



Integrated Cognitive Behavioral Therapy (ICBT) For PTSD and Substance Use in Iraq and Afghanistan Veterans: A Feasibility Study

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Abstract

Co-occurring posttraumatic stress disorder (PTSD) and substance use disorder (SUD) is prevalent in military Veterans and is associated with poorer outcomes than either disorder alone. The current pilot study examines the feasibility of delivering integrated cognitive behavioral therapy (ICBT) for co-occurring PTSD-SUD to Veterans who served in Iraq and Afghanistan. Our primary aims were testing the feasibility of engaging and retaining Veterans with a complex clinical presentation in a 12-week structured therapy. We focused on two feasibility outcomes: 1) acceptability; and 2) tolerability. We also examined clinically meaningful change in PTSD and depressive symptoms as a secondary aim. Over the course of the study, we recruited 12 eligible Veterans, 6 of whom completed ICBT. We encountered challenges related to engaging and retaining Veterans in treatment and discuss adaptations and refinements of ICBT or other integrated treatments for returning Veterans with co-occurring PTSD-SUD to increase feasibility with military Veterans.

Keywords

Posttraumatic stress disorder; Substance use; Military Veterans; Comorbidity; Treatment

Introduction

Co-occurring posttraumatic stress disorder (PTSD) and substance use disorders (SUD) are common and clinically challenging in both civilian [1,2] and military settings [3,4]. When compared with either disorder alone, comorbid PTSD-SUD is associated with greater symptom severity, poorer psychosocial functioning [5-7], poorer physical health [8,9], increased risk of suicidality [10], and negative treatment outcomes [6,11,12]. Despite substantial concern in Veterans Affairs (VA) Medical Centers about the growing number of Veterans returning from service in Afghanistan (Operation Enduring Freedom; OEF) and Iraq (Operation Iraqi Freedom; OIF, Operation

New Dawn; OND) with co-occurring PTSD-SUD, few studies have examined the process of engaging and retaining returning Veterans in integrated treatments.

The inherent challenges in engaging and retaining OEF/OIF/OND Veterans in mental health treatment have been recently documented. Research indicates that OEF/OIF Veterans with younger age and/or dual diagnoses are least likely to attend a sufficient course of evidenced based treatment within the first year of initial PTSD diagnosis [13]. Maguen and colleagues [14] found that OEF/OIF/OND Veterans with a psychiatric diagnosis did not engage in mental health care for more than 2 years after their last deployment and that 75% of OEF/OIF/OND Veterans in the VA system for at least one year had not engaged in minimally adequate mental health treatment. These findings were echoed by Seal and colleagues [15] who found that among 49,425 OEF/OIF Veterans diagnosed with PTSD, only 9.5% attended 9 or more VA mental health treatment sessions in 15 weeks or less in the first year after diagnosis, a standard of treatment closely monitored by VHA. Clearly, more data are needed to explicate the process of treatment engagement among OEF/OIF/OND Veterans, particularly with regard to integrated PTSD-SUD treatments.

Integrated treatment approaches for Co-Occurring PTSD and SUD

Perhaps the most widely disseminated approach for addressing PTSD-SUD to date is Seeking Safety [16], a manualized approach incorporating cognitive-behavioral, interpersonal, and growth/empowerment aspects, typically delivered in a group format. Early research on Seeking Safety with civilian women demonstrated some efficacy in reducing PTSD symptoms and substance use [17]; however, a recent multisite trial did not yield significant group differences when Seeking Safety was compared to a comparison health education condition [18]. Research on Seeking Safety with male Veterans is limited. One recent study found greater reductions in drug use in the Seeking Safety condition compared to SUD treatment as usual, but no group differences in alcohol use or PTSD symptoms were observed [19]. Notably, only a small number ($n = 4$) of OEF/OIF Veterans were recruited for this study. Norman and colleagues [20] conducted an open pilot trial of Seeking Safety with OEF/OIF Veterans and found the therapy to be generally well tolerated; however, significant issues in terms of recruitment and retention, particularly among heavier drinkers, were reported.

Another integrated treatment that has garnered support is Concurrent Treatment of PTSD and Substance Use Disorders Using Prolonged Exposure (COPE; [21]), which integrates components from motivational enhancement and CBT for substance use, psychoeducation, and exposure treatment. COPE was found to significantly reduce PTSD symptom severity when combined with usual treatment in a community sample, but no differences were found in relation to substance use, depression, or anxiety [22]. To our knowledge, the only research examining COPE in the Veteran population consists of a case study [23]. Overall, effectiveness data on integrated treatments for PTSD-SUD among Veterans is lacking and the few studies that exist include very small numbers from the OEF/OIF/OND era.

