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ORIGINAL ARTICLE

Is Integrated CBT Effective in Reducing PTSD Symptoms and Substance Use in Iraq and Afghanistan Veterans? Results from a Randomized Clinical Trial

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Abstract

This study is the first to examine integrated cognitive behavioral therapy (ICBT) in a sample of military veterans with co-occurring posttraumatic stress disorder (PTSD) and substance use disorders (SUD). Generalized linear mixed models were used to examine primary outcomes from a small, randomized clinical trial comparing ICBT plus treatment as usual (TAU) to TAU only in a sample ($N = 44$) of U.S. veterans who served in Iraq and/or Afghanistan. A significant reduction in PTSD and SUD symptoms over time was detected in both conditions. One significant time-by-condition interaction effect for re-experiencing symptoms was observed, with ICBT showing greater reductions from baseline to post-treatment. Overall, the efficacy of ICBT in this veteran sample was not as robust as outcomes with non-veteran patients. Challenges to engagement and retention in treatment and further intervention adaptations for veterans are discussed.

Keywords Posttraumatic stress disorder · Substance use · Veterans · Cognitive behavioral therapy · Treatment outcomes

Introduction

The high prevalence of comorbid posttraumatic stress disorder (PTSD) and substance use disorders (SUD) is well documented in both civilian and military samples (Jacobsen et al. 2001). In civilian settings, up to 50% of those in treatment for SUD also have a lifetime diagnosis of PTSD (Brady et al. 2004; Jacobsen et al. 2001). Among U.S. military veterans, this comorbidity is even more pronounced, and there is ongoing concern about the emotional and physical wellbeing of veterans who served in Afghanistan (Operation Enduring Freedom; OEF) and Iraq (Operation Iraqi Freedom; OIF, Operation New Dawn; OND). For example, among OEF/OIF/OND veterans utilizing VA healthcare, 63% with an SUD also received a PTSD diagnosis (Seal et al. 2011).

Relative to either disorder alone, co-occurring PTSD-SUD is associated with greater severity of symptoms and poorer psychosocial functioning (Brady et al. 2004; Breslau et al. 1997; Norman et al. 2007; Ouimette et al. 1998), and increased risk of suicidality (Calabrese et al. 2011). Importantly, although co-occurring PTSD-SUD has historically been associated with poorer substance use treatment outcomes (Jacobsen et al. 2001), providing PTSD treatment early in the course of recovery from SUDs can lead to improvements in both PTSD and SUD symptoms (Ouimette et al. 2003). Two recent reviews concluded that patients with comorbid PTSD-SUD can likely benefit from more than one treatment approach and currently there is no "gold standard" treatment (Roberts et al. 2015).

Accordingly, several integrated approaches have been actively researched, including both exposure and

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non-exposure based treatments. For example, Co-occurring prolonged exposure (Brady et al. 2001; Mills et al. 2016) combines two effective treatments—Prolonged Exposure (PE; Foa et al. 2007) for PTSD and relapse prevention for substance use. In a randomized controlled trial with civilians, COPE reduced PTSD symptom severity relative to treatment as usual, though no differences were found for substance use (Mills et al. 2012). Outcomes from a recently completed study of COPE with military veterans have yet to be published.

Perhaps the most widely implemented non-exposure based approach has been Seeking Safety, a group or individual approach that focuses on present-centered coping skills (Najavits et al. 1998). Seeking Safety has been shown to be feasible to deliver, well tolerated by patients, and has been recommended for use in VA settings (Boden et al. 2012; Cook et al. 2006; Najavits et al. 2016; Norman et al. 2010). However, seeking safety has been primarily studied with women and has not consistently demonstrated effectiveness in reducing either PTSD or substance use symptoms, including among male veterans (Boden et al. 2012; Hien et al. 2009).

Prior research has documented low rates of utilization of psychotherapy among returning veterans (Haller et al. 2016; Seal et al. 2010) and high dropout rates, particularly from exposure-based PTSD treatments (e.g., Kehle-Forbes et al. 2016; Szafranski et al. 2017). In addition, providers are often concerned about the tolerability of exposure-based treatments (Cook et al. 2004; Ruzek et al. 2014), which may be especially true for clients with active substance use or at risk for relapse. Integrated Cognitive Behavioral Therapy (ICBT; McGovern et al. 2011, 2015) is a 12-session manual-guided treatment that was developed as an alternative to exposure-based therapies, and delivers content relevant to both disorders (i.e., psycho-education, breathing retraining, and cognitive restructuring). Similar to other integrated treatments, ICBT seeks to address both PTSD and substance use symptoms simultaneously. However, there are substantive differences among these approaches. ICBT differs from COPE in that it does not involve exposure to details of the trauma; it is also distinct from Seeking Safety in that it directly addresses trauma-related cognitions and applies CBT skills in depth. A potential benefit of ICBT is that it has been found to be highly transferable to patients (excellent therapy retention) and therapists (high levels of adherence and competence ratings), acceptable to clinicians and patients, and delivered with high levels of adherence and competence in routine practice settings (Meier et al. 2015). These aspects may be particularly relevant since the difficult task of engaging and retaining military veterans, particularly younger OEF/OIF/OND era veterans, is well known.

