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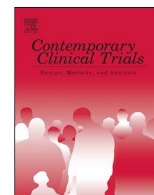

Evaluation of an integrated treatment for active duty service members with comorbid posttraumatic stress disorder and major depressive disorder: Study protocol for a randomized controlled trial

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ABSTRACT

Posttraumatic stress disorder (PTSD) commonly co-occurs with major depressive disorder (MDD) in both civilian and military/veteran populations. Existing, evidence-based PTSD treatments, such as cognitive processing therapy (CPT), often reduce symptoms of both PTSD and depression; however, findings related to the influence of comorbid MDD on PTSD treatment outcomes are mixed, and few studies use samples of individuals with both conditions. Behavioral activation (BA), an approach that relies on behavioral principles, is an effective treatment for depression. We have integrated BA into CPT (BA + CPT), a more cognitive approach, to address depressive symptoms among active duty service members with both PTSD and comorbid MDD. We describe an ongoing randomized controlled trial investigating the efficacy of our innovative, integrated BA + CPT intervention, compared with standard CPT, for active duty service members with PTSD and comorbid MDD. We detail the development of this integrated treatment, as well as the design and implementation of the randomized controlled trial, to evaluate its effect on symptoms.

1. Introduction

Posttraumatic stress disorder (PTSD) results from exposure to a traumatic event and is often comorbid with major depressive disorder (MDD; [20,40]). Individuals with both PTSD and MDD, compared with those with either condition alone, present with more distorted trauma-related and depressive cognitions, increased suicide risk, and greater impairment and symptom severity (e.g., [15,29,31,47]). Furthermore, this comorbidity is associated with poorer occupational and social functioning [4] and greater health care utilization (e.g., [6,44]).

Rates of PTSD and MDD comorbidity are particularly high in military and veteran samples [40]; among military personnel previously deployed in support of Operations Enduring and Iraqi Freedom, two-thirds of those who had PTSD also met criteria for probable MDD [25,41]. High prevalence rates of comorbid MDD and PTSD in military populations, along with the impairments associated with this comorbidity, highlight the need for care that effectively addresses both disorders. Unfortunately, psychological interventions specifically targeting this comorbidity are lacking. Patients with both PTSD and MDD often receive trauma-focused, evidence-based treatments (EBTs) focusing on PTSD, such as cognitive processing therapy (CPT; [33]) or prolonged exposure (PE; [13]), both of which reduce symptoms of depression as well as PTSD [39]. However, because the vast majority of studies do not use samples meeting diagnostic criteria for both PTSD and MDD, the effectiveness of trauma-focused EBTs in mitigating depression remains unclear for these individuals.

A significant evidence base supports the efficacy of behavioral activation (BA; [19]) for treating mild, moderate, and severe depression

Abbreviations: BA, behavioral activation; BA + CPT, integrated BA and CPT interventions; BATD-R, Brief Behavioral Action Treatment for Depression: Revised Treatment Manual; BTBIS, Brief Traumatic Brain Injury Screen; CAPS-5, Clinician Administered PTSD Scale for DSM-5; CPT, cognitive processing therapy; CPT-C, cognitive processing therapy with cognitive therapy only; CSQ-8, Client Satisfaction Questionnaire-8; DoD, Department of Defense; DSM-5, Diagnostic and Statistical Manual of Mental Disorders, 5th Edition; EBT, evidence-based treatments; MADRS, Montgomery-Åsberg Depression Rating Scale; MDD, major depressive disorder; MLM, multilevel modeling; NHCP, Naval Hospital Camp Pendleton; NMCSD, Naval Medical Center San Diego; PCL-5, PTSD Checklist for DSM-5; PE, prolonged exposure; PHQ-9, Patient Health Questionnaire 9-item depression scale; PTSD, posttraumatic stress disorder; SCID-5-CT, Structured Clinical Interview for DSM-5 Disorders, Clinical Trials version; TBI, traumatic brain injury; VA, Department of Veterans Affairs

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(e.g., [8,9]), and BA is a flexible protocol that can be readily combined with trauma-focused EBTs for PTSD. Several studies have integrated BA into trauma-focused EBT protocols. These uncontrolled studies have yielded generally positive results for PTSD symptoms but mixed findings for depression (see [1,17]). However, there are significant limitations in the current literature that the present study aims to address. First, studies that combined BA with trauma-focused treatments have not exclusively sampled individuals with comorbid PTSD and MDD, despite the fact that these are the patients most likely to benefit from combined treatments. Second, no study to date has provided a strong test by comparing an integrated treatment for PTSD and MDD with an EBT for PTSD, which is known to reduce both PTSD and depressive symptoms. The goal of this study is to evaluate whether service members with comorbid PTSD and MDD experience greater improvement in the symptoms of both conditions following a treatment protocol that adds BA to CPT (BA + CPT), compared with CPT alone.

2. Design and methods

This prospective, longitudinal study will screen up to 100 active duty service members seeking mental health treatment to identify at least 80 individuals who meet study criteria and are eligible to participate. Recruitment began in October 2015 and is expected to take three years. Participants are randomly assigned to receive BA + CPT or standard CPT only. Eligible individuals complete clinician-administered and self-report PTSD and depression measures prior to, following, and three months after completion of treatment; change in depressive symptom severity will be the primary outcome. Participants also complete self-report measures at each treatment session in order to monitor changes in symptoms throughout treatment.

