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Treatment of trauma related anger in operation enduring freedom, operation Iraqi freedom, and operation New Dawn veterans: Rationale and study protocol☆

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ABSTRACT

Background: Problems with anger and aggression are highly prevalent in Veterans of multiple war eras, including the most recent conflicts in Afghanistan (Operation Enduring Freedom; OEF) and Iraq (Operation Iraqi Freedom; OIF). The consequences of these problems, such as increased rates of divorce, domestic violence, occupational instability, arrests and incarceration, are often devastating. Despite the seriousness of these problems, relatively little is known about effective treatments for anger in Veterans.

Method and design: This paper describes the rationale and study protocol of a randomized controlled trial comparing an adapted cognitive behavioral intervention (CBI) with an active control condition (supportive intervention, SI) for the treatment of anger problems in OEF/OIF Veterans. The sample includes 92 OEF/OIF Veterans, randomized to CBI or SI. Both treatments include 12 weekly, 75-min individual sessions. Participants are assessed at baseline, after sessions 4 and 8, at post-treatment, and at 3 and 6 months post-treatment. Primary outcomes are reduction in anger and aggression; secondary outcomes are improved functioning and quality of life. We hypothesize that CBI will be associated with significantly more improvement than SI on primary and secondary measures.

Discussion: Findings from this study will help to address the gap in evidence for effective treatments for anger in Veterans. The use of an active control condition will provide a stringent test of the effects of CBI beyond that of common factors of psychotherapy such as therapeutic relationship, mobilization of hope, and support. Findings have the potential to improve treatment outcomes for Veterans struggling with post-deployment anger problems.

1. Introduction

Associations between combat and post-war problems with anger are well documented. Increased rates of anger have been shown among Veterans of multiple wars, including World War II [12,15], the Vietnam War [18,20], and more recently, the Afghanistan (Operation Enduring Freedom – OEF) and Iraq (Operation Iraqi Freedom – OIF) conflicts [13,14,29]. Reported rates of problematic anger or aggression in individuals having served in OEF/OIF have been as high as 57% in combat Veterans receiving VA medical care [29], and 67% in active duty soldiers 4 months after return from deployment [39]. The consequences of these problems can be devastating, including increased risk for divorce, domestic violence, job loss and instability, and other serious impairments in family, social, and occupational functioning [18].

Cognitive behavioral treatments for anger have been shown to be effective in civilian samples [2,7,8], but given the unique aspects of military training and combat that contribute to problematic anger, these findings cannot be assumed to generalize to Veterans. Military training involves responding to threat with aggression, aggression is powerfully re-enforced by survival, and repeated exposure to life threatening situations such as occurs in a warzone can result in a lower

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threshold for perception of threat and for anger reactions.

Despite the seriousness of anger problems among Veterans, little is known about effective treatments in this population. The few controlled studies to date have either had small sample sizes [3,32], or no control group [11,21,23]. We conducted a pilot study [32] of a cognitive behavioral treatment [24] that we adapted for OEF/OIF Veterans. This is the only study of anger treatment to our knowledge that has focused exclusively on OEF/OIF Veterans. Promising findings from this pilot led to the initiation of the current study.

The primary aims of this study (ClinicalTrials.gov ID: NCT02157779) are to test the efficacy of the adapted treatment, Cognitive Behavioral Intervention (CBI), on primary outcome measures of anger and aggression, and on secondary measures of functioning, quality of life, and PTSD symptoms at post-treatment and at 3 and 6 month post-treatment assessments. We hypothesize that CBI will be significantly superior to an active control condition on primary and secondary outcomes. Secondary aims are to examine mechanisms of action of CBI (hypothesizing that change in arousal, cognitive and behavioral domains of anger will mediate treatment outcome for CBI), and to explore the effects of CBI for those with and without PTSD. For the latter, we expect that the direction of effects will support superior outcome for CBI relative to SI for both those with and without PTSD. We also expect that participants with PTSD will show less improvement in both CBI and SI than participants without PTSD.

2. Methods

The study is a single blind randomized clinical trial (RCT) designed to test the efficacy of CBI compared to a supportive therapy comparison condition (Supportive Intervention – SI).