There is a growing evidence base for ICBT as an adjunctive treatment to standard SUD care. In a randomized clinical trial conducted within community addiction programs, individuals who received ICBT (compared with Individual Addiction Counseling; IAC) had fewer re-experiencing symptoms and were less likely to meet criteria for PTSD at post treatment (McGovern et al. 2011). A larger multisite RCT revealed better substance-related outcomes for ICBT plus treatment as usual (TAU), compared with TAU only. However, ICBT and IAC equivalently and significantly reduced PTSD symptoms (McGovern et al. 2015). Further research on the efficacy of ICBT is warranted and it has not been adapted for or tested with military veterans. Also, ICBT has not been examined as a viable treatment option in the context of group therapy, which is a common modality offered in VA settings (Rosen et al. 2004).

The Present Study

The current study builds on previous research demonstrating efficacy of ICBT with civilians. We adapted ICBT for veterans, and modified it for delivery in a combined individual and group therapy format. Within the framework of the NIDA stage model of behavioral therapy development (Rounsaville et al. 2001), the primary aim of this Stage I Phase III research was to conduct a randomized pilot trial comparing ICBT plus VA treatment as usual (TAU) versus TAU only, in a sample of OEF/OIF/OND veterans with co-occurring PTSD-SUD. Based on previous research with ICBT, we hypothesized that veterans receiving ICBT plus TAU would report greater reductions in PTSD symptoms and substance use compared to those receiving TAU only.

Method

As part of a larger three-phase project, this is a randomized, repeated measures, pilot trial of ICBT. Participants were sampled from specialty PTSD, Substance Use, and Returning Veteran clinics at a VA Medical Center (VAMC) in the Northeastern U.S. VA clinicians delivered ICBT, and PTSD symptoms and substance use were assessed at three time points—baseline, post treatment, 3-month follow-up. 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 21-month period (February 2012 to November 2013; see Fig. 1 for consort diagram). In order to facilitate recruitment, study personnel attended both the Substance Abuse Treatment Program (SATP) and PTSD Clinic team meetings on a weekly basis, and distributed advertising material (e.g., flyers, brochures) throughout the

