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Web-delivered CBT reduces heavy drinking in OEF-OIF veterans in primary care with symptomatic substance use and PTSD

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Abstract

Veterans from conflicts such as the wars in Iraq and Afghanistan commonly return with behavioral health problems, including Post-Traumatic Stress Disorder (PTSD) and hazardous or harmful substance use. Unfortunately, many veterans experience significant barriers to receiving evidence-based treatment, including poor treatment motivation, concerns about stigma, and lack of access to appropriate care. To address this need, the current study developed and evaluated a web-based self-management intervention based on cognitive behavioral therapy (CBT), targeting PTSD symptoms and hazardous substance use in a group of symptomatic combat veterans enrolled in VA primary care. Veterans with PTSD/subthreshold PTSD and hazardous substance use were randomized to primary care treatment as usual (TAU; n=81) or to TAU plus a web-based CBT intervention called Thinking Forward (n=81). Thinking Forward consisted of 24 sections (approximately 20 minutes each), accessible over 12 weeks. Participants completed baseline and 4-, 8-, 12-, 16- and 24-week follow-up assessments. Three primary outcomes of PTSD, alcohol and other drug use, and quality of life were examined. Significant treatment effects were found for heavy drinking, but not for PTSD or quality of life. The effect of the intervention on heavy drinking was mediated by intervening increases in coping, social support, self-efficacy, and hope for the future. These results demonstrate the promise of a web-based, self-management intervention for difficult-to-engage OEF/OIF veterans with behavioral health and substance use concerns.

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Keywords

technology; intervention; veterans; PTSD; alcohol; substance abuse; CBT

Introduction

Over 2.5 million US soldiers have served in military efforts in or near Afghanistan (Operation Enduring Freedom; OEF) or Iraq (Operation Iraqi Freedom; OIF; Operation New Dawn, OND). Often, soldiers experience significant stressors during deployment that result in mental health or substance use problems. In fact, over two thirds (69%) of OEF/OIF veterans seeking services at Veterans' Administration (VA) medical centers screened positive for a behavioral health problem (Seal et al., 2009), with over half (53%) of OEF/OIF veterans screening positive for PTSD (Helmer et al., 2009) and 23-27% screening positive for hazardous alcohol use (Jakupcak, et al., 2008; McDevitt-Murphy et al., 2010). Rates of comorbidity are high in OEF/OIF veterans; 63% of recent combat veterans with alcohol use disorder also have PTSD (Seal et al., 2010). Drug misuse (particularly opioids), depression, and chronic pain also are elevated among OEF/OIF veterans (Helmer et al., 2009; Seal et al., 2009). Further, the presence of these behavioral health concerns is associated with significant impairment in multiple areas, including increased suicide risk, poorer psychosocial functioning, poorer physical health, and poorer work productivity, all of which are associated with significant public health costs (Hoge, et al., 2007; Jakupcak et al., 2008; McDevitt-Murphy et al., 2010).

The high comorbidity of PTSD and hazardous substance use in OEF/OIF veterans is complicated by their reciprocal effect on each other. Individuals may self-medicate PTSD symptoms and hazardous alcohol or other drug use may place individuals at higher risk for exposure to trauma, hinder their ability to process or resolve trauma, or exacerbate certain PTSD symptoms (Jacobsen, Southwick, & Kosten, 2001; Khantzian, 1997). Given the complexity of the relationship between PTSD and substance use and the high levels of comorbidity, integrated treatment approaches are indicated. In addition, a large portion of veterans with comorbid PTSD and substance use disorders (SUD) report that they would prefer an integrated, rather than a sequential or separate, treatment approach (Back, Brady, Jaanimagi, & Jackson, 2006). Several face-to-face integrated approaches have been developed and tested, with some positive results (see McCauley, et al., 2012; McGovern, et al., 2011; Prins, Cimpean, & Schnurr, 2009) for a review.

An additional challenge in providing treatment for co-occurring PTSD and hazardous substance use is that many OEF/OIF veterans do not seek behavioral health treatment: only half who screened positive for PTSD and 18% who screened positive for hazardous alcohol use report using any type of behavioral health treatment (Erbes, Westermeyer, Engdahl, & Johnsen, 2007). Veterans have identified many treatment barriers, including poor confidence in treatment effectiveness, fear of increasing symptoms, stigma, practical barriers (e.g., transportation, treatment availability), and avoidance symptoms characteristic of PTSD (Hoge et al., 2004; Pietrzak, et al., 2009b; Stecker, McGovern, & Herr, 2012).