2.1. Participants

For study inclusion, participants were required to: (1) be current or former members of the military (active duty, National Guard, or Reserve), who served in OEF, OIF, or Operation New Dawn – OND); (2) endorse having experienced at least one DSM-5 Criterion A traumatic event while deployed; (3) report moderate or severe problems with anger and at least 2 additional symptoms from the PTSD hyperarousal symptom cluster as measured by the Clinician Administered PTSD Scale for DSM-5 (CAPS-5); (4) provide consent to be randomized and participate in the study; (5) agree to refrain from other active PTSD or CBT treatment, or any treatment focused on problems with anger during the intervention phase; and (6) if taking psychotropic medications, to have been on a stable dose for at least 4 weeks. Participants were excluded if they had any of the following: (1) DSM-5 substance or alcohol use disorder, severe (at least 6 criteria determined by the Structured Clinical Interview for DSM-5 Disorders (SCID-5); (2) psychotic symptoms, or mania or manic episode within the previous 3 months (determined by the SCID-5); (3) current suicidal or homicidal ideation requiring hospitalization (determined by follow-up clinical risk assessment by a licensed and credentialed provider upon positive responses to interview or self-report items regarding suicidal ideation); or severe cognitive impairment precluding the ability to comprehend interview questions (if suspected, to be confirmed by mental status exam).

2.2. Procedures

The study protocol was reviewed and approved by the Institutional Review Board of the local Veterans Affairs Medical Center. Participants were self-referred or referred by mental health clinicians throughout the mental health service of the VAMC. An initial screening procedure provided potential participants with information about the study, and asked questions regarding deployment (i.e., whether OEF, OIF, OND), and whether there had been any changes in psychotropic medications during the previous four weeks. Participants meeting initial screening were scheduled for an interview to further describe the study, obtain written informed consent for study participation, and to determine eligibility according to inclusion and exclusion criteria. Participants determined to be eligible then completed the rest of the baseline assessment, including additional interview and self-report measures. Participants were asked if they were willing to have a collateral reporter (significant other or other person with whom they had a minimum of 5 h of contact per week) to provide an additional perspective on change following treatment. Participants who agreed were asked to sign an additional consent to provide permission to contact the identified individual. Collaterals were fully informed of the study requirements and asked to sign informed consent.

Participants were randomly assigned to CBI or SI using urn randomization, a stratified randomization technique that systematically biases the randomization in favor of balance among the treatment condition on stratification variables [36,38]. Gender, PTSD diagnosis, and time since return from deployment (≤ 2 years vs. > 2 years) were used as balancing factors.

2.3. Outcome and mediator measures

Table 1 summarizes study measures and time of administration. Primary outcome measures for the study are the Anger Expression Index (AX-I) from the State-Trait Anger Inventory-2 (STAXI-2 [35]; and the Aggression Scale score from the Overt Aggression Scale-Modified (OAS-M; [4]. In addition to the baseline assessment, these measures are administered following the 4th and 8th treatment session, at the end of treatment, and at 3- and 6- month post-treatment follow-up assessments. Supplemental anger measures include the Anger Consequences

Table 1
Schedule of assessments.

Domain	Screening	Pre-Tx	Sessions 4 and 8	Post-Tx	Follow-up (3 and 6 months)
Inclusion/exclusion Criteria					
SCID	X				
CAPS	X			X	X
Sample Characterization					
SNAP-2		X			
CTQ		X			
Combat Exposure		X			
BSI		X	X	X	X
BAM (Use subscale)		X	X	X	X
Anger					
OAS-M[a]		X	X	X	X
STAXI-2[a]		X	X	X	X
ACQ[a]		X		X	X
DAR (weekly)					
Function/QOL					
LIFE psychosoc		X		X	X
OQ		X		X	X
WHOQOL-BREF		X		X	X
Mediators					
NAS arousal		X	X	X	
NAS cognitive		X	X	X	
NAS behavioral		X	X	X	
Other Measures					
Tx Satisfaction				X	
LIFE Tx section		X		X	X

Clinician administered interviews are in italics.
ACQ = Anger Consequences Scale; BAM = Brief Addiction Monitor; BSI = Brief Symptom Inventory; CTQ = Childhood Trauma Questionnaire; DAR = Dimensions of Anger Scale; *LIFE = Longitudinal Interval Follow-Up* Evaluation; NAS = Novaco Anger Scale; *OAS-M = Overt Aggression Scale Modified;* OQ = Outcomes Questionnaire; SNAP-2 = Schedule for Nonadaptive and Adaptive Personality-2nd Edition; STAXI-2 = State Trait Anger Inventory-2; WHOQOL-BREF = The World Health Organization Quality of Life.
[a] Collateral assessments are administered at pre- and post-treatment.