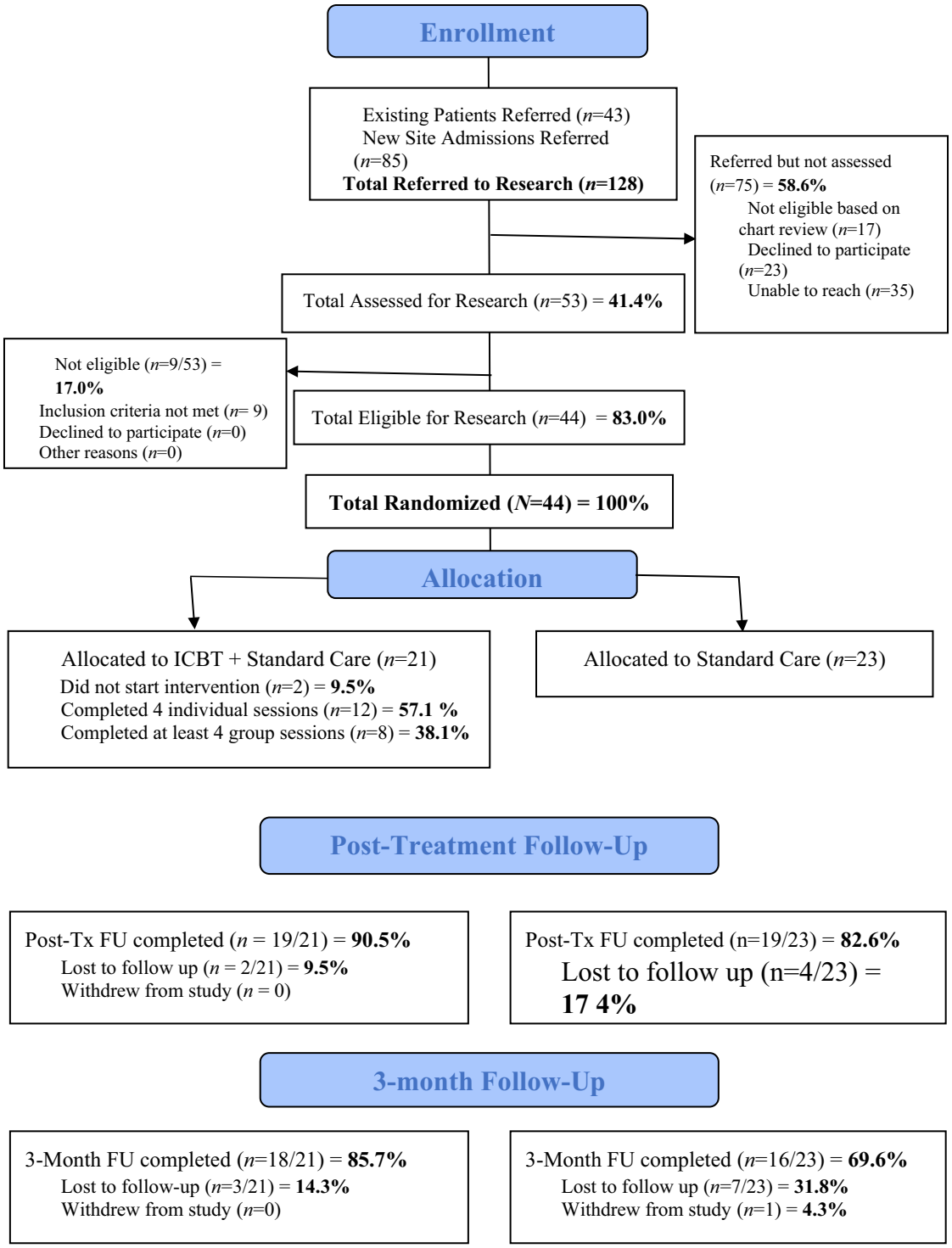

Fig. 1 CONSORT diagram of study participation

VA facility. Eligibility criteria were as follows: (1) OEF/OIF/OND Veteran status; (2) current diagnosis of PTSD (past month); (3) diagnosis of a substance use disorder (SUD) within the past year; and (4) willing and able to provide informed consent. In order to obtain a representative sample of veterans with co-occurring PTSD and SUD, only three exclusion criteria were applied: (1) acute psychotic disorder or acute psychosis; (2) psychiatric hospitalization or suicide attempt within the past month, unless hospitalization was directly related to substance intoxication or detoxification;

or (3) unstable medical or legal situations rendering study completion unlikely.

Eligible participants were randomized (in groups of two in order to facilitate group formation) to one of two study conditions: (1) ICBT + treatment as usual (TAU) or (2) TAU only. Participants received $60 for the baseline assessment, $70 for the post-treatment follow-up, and $80 for the 3-month follow-up.

Study Therapy

Integrated Cognitive Behavioral Therapy (ICBT) is a manual-guided intervention designed to improve both PTSD symptoms and substance use. ICBT focuses on three primary areas: (1) psychoeducation regarding PTSD symptoms, substance use, their interrelation and treatment; (2) breathing retraining, 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. A patient workbook was used in conjunction with the therapist manual. Sufficient therapy dose was set a priori at a minimum of attendance at 8 of 12 sessions, equivalent to completion of 75% of the planned ICBT sessions.

ICBT was adapted for use with veterans from our previous work (McGovern et al. 2010). Based on our Phase I open feasibility trial with veterans (Capone et al. 2014), language in the manual and workbook was revised to include more Veteran focused terminology and relevant examples (e.g., combat-related versus civilian situations). We delivered ICBT in a combined individual and group format in keeping with the widespread use of group modalities in VA settings for the treatment of PTSD and SUD (Rosen et al. 2004). We reasoned that adding a group component would provide the social support and common factors associated with group treatment, and would make ICBT more transportable to the VA system. We further reasoned that including initial one-on-one sessions may be less threatening to OEF/OIF/OND veterans and may ease the process of seeking help for substance use or PTSD. The group utilized an open format (i.e., each group was free-standing with content relevant to existing and first-time attendees), which was expected to maximize access and implementation.

Thus, ICBT sessions 1–4 were delivered individually, with a focus on rapport building, introducing mindfulness and breathing retraining, building motivation for change, and teaching CBT skills (i.e. flexible thinking). Participants then transitioned to a group for sessions 5–12 where they learned to identify and label emotions, applied flexible thinking to trauma and substance use cognitions, and developed a relapse prevention/crisis plan. When group sessions were not available due to low numbers of participants, the ICBT content was delivered individually.

Treatment as Usual

Study participants were allowed to continue in their usual VA care, such as medication management and individual or group psychotherapy in the substance use treatment program or PTSD clinics from which they were referred. Most typically, treatment as usual consisted of skills training (e.g., anger management, relapse prevention) or supportive therapy; however, we did not require participants to refrain from engaging in trauma-focused treatments.

Therapist Training and Quality Monitoring

Four study therapists delivered ICBT, two were postdoctoral fellows in clinical psychology, one a masters-level clinician (doctoral student in clinical psychology), and one a masters-level social work student. All had previous clinical experience providing treatment for PTSD and/or substance use disorders with veterans. Therapists first received didactic training in ICBT consisting of a review of the extant research on co-occurring PTSD-SUD, overview of the therapist manual and participant workbook, and demonstrations of specific ICBT skills via role plays. Therapists were supervised using audio recordings of ICBT sessions. An experienced VA clinical psychologist supervised study therapists in weekly group supervision sessions that included a case review of all active participants and review of specific recorded sessions. In addition, twice monthly group consultation session was conducted via teleconference with the ICBT expert members of the research team on general clinical issues and engagement aspects of the treatment process.

As noted, all ICBT sessions were audio recorded for the purposes of supervision, and 79.4% ($n = 50$) were reviewed and rated for treatment fidelity by the supervising clinical psychologist using the Adherence and Competence Index (ACI). The ACI includes two 7-point scales to evaluate adherence [1 = *not at all* (0%) to 7 = *extensively* (> 90%)] and competency (1 = *very poor* to 7 = *excellent*) on specific elements for each session. Scores at or above 4 were considered to be adequate a priori. Therapists demonstrated good adherence and competence levels across individual ICBT sessions (adherence: $M = 5.03$; competence: $M = 5.12$).

Baseline and Repeated Measures

Demographic Information

A review of participants' electronic VA medical record was conducted to extract military service era, age, gender, race/ethnicity and marital status.