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Integrated Cognitive Behavioral Therapy (ICBT) is a manual-guided intervention with a growing evidence base among civilian populations and has recently been adapted to meet the needs of OEF/OIF/OND Veterans. ICBT is typically delivered in an individual format and was originally conceptualized as an adjunct PTSD treatment for patients with severe mental illness [24]. McGovern and colleagues adapted this approach for patients with co-occurring PTSD-SUD in community addiction treatment programs, as initial trials proved both feasible and promising in reducing PTSD and SUD symptoms [25]. A recent randomized controlled pilot trial ($n = 33$) of ICBT resulted in significantly greater reductions in PTSD symptoms in the ICBT condition compared to individual addiction counseling treatment as usual, while both conditions yielded improvements in alcohol and drug use [26]. The feasibility and efficacy of ICBT in reducing both PTSD and substance use among civilians with co-occurring disorders suggests it may be a promising intervention for military populations as well.

The present study

The present study tested the feasibility of ICBT adapted for use with treatment-seeking OEF/OIF/OND Veterans. The Stage Model of Behavioral Therapy [27,28] proposes that Stage I research involves therapy and manual development (Stage Ia) followed by pilot testing of the intervention (Stage Ib) in order to demonstrate feasibility of recruitment, patient acceptance of the treatment, and clinically significant improvement in one or more domains. Consistent with this approach, we conducted a Stage Ib feasibility study with a small sample of Iraq and Afghanistan veterans in order to evaluate the acceptability and tolerability of ICBT. Modification of the existing ICBT was necessary for suitability with Veterans and for delivery in a combined individual and group format. Our primary aims were testing the feasibility of engaging and retaining OEF/OIF/OND Veterans with co-occurring PTSD-SUD in a 12-week structured therapy in a typical VA outpatient clinic. We also examined clinically meaningful change in PTSD and depressive symptoms.

Method

Design

The current study utilized an open-label, single group, repeated measures feasibility design. Participants were sampled from PTSD, Substance Abuse, and Returning Veteran clinics at a VA Medical Center (VAMC) in the Northeastern U.S. All eligible participants were invited to receive ICBT and complete three in-person assessments: baseline, post-treatment and 3-month follow-up. We defined two process variables as follows: 1) *Acceptability*: Operationalized as enrollment in the research and attendance at one or more ICBT sessions; and 2) *Tolerability*: Defined a priori as completion of 8 or more ICBT sessions (66.7% of the planned therapy dose). We also examined clinically meaningful change in PTSD and depressive symptoms using the standard error of measurement (SEM) for the CAPS (11.14) and PHQ-9 (4.36) total scores. Consistent with previous behavioral therapy research, we defined meaningful change as a reduction in scores by at least one SEM [29]. Four institutional review boards from the study site and investigator affiliated institutions reviewed and approved all procedures.

Participants and sampling

Recruitment took place over a 9 month time period (February 2011 to November 2011). Weekly study representation in both the Substance Abuse Treatment Program (SATP) and PTSD clinics team

meetings, as well as recruitment advertising material (e.g. flyers, brochures) were utilized to facilitate recruitment. Participating Veterans received \$60 for the baseline assessment, \$70 for the post-treatment follow-up assessment, and \$80 for the 3-month follow-up.

Broad and inclusive eligibility criteria for the pilot trial were as follows: 1) OEF/OIF/OND Veteran status; 2) current diagnosis of PTSD; 3) diagnosis of a substance use disorder within the past year; and 4) willing and able to provide informed consent. Exclusion criteria included: 1) acute psychotic disorder or psychotic symptoms; 2) a psychiatric hospitalization or suicide attempt within the past month, unless related to substance intoxication or detoxification; or 3) unstable medical or legal situations rendering study completion unlikely. At this early stage of treatment development, we allowed participants to remain in the standard mental health treatment that they were currently receiving (e.g. PTSD or SUD skills groups, individual psychotherapy, medication management).

Study therapy

Integrated Cognitive Behavioral Therapy (ICBT) is a manual-guided therapy comprised of three primary skills designed to improve PTSD symptoms and substance use: 1) Patient Education about PTSD, substance use, their interrelation, and treatment; 2) Mindful Relaxation, a combination of centering and breathing techniques; and 3) Flexible Thinking, a cognitive restructuring approach and functional analysis of the links among activating events, beliefs and emotional or behavioral consequences (ABCs). As with most cognitive behavioral therapies, ICBT includes practice assignments between sessions designed to reinforce skill acquisition outside of the therapy sessions. A patient workbook is used in conjunction with the therapist manual.

