



Psychosocial rehabilitation after war trauma with adaptive disclosure: Design and rationale of a comparative efficacy trial

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ABSTRACT

Background: Posttraumatic stress disorder (PTSD) from warzone exposure is associated with chronic and disabling social and occupational problems. However, functional impairment is rarely assessed or targeted directly in PTSD treatments, which instead focus on symptom reduction. Trauma-related contributors to diminished functioning, including guilt, shame, and anger resulting from morally compromising or loss-based war experiences, are also underemphasized. The goal of this clinical trial is to fill a substantial gap in the treatment of military-related PTSD by testing a modified Adaptive Disclosure (AD) therapy for war-related PTSD stemming from moral injury and traumatic loss focused on improving psychosocial functioning AD.

Method and design: This paper describes the rationale and design of a multi-site randomized controlled trial comparing AD to Present-Centered Therapy (PCT). We will recruit 186 veterans with PTSD, who will be assessed at baseline, post-treatment, and 3- and 6-months post-treatment. Primary outcomes are functional changes (i.e., functioning/disability and quality of life). Secondary outcomes are mental health variables (i.e., PTSD, depression, guilt, shame). We hypothesize that veterans treated with AD will experience greater improvements in all outcomes compared to those treated with PCT.

Discussion: This trial will advance knowledge in rehabilitation research by testing the first therapy specifically designed to address psychosocial functioning among veterans with war-related PTSD. The results may improve the quality of mental health care for veterans by offering an ecologically sound treatment for experiences that are uniquely impactful for war veterans.

1. Introduction

Posttraumatic stress disorder (PTSD) is a prevalent and disabling condition among war veterans, posing a significant public health burden. Approximately 20% of the 2.5 million service members who served in Iraq and Afghanistan have or will develop clinically significant PTSD [11,23,26]. PTSD causes private suffering and has a uniquely damaging ripple effect on relationships, productivity, and healthcare costs. Veterans with PTSD suffer from a variety of co-morbid mental and physical health conditions [3,18] and are heavy service-utilizers (e.g., [4]). They also have extensive functional impairments, including occupational problems [12,30], family and relationship difficulties (e.g., [29]), aggressive and risky behaviors (e.g., [24]), and reduced quality of life (e.g., [3]).

Although considerable gains have been made in the VA's dissemination of PTSD treatments that are highly effective with civilian

trauma survivors, these therapies have been shown to work less well for veterans [34,35,42]. This may be partly due to a lack of attention to military culture and the unique harms of war trauma in treatments developed for civilians [22]. Veterans who have been deployed to warzones have often experienced numerous, complex traumatic events. These events may involve not just danger and threats to veterans' lives, but also challenges to or violations of their moral or ethical standards (i.e., moral injury [MI]), and traumatic losses (TL) of friends and comrades [36]. In addition, existing PTSD treatments have failed to demonstrate an impact on functioning and quality of life (e.g., [7]), problems that are no less related to the warzone trauma being targeted in treatment. Instead, symptom change is typically the sole metric of success.

The aim of the clinical trial described here is to fill a substantial gap in veterans' PTSD treatment by creating and testing a treatment for war-related PTSD that: (a) attends to the role of military culture and

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warzone exposure in the experience of trauma; (b) provides guidance for targeting MI and TL directly, along with life threat; and (c) emphasizes improving psychosocial functioning. This treatment builds on the existing Adaptive Disclosure (AD; [22]) treatment manual by incorporating skills training in mindfulness and compassion, as well as behavioral contracting to improve functioning in occupational, relationship, and family roles. In this paper, we describe the rationale and design of a multi-site randomized controlled trial in which AD will be compared to another active treatment (Present-Centered Therapy [PCT]). If found to be effective, the modifications to AD will fill a care-gap in the treatment of veterans with PTSD by reducing suffering and helping veterans reclaim or establish positive relationships, work roles, and self-care routines.

2. Method

2.1. Participants

This is a multi-site study comprising investigators from VA sites in Minneapolis, MN, San Diego, CA, San Francisco, CA, and Boston, MA. The Boston site serves as the coordinating center for the study and conducts independent assessments of participants' outcomes. The Minneapolis, San Diego, and San Francisco VAs serve as recruitment and treatment sites. Male and female veterans obtaining care at the three treatment sites are eligible for study participation. We will recruit a sample of 186 veterans with PTSD as a result of the Iraq or Afghanistan Wars. Based on the patient demographics at each site, we expect approximately 10% of participants to be women and 16% to be members of diverse racial and ethnic groups.