Treatment Services Received (TSR; McLellan et al. 1992)

The TRS tracked previous and current mental health treatment related to PTSD and SUD including type (e.g., pharmacotherapy, case management), setting (e.g., inpatient hospitalization, residential treatment, outpatient), and format (e.g., group, individual).

Structured Clinical Interview for DSM-IV-TR, Patient Edition (SCID-I/P; First et al. 2002)

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; Blake et al. 1995)

The CAPS is a structured diagnostic interview and is widely regarded as the "gold standard" for determining PTSD diagnosis and symptom severity. The CAPS for DSM-IV 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 recorded for current symptoms (past 30 days) and a diagnosis required that participants met DSM symptom criteria as well as an overall total score of 44 or above. The CAPS was used to determine initial eligibility status as well as for tracking severity of PTSD symptoms over time. Recorded interviews were reviewed for interrater reliability across two ($n = 23$) or three independent coders ($n = 16$), and demonstrated excellent reliability, with intraclass correlations (ICCs) ranging between .93 and .99 for cluster and total scores.

Addiction Severity Index (ASI; McLellan et al. 1985)

The ASI is a multi-dimensional semi-structured interview that provides information on both lifetime and recent (past 30 days) substance-related problems. Summary composite scores provide information on problem severity at baseline and over time. The present study utilized a self-report version (103 items) of the ASI that includes two composite scores on drug and alcohol problem severity. The self-report version of the ASI has been found to be reliable and valid among VA samples (Rosen et al. 2000).

Timeline Followback (TLFB; Sobell et al. 1979)

The TLFB interview method gathers information about occurrences of drug (e.g., non-prescribed medications, overuse of prescribed medications, benzodiazepines, cocaine, opiates, heroin) and alcohol use over the past 90 days using a calendar format. The TLFB was completed at baseline, post-treatment, and 3-month follow-up, yielding a continuous record across all phases of study participation. Data from the TLFB was used to calculate percentages for days participants used alcohol, used any drug, or were abstinent from all substances.

Toxicological Data

Both urine toxicology and breathalyzer data were collected to detect substance use at the baseline and follow-up assessments. We used the Alco-Sensor III breathalyzer to measure participants' blood alcohol content (BAC) and Integrated iCup to test for cannabis, cocaine, benzodiazepines, amphetamine, methamphetamine, and opioid use.

Data Analysis Plan

We first conducted preliminary analyses that included Chi square and *t* tests with demographic characteristics and baseline symptom measures to determine the effectiveness of our randomization to treatment conditions and to identify potential covariates to be controlled for in our models. Next, we examined rates of treatment completion and average sessions attended for those in the ICBT condition. Additionally, we examined the frequency of participants who received additional services as a part of TAU and evaluated the average number of treatment occurrences for each type of service at post-treatment (i.e., SUD group and individual sessions, inpatient/residential, or detoxification; PTSD group and individual sessions, PTSD/SUD group and individual sessions, VA medication appointments or follow-ups, psychiatric hospitalizations, or other community services [e.g., AA/NA meetings]). We also conducted a series of t-tests to consider differences in the number of occurrences of these services across treatment conditions, and applied a Bonferroni correction to account for the number of tests ($p \leq .005$).

After examining data for violations of univariate normality, using SPSS© Version 22.0 software (IBM Corporation 2013), we ran a series of covariance pattern (unstructured) general linear mixed models (GLMM) to evaluate the presence of time (baseline, post treatment, 3-month follow-up), condition (ICBT, TAU), and time-by-condition interaction

effects on primary dependent variables—CAPS total score, re-experiencing, avoidance/numbing, and hyperarousal subscale scores, percent days using alcohol, percent days using drugs, percent days abstinent from alcohol and drugs, ASI alcohol composite, ASI drug composite, and positive toxicology results. Use of a covariance pattern model within a GLMM framework enabled use of all available observations within a given phase of data collection and took the correlated nature of the data into account (Fitzmaurice et al. 2011). Scores obtained at baseline, post-treatment, and 3-month follow-up (set to discrete values of 0, 1, and 2 respectively) were considered as fixed effects. A maximum likelihood method was used to handle missing data (Schafer and Graham 2002).

In addition, we used plotted graphs of group means to provide visual depictions of trends over time. When a significant time-by-condition interaction effect was observed, we conducted follow-up pairwise comparisons of mean differences (using estimated marginal means) and simple slope analyses to determine the presence of group and time effects. We conducted the primary analyses using an intent to treat (ITT) approach, and secondary analyses consisted of similar models using the subsample of participants who were deemed treatment completers.

Results

Preliminary Analyses

Using Chi square and independent sample t-tests, we found no s ignificant differences in demographic characteristics or baseline symptom severity across treatment conditions (Table 1). Descriptive statistics across all three time points are provided in Table 2.

Treatment Completion

Of those enrolled in the ICBT condition ($n = 21$), 38.1% ($n = 8$) reached completer status (i.e., attended at least eight sessions of ICBT). The mean number of sessions attended for all ICBT participants was 5.48 ($M = 4.57$ for individual sessions, $M = .90$ for group sessions). See Fig. 2 for survival analysis of ICBT session attendance.