2.1. Participants

The final sample will consist of 80–100 active duty service members who meet current diagnostic criteria for both PTSD and MDD and are seeking treatment at Naval Medical Center San Diego (NMCSD), its branch clinics, or Naval Hospital Camp Pendleton (NHCP). Participants are screened at the initial assessment and voluntarily sign a consent form before the start of any study-related procedures. To be eligible for study participation, individuals must: (a) be active duty service members seeking mental health treatment at one of the study sites; (b) have a current diagnosis of PTSD based on Diagnostic and Statistical Manual of Mental Disorders (5th Edition [DSM-5]; [2]) criteria as a consequence of any index traumatic event (e.g., combat, military sexual trauma, child abuse, motor vehicle accident), assessed with the Clinician Administered PTSD Scale for DSM-5 (CAPS-5; [49]); and (c) have a current diagnosis of MDD based on DSM-5 criteria as assessed by the Structured Clinical Interview for DSM-5 Disorders, Clinical Trials version (SCID-5-CT; [12]).

As the study intervention is being implemented within standard clinical care, the current study is designed to have broad eligibility criteria. Exclusion criteria reflect those customary in the CPT literature as well as in standard clinical practice at the participating Navy facilities including: (a) unmanaged psychosis or manic episode in the past year (assessed with SCID-5-CT); (b) substance use disorder warranting primary substance use treatment or detoxification (assessed with SCID-5-CT); and (c) participation in concurrent psychotherapies directly targeting PTSD (e.g., eye movement desensitization and reprocessing; cognitive-behavioral conjoint therapy; present centered therapy; PE) or depression (e.g., acceptance and commitment therapy; cognitive-behavioral therapy; interpersonal psychotherapy). Active duty service members who received CPT, BA, or any other psychotherapy for PTSD or MDD prior to enrolling in the study are still eligible for participation if they meet study criteria at the initial assessment. Service members engaged in treatment for issues other than PTSD or depression, such as 12-step programs for non-primary substance problems or couples therapy for relationship issues, remain eligible. Service members with an active plan and intention to commit suicide are excluded and treated as clinically appropriate, including use of emergency services when indicated. Service members with ideation but without intention are eligible to participate. Psychotropic medication use is not an exclusion factor but is monitored to determine whether random assignment to treatment results in unequal medication use between conditions at baseline. We will also examine medication use at post-treatment and follow-up to determine if there is a difference in medication use between groups after receiving the study intervention.

2.2. Treatment

We used blocked randomization to randomize eligible service members to receive either BA + CPT or standard CPT. The randomization scheme for these two treatments occurred in series of blocks of 10 and was designed to provide balance between the groups throughout the duration of the study. Both treatments are manualized (i.e., the standard protocol, including the trauma account delivered as outlined in the manual) and delivered by trained and credentialed mental health clinicians at the study sites. As is typically the case, CPT is delivered in 12 weekly, 60-min, individual therapy sessions. Every effort is made to see patients once per week for a total of 12 weeks. However, due to illnesses, vacations, service-related travel, or other situations that may arise, therapy may be extended across a period longer than 12 weeks; clinicians make every effort to complete the treatment within 20 weeks.

CPT has been found efficacious and effective for treating PTSD and related symptoms following traumatic events [34–36]. This treatment is based on social cognitive theories of PTSD, which suggest that how a person construes the traumatic event will affect his or her subsequent emotional responses and behavior. The techniques used in CPT are designed to assist individuals in examining their beliefs about the traumatic event and modifying them as needed in order to arrive at more realistic beliefs and resulting emotions. CPT was selected as the central active intervention based on prior research demonstrating its efficacy and effectiveness for treating PTSD in military veteran populations [7,27,48]. CPT is also one of the treatments recommended by the Department of Defense (DoD), the Department of Veterans Affairs (VA), and the International Society for Traumatic Stress Studies. Although PE is another PTSD treatment recommended by all three organizations, CPT was selected for this study because its cognitive focus may better complement the behavioral focus of BA. In contrast, the PE protocol, which places significant emphasis on behavioral principles, may have greater overlap with the BA protocol, thereby reducing the benefits of a combined therapy protocol. Finally, CPT may be particularly appropriate for military personnel as it has been shown to produce significant decreases in guilt-related distress [27], which may be particularly relevant for combat-related traumas. In consideration of our study sample, we chose the Veteran/Military Version of CPT, which has been modified (e.g., by providing specific examples relevant to active duty service members. Resick, Monson, & Chard, 2008) to better address the unique needs of military populations.

2.2.1. BA + CPT

Integrated treatments are recommended for individuals with PTSD and comorbid disorders [14]. For the present study, BA was selected to enhance CPT based on its strong empirical support as a treatment for depression [16,18,24,26], particularly among individuals with greater depression severity [10]. Logically, BA, which has a behavioral emphasis, would seem to complement CPT, which has a cognitive emphasis. Incorporating behavioral tasks into CPT may further improve PTSD symptoms by encouraging individuals to challenge their maladaptive cognitions through behaviorally testing their beliefs. There are several ways in which integrating BA into CPT may lead to reductions in depressive symptoms. First, BA promotes engagement in activity in order to increase individuals' exposure to natural reinforcers, which

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