Two strategies to help engage veterans in care are to provide behavioral health services within easy to access settings, such as primary care, and to use technology to allow veterans to engage outside of formal treatment settings. Veterans with mental health problems often present in primary care clinics for routine care providing an opportunity for intervention at this level of care (Zlotnick et al., 2004). Technology-delivered interventions have demonstrated feasibility and are acceptable within a variety of populations, including those with PTSD, hazardous substance use, and military personnel (Grubaugh, et al., 2008; Marsch, 2011; Wilson, et al., 2008). Developing novel treatments that can be delivered remotely may be of particular importance in addressing PTSD, as individuals with this diagnosis may be more likely to reside in more remote, less populated areas in order to reduce overstimulation, hyperarousal, and interpersonal conflict (Morland, Frueh, Pierce, & Miyahira, 2003). Computer-delivered CBT interventions to target PTSD (Klein et al., 2010; Roy-Byrne et al., 2010) and SUD (Bickel, Marsch, Buchhalter, & Badger, 2008; Carroll et al., 2009) have been found to be efficacious, including interventions targeting hazardous alcohol use (Riper et al., 2011) and PTSD (Litz et al., 2007) among veterans.

One published study reported on an 8-session, web-based CBT intervention for veterans who reported hazardous drinking; Brief and colleagues (2013) reported that participants in the VetChange intervention showed significant decreases in self-reported drinking and PTSD symptoms. Although the Brief et al. study suggests that a web-based CBT intervention holds promise for veterans with hazardous substance use and PTSD, it is important to note that the VetChange intervention targeted hazardous drinking in veterans and did not specifically address PTSD, either for inclusion in the study or in the intervention content, whereas the current intervention is meant to fill the need for an integrated treatment of hazardous alcohol and other drug use and PTSD symptoms among OEF/OIF veterans. In addition, Brief et al. recruited participants from the internet and relied solely on online self-report assessments for data collection, while the current study used rigorous in-person interviews for data collection (including self-reports from collaterals as a validity check) and recruited non-treatment seeking persons with clinically elevated levels of PTSD and substance use from primary care settings.

The primary aim of this clinical trial was to test an intervention designed to increase access to and engagement in CBT, as well as deliver a reliable and low cost treatment that did not increase demand on providers' time or training. A detailed description of our iterative development process involving both veteran and behavioral health clinician input has been reported (Possemato et al., 2015). Due to name overlap with another web-based program for veterans, we have changed the name of the program from "Coming Home and Moving Forward" to "Thinking Forward". The current article describes the evaluation of the Thinking Forward intervention in a randomized clinical trial.

A secondary aim of our research was to investigate theorized mediators of treatment outcome. It was hypothesized that deficits in the ability to cope with life stress maintain hazardous alcohol and drug use and psychiatric symptoms. CBT teaches coping skills and aims to increase self-efficacy for positive coping, helping people more successfully manage stressors, including high-risk situations for substance use. The acquisition of coping skills and self-efficacy has often been shown to be mechanisms of change in CBT (Hendricks,

Delucchi, & Hall, 2010; Litt, Kadden, Kabela-Cormier, & Petry, 2008), including one study that showed that coping mediated the effect of a computer-delivered CBT intervention on substance use outcomes (Kiluk, Nich, Babuscio, & Carroll, 2010). In addition to improving coping, CBT also focuses on restructuring dysfunctional cognitions (e.g., Beck, 1997). Research has shown that changes in dysfunctional cognitions mediate the effects of CBT on PTSD (Kleim et al., 2013; Muresan et al., 2012).

In addition to CBT-specific mediators, we also were interested in testing purported mechanisms of change, such as positive social support, hope for the future, readiness to change, and therapeutic alliance, that have been shown to correlate with treatment outcomes across a number of different treatment modalities targeting both substance use and psychiatric symptoms (e.g., Dunn, Deroo, & Rivara, 2001; Stein et al., 2009; Kaskutas, Bond, & Humphreys, 2002; Magura et al., 2003; Morgenstern, Labouvie, McCrady, Kahler, & Frey, 1997; Knaevelsrud & Maercker, 2007). One possible mediator that has recently received attention in treatments focused on combat veterans is resilience. Resilience is often defined as having the coping resources to thrive in the face of adversity. CBT is thought to foster resilience by teaching skills that enable emotional awareness and stability, positive social interactions, and effective coping strategies (Lee, Sudom, & Zamorski, 2013). Resilience has been found to mediate the association between post-deployment stressors and behavioral health outcomes (Wooten, 2012).

Given the existing theory and research described above, we selected several variables to test as potential mediators of our novel intervention. Coping responses and self-efficacy were selected based on our use of core CBT strategies, including cognitive restructuring, functional analysis of substance use, and problem solving. Thinking Forward also has a specific focus on readiness for change (module 2) and social support (Communicating with Others Module and Preventing Stress from Ruining Relationships Module). Additionally, hope for the future and resilience were selected as potential mediators, consistent with the overarching theme of Thinking Forward being a strength-based approach focused on healthy re-integration, and therapeutic alliance has been shown to mediate the effects of a variety of interventions (Maisto, et al., 2015).