TAU Services

Post-treatment data ($n = 22$) indicated that participants were involved in TAU to varying degrees during the course of treatment, with medication appointments, other community services, and PTSD individual sessions being the most frequently reported services received across conditions. Overall, the frequencies of engagement in each activity within condition were as follows: SUD-focused group (ICBT: 27.3%, $M = 7.27$, $SD = 17.44$; TAU: 18.2%, $M = .55$, $SD = 1.51$), SUD-focused individual sessions (ICBT: 18.2%, $M = 1.45$, $SD = 3.70$; TAU: 27.3%, $M = 1.18$, $SD = 2.14$), inpatient/residential (ICBT: 27.3%, $M = .27$, $SD = .47$; TAU: 9.1%, $M = 09$, $SD = .30$), inpatient detoxification (ICBT: 18.2% $M = .55$, $SD = 1.29$; TAU: 0.0%), PTSD group (ICBT: 20.0%, $M = 1.27$, $SD = 2.89$; TAU: 18.2%, $M = 4.80$, SD = 11.59), PTSD individual sessions (ICBT: 63.6%%, $M = 5.55$, $SD = 6.23$; TAU: 81.8%, $M = 5.36$, $SD = 4.13$, PTSD/SUD integrated group (0.0% for both conditions), PTSD/SUD individual sessions (ICBT: 40.0%, $M = 2.40$, $SD = 3.29$; TAU: 0.0%), medication appointments or follow-ups (ICBT: 90.1%, $M = 3.64$, $SD = 4.37$; TAU: 90.1%, $M = 1.91$, $SD = 1.38$), psychiatric hospitalizations (ICBT: 18.2%, $M = .36$, $SD = .81$; TAU: 0.0%), or other community services (81.8%, $M = .18$, $SD = .41$ both for ICBT and TAU). Using t tests, we did not find any significant differences in non-study related treatment occurrences between ICBT plus TAU and TAU conditions from baseline to post-treatment ($p > .005$).

Primary Analyses

PTSD Symptoms

GLMM analyses showed significant time effects for CAPS total score, $F(2, 44) = 17.58$, $p < .001$; re-experiencing, $F(2, 34.26) = 8.58$, $p = .001$; avoidance/numbing, $F(2, 33.99) = 7.45$, $p = .002$; hyperarousal, $F(2, 33.19) = 8.30$, $p = .001$, indicating a decline in PTSD symptoms across both study conditions over time. We did not observe a significant time x condition interaction, indicating a lack of superiority in main effects of ICBT relative to TAU alone on PTSD symptoms overall.

We did detect a time-by-condition interaction effect for re-experiencing symptoms, $F(2, 34.26) = 4.22$, $p = .023$, suggesting the presence of a significant difference over time across conditions. Follow-up analyses revealed that there was a simple effect of time within the ICBT condition ($F(2, 33.780 = 11.71$, $p < .001$), and that this significant mean difference (MD) was observed between baseline and post-treatment ($MD = -6.81$, $SE = 1.43$, $p = .001$) and baseline and 3-month follow-up ($MD = -7.61$, $SE = 1.62$, $p < 001$). Considering the simple effect of condition over time, reduction in re-experiencing symptoms was greater in the ICBT condition than TAU ($MD = -3.97$, $SE = 2.50$) between baseline and post-treatment, but did not reach significance ($F(1, 41.20) = 2.51$, $p = .121$). Further explicating the significant interaction, the plotted graph of unadjusted means for re-experiencing symptoms over time for both conditions similarly depicts a trend in favor of ICBT (Fig. 3).

Table 1 Patient demographics and baseline diagnoses, substance use and PTSD characteristics (N = 44)

Participant characteristics	ICBT ($n = 21$) n (%) or M (SD)	TAU ($n = 23$) n (%) or M (SD)	χ^2/t
Age	36.48 (9.82)	32.09 (7.65)	− 1.28
Gender (male)	20 (95.2%)	22 (95.7%)	.00
Race			2.94
White	18 (85.7%)	19 (82.6%)	
Black	2 (9.5%)	2 (8.7%)	
Asian	1 (4.8%)	0 (0.0%)	
Multiracial	0 (0.0%)	2 (8.7%)	
Ethnicity (not Hispanic or Latino)	20 (95.2%)	18 (81.8%)	1.88
Marital status			4.39
Married	5 (23.8%)	9 (39.1%)	
Divorced/separated	12 (57.1%)	6 (26.1%)	
Never married	4 (19.0%)	8 (34.8%)	
Number of deployments	2.05 (1.11)	1.65 (1.07)	− 1.20
Primary trauma type			2.94
Military	20 (95.2%)	21 (91.3%)	
Childhood sexual assault	1 (4.8%)	0 (0.0%)	
Adult sexual assault	0 (0.0%)	1 (4.3%)	
Military sexual assault	0 (0.0%)	1 (4.3%)	
CAPS[c] total score	76.33 (14.71)	78.78 (16.65)	.52
Re-experiencing	23.29 (5.66)	32.57 (7.67)	− .88
Avoidance/numbing	29.24 (7.67)	24.74 (6.68)	1.54
Hyperarousal	23.81 (5.02)	24.74 (6.13)	.55
Lifetime substance diagnosis			
Alcohol use disorder	17 (81.0%)	20 (87.0%)	.30
Cannabis use disorder	4 (19.0%)	7 (30.4%)	.76
Cocaine use disorder	4 (19.0%)	2 (8.7%)	1.00
Opioid use disorder	3 (14.3%)	2 (8.7%)	.34
Sedative use disorder	1 (4.8%)	0 (0.0%)	1.12
Polysubstance use disorder	0 (0.0%)	1 (4.3%)	.93
Positive urine toxicology	8 (38.1%)	9 (40.9%)	1.08
Timeline followback[a]			
Percent days used alcohol	.33 (.31)	.51 (.40)	1.64
Percent days used drugs	.25 (.37)	.26 (.39)	.06
Percent days abstinent	.47 (.35)	.35 (.35)	− 1.17
ASI[b] scores			
Alcohol composite	.31 (.22)	.42 (.28)	1.38
Drug composite	.12 (.16)	.10 (.11)	− .48

