (PSG) was used to exclude those with an apnea-hypopnea index greater than 15 events per hour. Consistent with prior studies [12,37], eligible veterans endorsed clinically

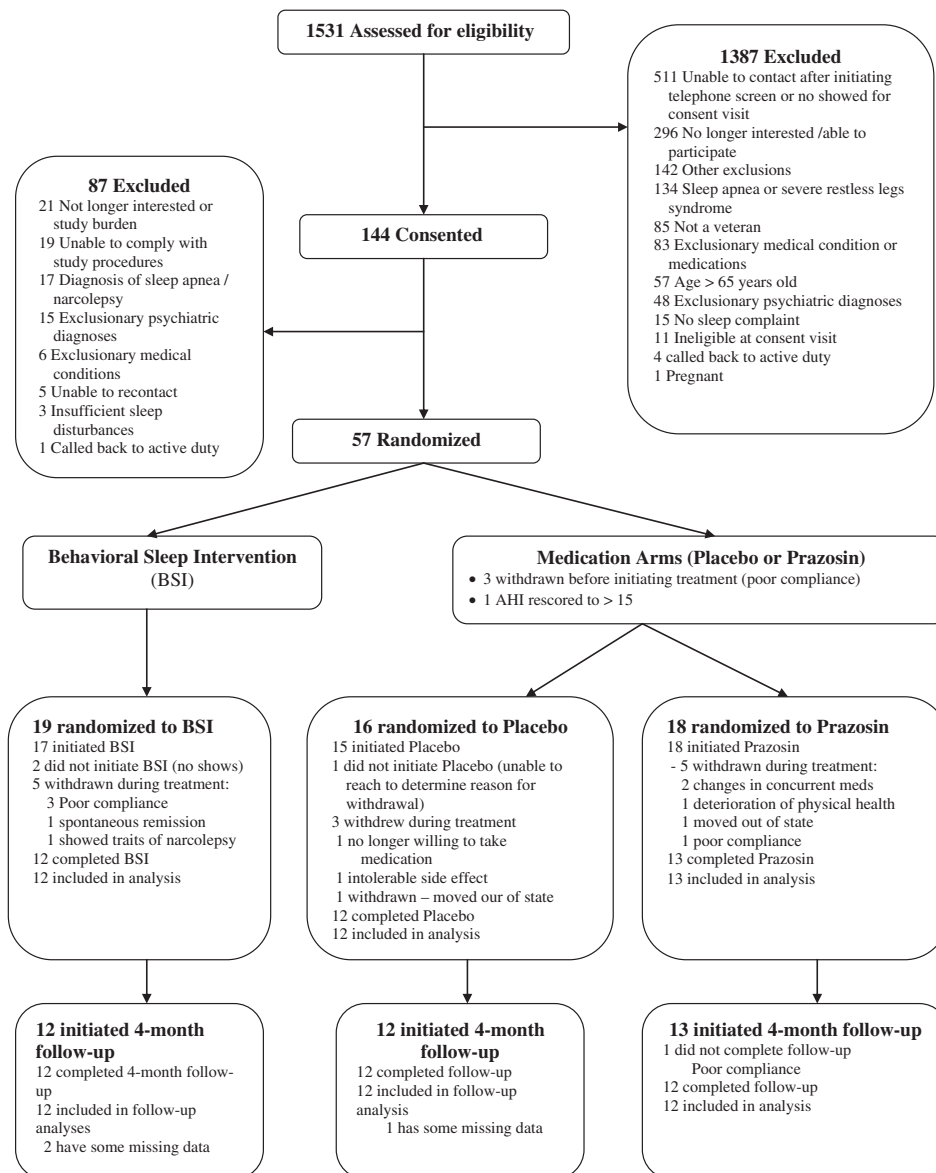


Fig. 1. CONSORT Chart.

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