ICBT was adapted for Veterans from Version 4.0 of the CBT for PTSD in addiction treatment Therapist Manual and Patient Workbook [30]. First, certain language in the manual and handouts was revised to include more Veteran focused terminology (e.g. "breathing retraining" vs. "mindful relaxation") and traumatic life event examples (e.g. combat-related vs. civilian situations). Additionally, a combined individual and group format was utilized in keeping with the widespread use of group modalities in VA settings for the treatment of PTSD and SUD [31]. The first four sessions were conducted in individual format and addressed group preparation, motivational enhancement, and individual skill issues prior to transitioning to the group format. We reasoned that maintaining an open group format (i.e. each group is free-standing and relevant to existing and first-time attendees) would maximize access and implementation. In order to ensure adequate coverage of ICBT material and support participants' efforts to engage in the study, we conducted ICBT sessions individually when group format was unavailable.

Therapist training and quality monitoring: Two ICBT research therapists, one a postdoctoral fellow in clinical psychology and the other a masters-level clinician (doctoral student in clinical psychology), delivered ICBT. Both were experienced in delivering PTSD and SUD interventions, and had first received didactic training related to specific skills in ICBT. ICBT sessions were recorded, and an experienced VAMC clinical psychologist supervised study therapists weekly. In addition, twice monthly group consultation sessions were conducted via teleconference with the ICBT expert members of the research team on general clinical issues and engagement aspects of the treatment process.

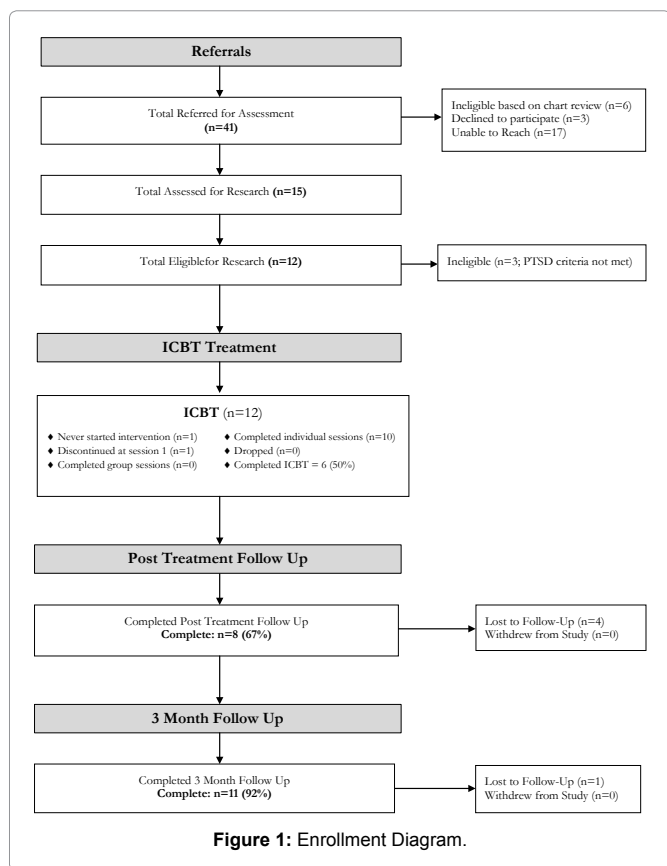


Figure 1: Enrollment Diagram.

Baseline and repeated measures

Demographic information: A review of the patient’s electronic VA medical record was conducted to extract the following information: Military service era, age, gender, race/ethnicity and marital status.

Structured clinical interview for DSM-IV-TR, patient edition (SCID-I/P; [32]). The SCID-I/P is a clinician administered, semi-structured interview that assesses lifetime and current Axis I diagnoses according to DSM-IV-TR criteria. For the present study, Section E, which assesses substance use disorders, was administered at the baseline assessment to determine eligibility.

Clinician administered PTSD scale (CAPS; [33]). The CAPS is a structured diagnostic interview and is widely regarded as the “gold standard” for determining PTSD diagnosis and symptom severity. The CAPS yields a total score, subscale scores on the B (re-experiencing), C (avoidance) and D (hyperarousal) criteria, and a PTSD diagnosis (present/absent). In the present study, CAPS ratings were made for current symptoms (past 30 days) according to DSM-IV criteria at baseline, post-treatment and the 3-month follow-up.