[a]Past 90 days

[b]Addiction Severity Index (ASI)

[c]Clinician Administered PTSD Scale (CAPS)

Alcohol and Other Substance Use

Similar to PTSD symptoms, on some substance use outcomes, both treatment groups decreased over time. Significant time effects emerged for percent days using alcohol, $F(2, 32.65) = 3.77$, $p = .034$; percent days abstinent, $F(2, 37.03) = 4.61$, $p = .016$; ASI alcohol composite, $F(2, 44) = 9.96$, $p < .001$; and ASI drug composite scores, $F(2, 44) = 9.01$, $p = .001$. No significant interaction (time x condition) effects were found for any of the substance use outcome measures.

Table 2 Unadjusted means and standard deviations of primary outcomes at baseline, post-treatment, and 3-month follow-up

Symptom severity	*n* (%) or M (SD)					
	Baseline		Post-treatment		3-Month follow-up	
	ICBT ($n=21$)	TAU ($n=23$)	ICBT ($n=19$)	TAU ($n=19$)	ICBT ($n=15$)	TAU ($n=16$)
CAPS total score	76.33 (14.71)	78.78 (16.62)	61.17 (18.27)	69.42 (26.26)	66.07 (17.60)	62.27 (26.26)
Re-experiencing	23.29 (5.66)	21.48 (7.67)	16.56 (6.78)	19.47 (9.13)	16.07 (7.89)	16.47 (10.61)
Avoidance/numbing	29.24 (7.67)	32.57 (6.68)	29.24 (7.67)	26.95 (13.03)	28.73 (9.01)	26.47 (16.01)
Hyperarousal	23.81 (5.02)	24.74 (6.13)	19.78 (7.16)	23.00 (8.07)	21.27 (6.54)	19.73 (9.48)
Percent days used alcohol	.33 (.31)	.51 (.40)	.20 (.25)	.34 (.39)	.31 (.39)	.35 (.41)
Percent days used drugs	.25 (.37)	.26 (.39)	.16 (.30)	.24 (.41)	.21 (.38)	.29 (.44)
Percent days abstinent	.47 (.35)	.35 (.35)	.67 (.32)	.49 (.43)	.50 (.42)	.45 (.43)
ASI alcohol composite	.31 (.22)	.41 (.28)	.27 (.23)	.32 (.23)	.34 (.25)	.28 (.23)
ASI drug composite	.12 (.16)	.10 (.11)	.06 (.09)	.09 (.09)	.08 (.11)	.06 (.09)
Positive toxicology results	4 (19.0%)	5 (21.4%)	2 (11.8%)	3 (17.6%)	1 (10.3%)	4 (24.1%)