Inclusionary criteria include (1) age 18 or older, (2) deployed to the Afghanistan and/or Iraq Wars, (3) meet the DSM-5 diagnostic criteria for PTSD (diagnosed by Clinician Administered PTSD Scale for DSM-5 (CAPS-5; Weathers et al. [43,44])), and (4) willing to complete 12 consecutive weekly sessions, lasting up to 90 min in duration, as well as 4 assessment sessions. Participants will be excluded if they have (1) bipolar or psychotic disorders, (2) current moderate to severe substance use disorder (other than caffeine or tobacco use disorders), (3) evidence of traumatic brain injury severe enough to influence the ability to understand and respond to study procedures, (4) suicidal or homicidal ideation severe enough to warrant immediate attention, or (5) concurrent enrollment in any cognitive-behavioral treatment or any other treatment that involves systematic disclosure of troubling deployment-related memories. Participants may participate in marital counseling or any supportive therapy, and may continue current pharmacological treatment if stable on medication for at least 6 weeks.

We initially planned to include only veterans with military-related PTSD whose primary trauma was of the moral injury or traumatic loss type. Prior to the start of the trial we decided to open enrollment to any veteran with military-related PTSD, regardless of the type of traumatic event(s) they experienced. We reasoned that including veterans with life-threat traumas, as well as loss and moral injury-based traumas, would obviate any recruitment difficulties, as life-threat traumas are more common than traumatic loss- and moral injury-based traumas [36]. This change did not alter the original study aims for two reasons. First, in the context of warzone trauma, differences between trauma types are often not clear-cut. Many life-threatening events also have elements of loss or moral injury (e.g., a life-threatening rocket attack in which a close comrade was killed; killing a child in self-defense) and vice versa, and can be reliably coded as such (Litz et al. [21], under review; [36]). Consequently, the approach and strategies employed in AD could be meaningfully applied to the sequelae of life-threat trauma. Second, even in the rare event that the event is focally life-threat based, the functional impact of PTSD symptoms from these experiences are no less targetable. For example, PTSD in veterans has been linked with unemployment and income disparities [30], family and relationship difficulties [15,37], and reduced physical health functioning [3]. AD

strategies, such as behavioral re-engagement and compassion training, can be helpful for redressing these difficulties.

2.2. Power calculation

Power calculations were based on a two-sided, two-sample *t*-test to compare the differences in mean change. Effect sizes were selected based on a trial comparing Acceptance and Commitment Therapy with PCT in veterans with mental health diagnoses, using the SDS [20], which showed a large effect size for reduction in disability ($d \approx 0.60$), a change of 1.2 points. Lang et al.'s [20] follow-up interval was 3 months. These correspond to 3-month changes of 1.2 points assuming a standard deviation for the change of 2.1 points as per Lang and colleagues. These power calculations inflate the variance to account for clustering of scores (sites by therapists), with an ICC = 0.02. To partially offset possible losses to follow-up, we will follow the Benjamini-Hochberg testing procedure, which is less conservative than the Bonferroni rule [2]. Each hypothesis is powered to compare outcome at 3 months. Analyses up to 6-months post-treatment are exploratory. Testing five hypotheses, each with Type I error of $1\% = 5\%/5$, then with 93 participants per arm, a two-sample *t*-test, comparing the difference between the 3-month changes, has 90% power to detect an absolute difference of 0.50 or larger assuming an effect size of 0.56. To have 80% power with 93 participants per arm requires an effect size of 0.50.

2.3. Study design

Veterans will be recruited primarily through referrals from mental health clinics. As such, veterans enrolled in this study will be drawn from the broader treatment-seeking population in each VA clinic. Referred veterans will be pre-screened by phone or in person for basic eligibility requirements and, if eligible, scheduled for an appointment in which consenting procedures and a more in-depth eligibility/baseline assessment will take place. The baseline assessment will be completed jointly by local study staff, who conducts the consenting and basic eligibility procedures, and the Boston-based independent evaluator (IE), who conducts the full clinical evaluation by phone.

During the baseline visit, local study staff obtains written informed consent for study participation and recording of assessments and treatment sessions. Participants then complete the PTSD Checklist for DSM-5 (PCL-5; Weathers et al. [43,44]), including writing a one-sentence description of their worst, most distressing traumatic event. If veterans meet the DSM-5 diagnostic criteria for PTSD on the PCL-5, based on the requisite symptoms endorsed at a moderate severity or greater, and do not endorse exclusion criteria, they will continue to the diagnostic assessment by telephone with the Boston IE. Once the IE confirms the presence of PTSD with the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5; Weathers et al. [43,44]), and the absence of any exclusionary criteria (e.g., severe suicidality, active moderate to severe substance use disorder), the participant will be randomized to one of the two therapy arms (i.e., AD or PCT) and scheduled for treatment.

In order to randomly assign veterans to PCT or AD, the Boston site will generate a stratified randomized permuted block scheme to randomly assign veterans to blocks by gender and minority status [39]. Strata size for gender and minority status will be based on the distribution of these variables at each site. Stratifying by gender and minority status will ensure appropriate accrual rates for participants with lower base-rate characteristics, as strata are based on the prevalence of these demographic variables and randomization occurs separately for each stratum.

Follow-up assessments, including full clinical interviews completed by telephone with the Boston IE, will be completed at post-treatment, and 3- and 6-months post-treatment. All evaluators will be blind to treatment condition, and evaluators will remind participants to help maintain their blind by not disclosing details about treatment

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