Addiction severity index (ASI; [34]). The present study utilized a self-report version (103 items) of the ASI which includes two composite scores on drug and alcohol problem severity. The composite scores are calculated by dividing each item by its maximum response and the total number of composite items. These values are then summed. Generally, reductions in the ASI drug or alcohol problem severity in the range of 10ths (vs. hundreds) are considered clinically significant. The self-report version of the ASI has been found to be reliable and valid among VA samples [35].

Timeline followback (TLFB; [36]). The TLFB interview method

Table 1: Patient demographics and baseline characteristics (N=12).

Demographics	
Age (sd)	38.25 (9.90)
Gender (male)	12 (100%)
Race (Caucasian/White)	12 (100%)
Not Hispanic or Latino	11 (91.7%)
Marital Status	
Married or living as married	4 (33.3%)
Divorced	4 (33.3%)
Never Married	4 (33.3%)
Baseline: PTSD severity	
PTSD diagnosis: positive	12 (100%)
CAPS Total	88.17 (11.65)
CAPS B Criteria Total Score (re-experiencing)	25.58 (5.14)
CAPS C Criteria Total Score (avoidance)	33.92 (7.76)
CAPS D Criteria Total Score (increased arousal)	28.67 (4.01)
Primary Trauma Type	
Combat	12 (100%)
Secondary Trauma Type	
Combat	8 (66.7%)
Adult Physical Assault	3 (25.0%)
Unexpected Death	1 (8.3%)
Chronological Sequence of Trauma and SUD	
Trauma → SUD	9 (75.0%)
SUD → Trauma → SUD	3 (25.0%)
Baseline Substance Severity	
Objective Measures	
Urine positive toxicology	3 (25.0%)
Alcohol positive breathalyzer	0.0%
3 Month Time-Line Follow Back	
Total Days Use Alcohol (n=10)	43.2 (32.47)
Total Days Use Drugs (n=4)	47.8 (38.66)
Percent Days Use Alcohol (n=10)	47.86 (35.91)
Percent Days Use Drugs (n=4)	52.58 (42.43)
PHQ Total	18.33 (4.83)
ASI Composite Scores	
Alcohol	0.385 (0.26)
Drug	0.085 (0.05)

gathers self-report information about quantity and frequency of drug and alcohol use over the past 90 days using a calendar format. The TLFB was completed at all three assessment points.

Toxicological data: Both urine screen and breathalyzer data were collected to detect substance use at the baseline and follow-up assessments.

Patient health questionnaire-9 (PHQ-9; [37]). The PHQ-9 is a brief, self-report measure of depressive symptoms consisting of 9 items rated on a Likert scale from 0-3. The PHQ-9 was administered at all three assessment points and yields a sum score (range is 0-27) reflecting depressive severity, with scores between 10-19 indicating moderate to severe symptoms and scores of 20 or above indicating severe depression.

Results

Participant demographics and baseline characteristics

Thirty-five Veterans who met screening criteria were referred by VA clinicians or via self-referral. Of these, 15 (43%) agreed to participate in the research study and provided informed consent (Figure 1) and 12 were eligible for participation following the baseline assessment. Baseline characteristics are presented in Table 1.

Table 2: Pre- and post-treatment PTSD, depression scores and clinically meaningful change. Clinically meaningful change reflects a decrease of at least one standard error of measurement (SEM) on the CAPS and PHQ total scores.

Participant	Pre-Tx CAPS	Post-Tx CAPS	Clinically Meaningful Change (Y/N)	Pre-Tx PHQ-9	Post-Tx PHQ-9	Clinically Meaningful Change (Y/N)
1	101	103	N	23	19	N
2	109	104	N	26	25	N
3	92	88	N	16	15	N
4	72	80	N	16	11	Y
5	90	88	N	19	18	N
6	95	80	Y	20	24	N
7	89	66	Y	15	12	N
8	87	68	Y	20	13	Y

Briefly, the average age was 38.25 ($SD = 9.90$) and all were Caucasian males. Participants had an average total CAPS score of 88.17 ($SD = 11.65$) indicating a high level of PTSD symptom severity. The primary trauma was military combat exposure (100%). More than half reported the onset of substance use disorder following trauma exposure (66.7%). Regarding substance use, in the 90 days prior to the baseline assessment, participants diagnosed with an alcohol use disorder ($n=10$) reported using alcohol on approximately 43 days. Participants diagnosed with a drug use disorder ($n=4$) reported using substances on approximately 48 days.