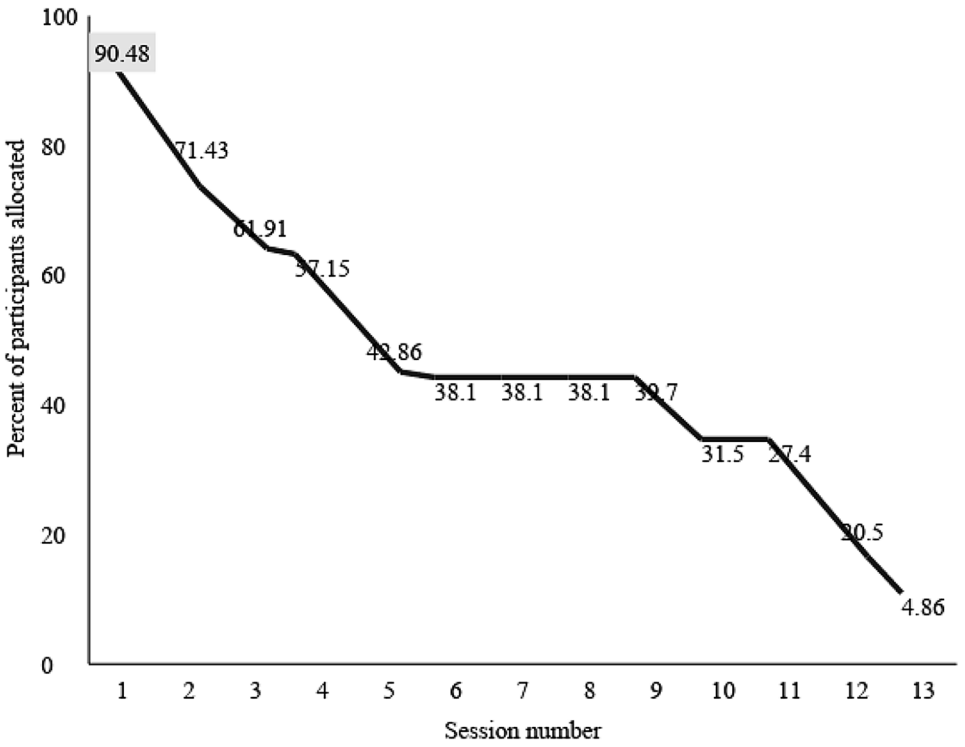

Fig. 2 ICBT session attendance by participants randomized to ICBT

Completer Analyses

Given the low rates of treatment completion among participants enrolled in the ICBT condition, we also ran a series of linear mixed models to evaluate the presence of time and time-by-completer status interaction effects on dependent measures of interest. No significant time-by-completer interaction effects emerged, although the interaction effects for ASI alcohol and drug composite scores approached significance. In addition, significant time effects ($p < .05$) were found for all PTSD symptom variables: CAPS total score, $F(2, 21) = 7.67$, $p = .003$; re-experiencing, $F(2, 14.00) = 11.62$, $p = .001$; avoidance/numbing, $F(2, 17.12) = 4.44$, $p = .028$; hyperarousal, $F(2, 16.91) = 7.67$, $p = .004$.

Discussion

This study represents the first randomized clinical trial of ICBT with military veterans. Although ICBT has demonstrated efficacy with civilians, we found limited evidence of

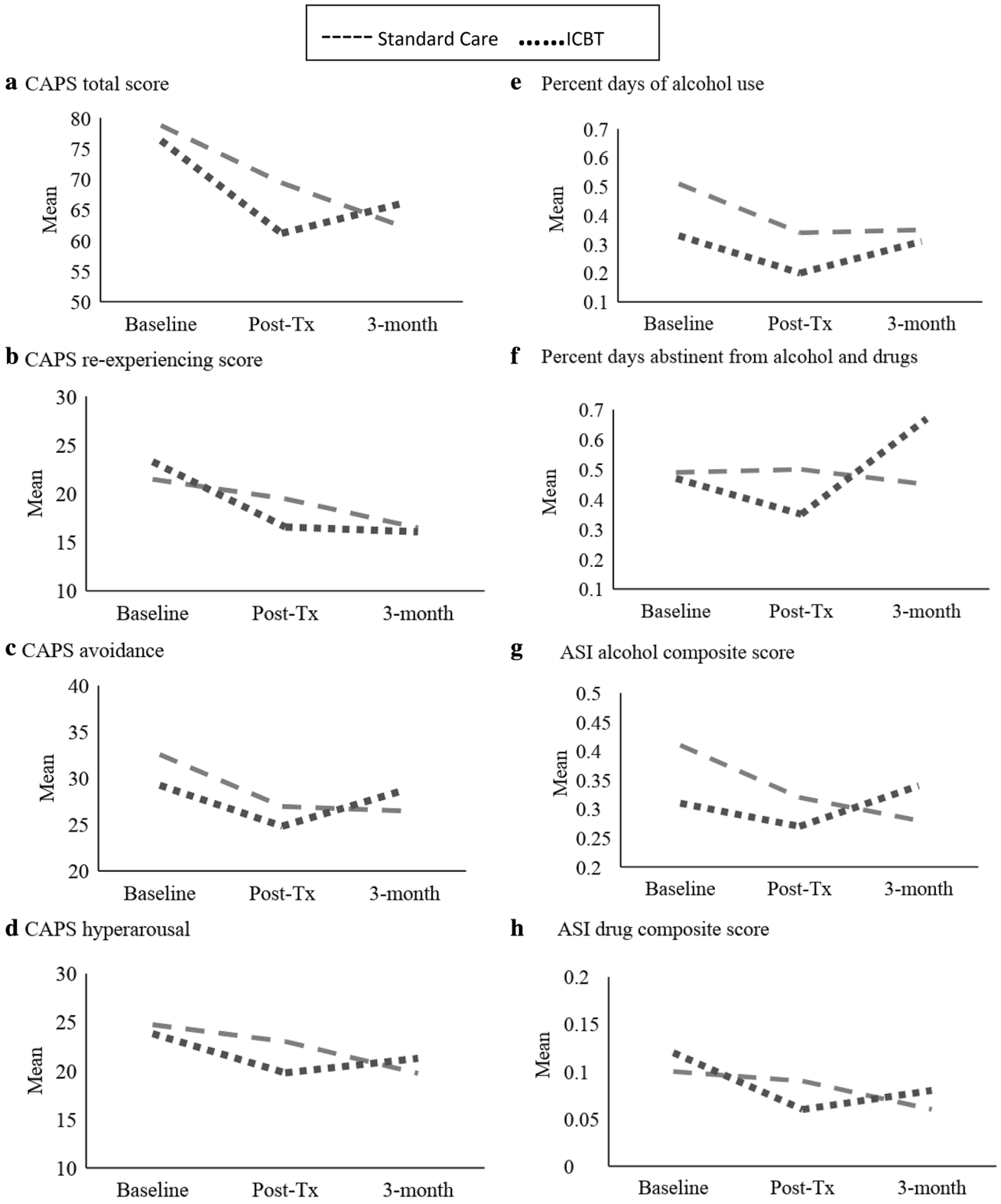

Fig. 3 Changes in primary outcomes by treatment type ($n = 44$)

efficacy using our adapted version with a veteran sample. We did find decreases in PTSD symptoms and alcohol and other substance use over time, but contrary to our hypotheses, only one significant time-by-condition interaction effect emerged. Specifically, consistent with prior work on ICBT (McGovern et al. 2011), we found that ICBT plus TAU participants experienced significant reductions in re-experiencing symptoms between baseline and post-treatment and baseline and 3-month follow-up relative to the TAU only condition. It is possible that veterans who received ICBT acquired skills (e.g. breathing retraining, cognitive restructuring) to more effectively manage distressing reminders of traumatic events. Alternatively, it is possible that simply engaging in the treatment, though not specifically focused on targeting trauma memories (e.g. by exposure), may have facilitated improvement in re-experiencing symptoms. Future research with larger samples should further examine treatment effects on PTSD symptom clusters.

