Official Title: Telephone-Facilitated Insomnia Treatment in Primary Care for OEF/OIF/OND Veterans

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Study Protocol

Background: Insomnia is a growing public health concern and is associated with a number of negative health outcomes and psychosocial impairment.[1-3] Sleep disturbances are highly prevalent in military personnel returning from recent deployments; impact psychosocial functioning, cognitive functioning, productivity, and quality of life; and are one of the most common reasons that veterans seek treatment.[4-5] While there have been prior trials examining the efficacy of insomnia treatment among veterans, much of this research has focused on sleep medications.[6-8] However, participants report a preference for behavioral interventions over sleep medications.[9-10] Although empirically-supported behavioral interventions for insomnia are typically offered to veterans through mental health clinics (e.g., Cognitive Behavioral Therapy for Insomnia [CBT-I]; generally lasting 6-8 sessions)[11], most veterans who need these treatments report a large number of barriers to seeking treatment, including the stigma associated with mental health care and number of sessions required for treatment completion.[12-14] Thus, many veterans who could benefit from these treatments do not get needed care.

Brief Behavioral Treatment for Insomnia (BBTI) is a four-session behavioral insomnia treatment that consists of two in-person and two telephone sessions. Research indicates BBTI provides significant improvement in sleep, mood, and health measures for elderly primary care patients in community clinics.[15] A preliminary study of a small sample of young veterans (n=40) suggests BBTI improves insomnia outcomes, but further research in a larger trial was recommended.[16]

Objectives: The first aim of the current project was to evaluate the efficacy of BBTI in a large veteran sample that was diverse in age. The primary outcome measure for the study assessed work and social functioning (Work and Social Adjustment Scale; WSAS)[17] and the secondary outcome measure examined sleep-related outcomes (Insomnia Severity Index; ISI).[18] The second aim was to determine whether BBTI gains in psychosocial functioning and insomnia severity were durable.

Design: The study was a parallel design, randomized, controlled trial (RCT) to test the efficacy of BBTI, compared to a progressives muscle relaxation training (PMRT) control condition. PMRT was matched for therapist time with two in-person and two phone sessions and has been used as a comparison treatment in prior insomnia research.[19-22] To evaluate the durability of BBTI gains, veterans randomized to BBTI also participated in a six-month follow-up visit to complete primary and secondary outcome measures.

Methods: Post-deployment veterans between 18-75 years of age were recruited through advertisements, referrals from local VA research studies or VA clinicians, and through direct mailings to veterans who had either received primary care at VA hospitals in the San Francisco Bay area or lived within a 40-mile radius of San Francisco. Interested veterans participated in an initial brief phone screen to ensure they met preliminary criteria. Veterans were invited to the San Francisco VA Medical Center, told about the study in detail, and completed consent procedures. Prior to randomization, participants completed demographic and medical history questionnaires, and a clinician-administered, mental health diagnostic interview (Structured Clinical Interview for DSM 5 [SCID-5][23] and Clinician Administered PTSD Scale [CAPS-5])[24]). These diagnostic interviews were repeated at post-treatment.

Ninety-three veterans with Insomnia Disorder were randomized 1:1 to either the BBTI or PMRT control arm within strata defined by age (18-50 vs. 51-75) and therapist assignment (one of

three therapists) within randomly generated block sizes (4, 6, and 8). Both BBTI and PMRT consisted of four treatment sessions (one 60-minute and one 30 minute in-person session, and two 20-minute phone-based sessions). Primary and secondary self-report outcome measures of psychosocial functioning (WSAS) and insomnia severity (ISI) were completed at baseline, mid-treatment and post-treatment (and at six-month follow-up for the BBTI group only).

Statistical Analysis & Results: The primary and secondary outcome variables were analyzed with separate linear mixed effects models, with participants as a random effect and time point, age group, and therapist as fixed factors. For each analysis, baseline values of the outcome variables were included as a covariate, with the first outcome time point being mid-treatment. Time point was treated as a categorical variable to avoid assumptions of linearity or any other functional form for outcome variables over time. Residuals from models were approximately normally distributed, so no transformations were considered. To address the first aim, treatment effects were defined as the difference between treatment arms at the post-treatment time point, after adjusting for baseline and stratification variables (age group and therapist). For the second aim, treatment durability effects were defined as the difference between post-treatment and six-month follow-up outcomes for the BBTI group, after adjusting for baseline and stratification variables (age group and therapist).

Two participants were not included in analyses because they were pilot participants that did not meet all eligibility criteria. Thus, ninety-one participants were included in the intent-to-treat analyses. Two of these 91 participants were withdrawn by staff during treatment or 6-month follow-up due to no longer meeting eligibility criteria, and therefore, did not have complete data. Further, five of the 46 individuals that completed BBTI treatment were lost to follow-up. The five BBTI completers at six-month follow-up (11%) could possibly bias comparisons between end of treatment and follow-up, although this loss to follow-up rate is also very low.

Participants ranged in age from 24 to 74 years (M=49 years); 80% were male (n=73), 19% were female (n=17) and 1% were transgender (n=1); 47% were Caucasian (n=43), 19% were Asian (n=17), 13% were Black/African American (n=13), 10% were Latino/Hispanic (n=9), 8% identified as multiracial or other (n=7) and 3% were Native American/Pacific Islander (n=3). Of the 91 participants, 43% served in the Army, 22% served in the Air Force, 21% served in the Navy, 16% served in the Marine Corps, and 6% served in one of the other service branches. Participants randomized to BBTI (n=46) reported significant improvement on measures of psychosocial functioning ($p=.02$) and insomnia severity ($p<.001$). Furthermore, participants in the BBTI arm reported no significant change in symptoms from post-treatment to six-month follow-up for psychosocial functioning ($p=.57$) and insomnia severity ($p=.17$), indicating that BBTI treatment gains were maintained during the follow-up period.

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