Acceptability

Of the 35 eligible Veterans referred to the study, 17 (49%) could not be reached by research staff at the address or phone numbers provided/on record and 3 (8%) declined to participate. Fifteen (43%) attended the baseline assessment eligibility interview and provided informed consent. Twelve of 15 (80%) met study criteria and were enrolled in the study. Among participants who were reached by research staff, the study protocol was determined to be acceptable by most, as 15 out of 18 (83%) attended the baseline interview. Of the 12 who met eligibility criteria, 11 (91.7%) attended at least one ICBT session, suggesting very good initial acceptability of the treatment.

Tolerability

Six of the eleven participants (54.5%) who began ICBT completed at least 8 sessions and received sufficient treatment dose. On average, treatment completers attended 10 ICBT sessions over the course of the treatment and participated in 1-2 group sessions. Groups averaged in size from 2-3 members per session. Time to complete treatment ranged between 13-23 weeks. Of those not receiving sufficient dose ($n=6$), 1 never started ICBT, 1 discontinued ICBT after the first session, and 3 discontinued treatment after completing 4 individual ICBT sessions. Data on reasons for dropout during the treatment portion of the study was not systematically obtained. Anecdotally, we are aware that 2 non-completers discontinued treatment due to requiring a greater level of care (e.g., residential treatment or inpatient hospitalization). Of the total sample, 8 (67%) completed the post-treatment follow-up and 11 (92%) completed the 3-month follow-up assessment.

Comparisons between treatment completers and non-completers on demographic (age, # of deployments) and clinical variables (social support as indicated by the ASI family/social composite, total CAPS score at baseline, SUD diagnoses, and sequence of trauma versus substance use onset) yielded no significant differences. However, non-completers were more likely to report onset of substance use

prior to experiencing a traumatic event. A larger sample is necessary to further examine meaningful differences between completers and non-completers for ICBT.

Clinically meaningful change

Eight participants had complete pre- and post-treatment data allowing for examination of clinically meaningful change. We examined CAPS and PHQ-9 total scores individually (see Table 2) and found that 3 participants exhibited a meaningful decrease in PTSD symptoms and 2 showed a meaningful decrease in depressive symptoms. It should be noted that two of the participants who demonstrated clinically noticeable change in PTSD symptoms at post-treatment were non-completers of ICBT.

Discussion

The goal of this study was to assess the feasibility of delivering an integrated cognitive behavioral treatment to OEF/OIF/OND Veterans with co-occurring PTSD and SUD. We focused primarily on acceptability and tolerability of the treatment and also examined clinically meaningful change in PTSD and depression pre- to post-treatment. Over the course of 9 months, we successfully recruited 12 eligible Veterans, 6 of whom completed ICBT. We encountered challenges related to acceptability, as indicated by slower than anticipated recruitment, and tolerability, as measured by retention and group participation. We discuss both of these areas next and provide suggestions for future research and strategies for improvement.

Acceptability and recruitment

Our initial recruitment efforts were based on clinician referrals. This proved difficult for meeting our recruitment goals, and we found it useful to recruit directly to Veterans through study advertisements in public areas throughout the hospital. Overall, recruitment flow remained slow but steady with 3-4 Veterans referred per month, with 41 potential referrals and 35 eligible based on chart review. Since nearly half (17) of referred Veterans were unable to be reached by research staff, the overall acceptability of ICBT to potential participants is difficult to ascertain. Unanswered phone calls may be indicative of study-related factors (e.g. disinterest in participation, mistrust of research, ambivalence about addressing trauma or substance use) or factors unrelated to research (e.g. stress at home, problems with phone service). Among those willing to speak with research staff about ICBT (18 Veterans), however, the majority (15 Veterans) scheduled and attended a baseline assessment and almost all (11/12) attended at least one ICBT session.

Tolerability and retention

Among those who completed ICBT, attendance was strong with an average completion of 10 out of 12 sessions. For this feasibility trial, participants were not required to complete ICBT within a certain timeframe. Several participants experienced unexpected or developmentally appropriate life events (e.g., ill family member, marriage, changing school schedules, barriers to child care) that precluded them from attending sessions consistently. As such, there was a wide range of time to complete the ICBT treatment, which presented significant challenges regarding retention and group formation.