Despite a growing number of clinical trials investigating treatment of comorbid PTSD-SUD, this population continues to pose treatment challenges. Even PTSD treatments with the largest evidence base (i.e., trauma focused approaches) have shown limited efficacy among patients with co-occurring SUD (e.g., Foa et al. 2013). Further, it remains an open empirical question as to whether there are facets of veterans' experiences and/or military-related traumas that are not as amenable to existing treatments (Barrera et al. 2013). As noted by Steenkamp and Litz (2013), the nature of deployment-related traumas may require different or adjunctive treatment approaches. Our findings may suggest that ICBT as delivered, despite tailoring to veterans, did not sufficiently attend to the complexity, or uniqueness, of military-related PTSD or its comorbidity with alcohol and substance use.

More broadly, our findings echo the challenges of engaging and retaining OEF/OIF/OND veterans in psychotherapy that have been well documented. OEF/OIF/OND veterans drop out of treatment at high rates and for a variety of personal (e.g., work obligations, confidentiality concerns) and treatment-related reasons (e.g., stigma, perceived ineffectiveness) (Hoge et al. 2014). Our inclusion of veterans with active SUDs likely added to attrition, yet is reflective of real world treatment implementation.

It is notable that our dropout rate was higher than that found in other studies of integrated PTSD-SUD treatments. Recent studies of COPE (Szafranski et al. 2017) and Seeking Safety (Najavits et al. 2018) with veterans reported higher rates of treatment completion using individual format. It is possible that our use of a combined individual/group format contributed to the dropout rate we observed. Indeed, previous ICBT trials (with non-veteran samples) using individual format showed higher retention rates. A recent systematic review of integrated treatments for co-occurring PTSD-SUD did not find evidence to support the effectiveness of group treatments (Roberts et al. 2015). Likewise, Resick and colleagues (2017) found less efficacy of CPT delivered in group versus individual format among active duty military personnel.

On the other hand, we were able to retain the majority of participants during the transition from individual to group sessions. Furthermore, qualitative feedback on reasons for drop out did not implicate the group format specifically and our sample encountered many other challenges to engagement (e.g., need for detox or acute hospitalizations related to substance use). As such, establishing whether an integrated CBT group format, or hybrid approach, is feasible and efficacious in treating veterans with this comorbidity requires further study.

Strengths and Limitations

In addition to the strengths of this study, namely the randomized design, use of gold-standard diagnostic interviews, and inclusion of a clinically representative sample of veterans with PTSD-SUD, several limitations should be considered. Our sample size was small, due in part to the challenges of engaging this population in mental health treatment; therefore, we had limited power for detecting differences across treatment conditions. In turn, this may limit the generalizability of our findings to the larger population of OEF/OIF/OND veterans. Similarly, our sample lacked racial and ethnic diversity, and was predominantly male, further limiting generalizability.

Our use of group format, while novel for ICBT, may also represent a limitation. Due to challenges related to engaging and retaining veterans in ICBT, the size of groups when available was quite small, typically about three participants, and occasionally the group content had to be delivered in individual format. As such, varying size hindered our ability to evaluate the effectiveness of the treatment in group format.

Finally, the TAU condition may be viewed as a limitation in that it was heterogeneous and in many cases quite active. We elected to allow veterans to continue receiving their usual care in order to examine the additive benefit of an integrated cognitive behavioral psychotherapy for PTSD-SUD, as this is not standard care in VA settings. However, it is possible that the additional PTSD and/or SUD treatment that the veterans in our study were receiving diluted observable treatment effects of ICBT.

Conclusions

In sum, we found greater reduction of re-experiencing symptoms with ICBT, relative to standard VA care alone, in a small sample of veterans returning from Iraq

and Afghanistan with co-occurring PTSD-SUD. Future research with this population should consider adding a motivational enhancement component to bolster treatment engagement. Additionally, research that incorporates technologies (i.e. telehealth, apps) to enhance treatment delivery and reduce barriers to care is warranted with this high-risk population. Our findings contribute to the growing body of literature evaluating integrated treatments for co-occurring PTSD-SUD in routine care settings. These data further underscore the challenges inherent in treating veterans with comorbid PTSD-SUD, and the need to improve existing approaches and develop novel interventions that will enhance treatment outcomes.

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Compliance with Ethical Standards

Conflict of interest Christy Capone, Candice Presseau, Elizabeth Saunders, Erica Eaton, Jessica Hamblen and Mark McGovern declare that they have no conflicts of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

Animal Rights This article does not contain any studies with animals performed by any of the authors.

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