Despite our best efforts to retain participants in the study treatment, the dropout rate was considerable (45.5%), higher than previous studies of ICBT. McGovern et al. [26] reported a 35% non-completion rate in a similar pilot trial of ICBT with patients

in community mental health settings. Greater severity of PTSD and SUD symptoms in the Veteran sample may have contributed to our higher dropout rate. Indeed, the average CAPS total score in the present study, 88.17 compared with 73.9 reported by McGovern and colleagues, would suggest this is the case. The fact that two participants dropped out of ICBT due to hospitalization also suggests a high level of acuity.

It is also likely that unique factors related to the Veteran population, particularly OEF/OIF/OND Veterans, made retention challenging. A recent study examining engagement and completion of evidence-based psychotherapy (EBP) for PTSD with Veterans found dropout rates of 50% and 30.9% for CPT and PE, respectively [38]. Of note, OEF/OIF/OND status was a significant predictor of EBP non-completion. Moreover, it is well documented that stigma plays a role in failure to engage in mental health treatment among young male Veterans [39,40], in addition to competing priorities related to school, employment, family obligations, and peers. Our experience with treatment engagement mirrors the challenges of other studies (e.g. [20]) focused on providing PTSD-SUD treatment to OEF/OIF/OND Veterans.

Tolerability of group format

The relatively slow recruitment pace affected our ability to deliver ICBT in a group format. We elected to maintain a rolling admission into the study, as opposed to delaying entry until a group cohort was formed in order to prevent dropouts during the waiting period. It is noteworthy that two participants dropped out of ICBT after completing the 4 individual sessions (just prior to beginning group sessions); however, these participants transitioned to a higher level of care after discontinuing the treatment making it unlikely that the group format was a significant factor. Given the small sample size and low number of group sessions completed in this pilot study, we are unable to draw firm conclusions regarding the tolerability of a group format among OEF/OIF/OND Veterans. This remains an important area of future investigation.

ICBT Modifications and Revised Research Strategies

An expected outcome of Stage I Phase I research with psychosocial therapies is the iterative process of refinement of the treatment. The challenges we encountered in conducting this Phase I project of ICBT with OEF/OIF/OND Veterans provided valuable information in terms of areas to refine or adapt regarding recruitment, engagement in treatment, and retention. First, exploring alternative avenues for recruiting potentially eligible Veterans (e.g. web-based advertising, working with various task forces and specialty clinics representing OEF/OIF/OND Veterans, the court system) is crucial. While most of the participants in this study (10/12) were referred by VA clinicians, we found it necessary to expand our reach by addressing Veterans directly. This resulted in a greater number of interested Veterans who did not meet our eligibility criteria, but overall was beneficial for recruitment. We also found it imperative to be flexible in scheduling appointments by offering daytime and evening hours to accommodate Veterans' work and school schedules. Future studies may also find it more fruitful to employ a "rafting" technique when randomizing to treatment condition in order to aid group formation. Rafting involves randomizing participants in pairs or small groups rather than individually, thereby increasing the number of participants randomized to the active treatment condition at the outset and potentially enhancing group formation.

Strengths and limitations

A primary strength of this study is the inclusion of Veterans with complex clinical presentations, yielding a more representative sample of patients with co-occurring PTSD-SUD than is often included in clinical research studies. Another strength is our use of gold standard in-person assessments of PTSD and SUD symptoms. Finally, our adaptation of ICBT to a VA setting and the combined individual/group format may also be viewed as a strength, as it provides support for adapting evidence based treatments derived in community samples to military samples. With respect to limitations, given the nature of a Phase I pilot study, the current study lacks the experimental rigor associated with a randomized controlled trial. Also, our sample size was small and consisted solely of Caucasian male Veterans. Our use of a group format may be a potential limitation if it led to premature termination from the treatment, though we are unable to accurately determine this with these data.

Future research

Research on treatment approaches for co-occurring PTSD-SUD continues to be an emerging and dynamic area. Not unique to this study, there are clear challenges in engaging and retaining patients with a high level of symptom severity and complex presenting problems. Innovative approaches to better engage returning OEF/OIF/OND Veterans in evidence-based treatments are needed. Recent research suggests the promise of integrated therapies such as ICBT. We conclude that experience gained from this feasibility study will lead to improvements in recruitment and retention of OEF/OIF/OND Veterans and in the adaptation of the ICBT manual and patient workbook. Further research, already underway, is evaluating these revisions within a randomized controlled pilot trial, comparing ICBT and standard VA care (addressing PTSD, SUD or both) to standard VA care alone. Continued clinical and research efforts must be a priority to address this vexing, prevalent and growing problem among returning U.S. military Veterans.

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