Method

Participants

The trial was registered at ClinicalTrials.gov (NCT01710943) and was approved by the Syracuse VAMC, Western New York VAMC, Syracuse University, and National Development Research Institutes Institutional Review Boards. Veterans ($N=162$) were recruited from primary care clinics in four VA facilities. To be included in the trial, participants needed to be OEF/OIF/OND veterans; report hazardous alcohol on the AUDIT (score ≥ 8 for men, ≥ 7 for woman; Babor, Higgins-Biddle, Saunders, & Monteiro, 2001) or substance misuse on the DAST-10 (score ≥ 2 ; Skinner, 1982); and report symptoms consistent with at least subthreshold PTSD (a military-related traumatic life event plus, at least, 1 re-experiencing symptom, 3 avoidance symptoms or 2 hyperarousal symptoms) on the Clinician Administered PTSD Scale (Blake et al., 1995). Participants who were currently receiving psychotherapy for PTSD or had incurred a change in dose or type of a psychiatric

medication that treats PTSD or a substance use disorder in the last two months were excluded from participation. Also, veterans in need of inpatient substance detoxification, who had a plan to harm themselves, or who had documentation of a psychotic disorder or moderate to severe traumatic brain injury in their VA medical chart were excluded.

Veterans were referred to the study by primary care providers or OEF/OIF/OND case managers. Referrals were facilitated by a case-finding protocol: using the electronic medical records, study staff generated lists of OEF/OIF/OND veterans who had screened positive on the standard screens delivered in VA primary care for hazardous alcohol use and PTSD (i.e., Audit-C and PC-PTSD). Research staff asked primary care providers to refer patients who screened positive. Referred patients were sent a letter in the mail introducing the study then telephoned and screened for combat stress reactions and current substance use. Recruitment letters and phone screens described the treatment as focusing on PTSD symptoms and hazardous substance use. Interested veterans were invited to come their local VA to complete the baseline interview.

Procedure

At the baseline interview, informed consent was administered. Then, participants were assessed for suicidality, hazardous alcohol or other drug use, and PTSD symptoms to determine eligibility. Eligible participants then completed the rest of the baseline assessment (described next) and were randomly assigned to Treatment as Usual (TAU) or TAU plus Thinking Forward. Permuted-block randomization was used to randomize participants based on whether or not they met DSM-IV criteria for a current alcohol or other drug abuse or dependence (as measured by the MINI) and diagnostic or subthreshold PTSD (as measured by the CAPS). Participants were assessed at baseline, weeks 4, 8 and 12 during the active intervention phase, and at 16 and 24 weeks (i.e., 1 and 3 month post-intervention follow-ups). Participants were compensated for the time they spent completing assessments at a rate of approximately \$25/ hour and could earn up to \$290 for completing all assessments. Participants were not compensated for completing treatment modules.

Measures

Four measures were used to assess eligibility and baseline health status. The Clinical Administered PTSD Scale (CAPS) assessed the 17 core symptoms of PTSD as defined in the DSM-IV in an interview format (Blake et al., 1995). Each symptom was scored separately on a five-point scale for frequency and intensity. A rating of at least 1 for frequency and 2 for intensity of PTSD symptoms on the CAPS were defined as “endorsed”. The CAPS is reliable and has excellent diagnostic utility compared to the SCID PTSD module. This measure was used to verify the presence of a criterion A traumatic event and document rates of full and subthreshold PTSD. Subthreshold PTSD was defined as meeting DSM-IV criterion B (re-experiencing) and either criterion C (avoidance) or criterion D (arousal), plus meeting criterion E (duration) and F (functional impairment; Schnurr, Lunney, Sengupta, & Spiro, 2005). All interviewers were trained and received in-person supervision from a licensed clinical psychologist for every baseline CAPS interview. In supervision, endorsed symptoms and item ratings were discussed and interview ratings were changed if the original rating was considered to be not accurate by the supervisor. Because

of this supervisor consensus method, inter-rater reliability ratings were not conducted for this study. The Alcohol Use Disorders Identification Test (AUDIT); (Babor et al., 2001) screened for hazardous alcohol use at baseline. Patients had to score 8 or higher for men and 7 or higher for women to be eligible for inclusion in the trial. The AUDIT is reliable, valid, and had acceptable internal consistency in this study ($\alpha=.75$). The Drug Abuse Screening Test-10 (DAST-10); (Skinner, 1982) was used to determine if patients met criteria for hazardous drug use at baseline as defined by a score of 2 or higher. The DAST-10 discriminates between persons with or without drug use disorders and has acceptable internal consistency in this study ($\alpha=.73$). The MINI International Neuropsychiatric Interview (MINI) assessed for DSM-IV substance use disorders and was administered in a computerized, self-report format. The MINI has comparable validity to well-established structured clinical interviews (Sheehan, 2004).

Three measures were used to assess the primary study outcomes and were administered at each time point. The Timeline Follow-Back (TLFB) interview assessed self-reported substance use using calendars to record past daily alcohol use in standardized drink quantities and use of other drugs (e.g., cocaine, opiates, cannabis) for the previous 90 days at baseline and since the last assessment at follow-ups. Primary outcomes derived were percent of drinking days, percent of heavy drinking days, and percent of drug use days. “Heavy” drinking was defined according to U.S. National Institute on Alcohol Abuse and Alcoholism criteria of 4 or more standard drinks on an occasion for women and 5 or more for men, with a standard drink defined as a beverage containing the equivalent of .6 ounce of pure alcohol. The primary alcohol outcomes of frequency of alcohol use and the frequency of heavy use are based on the reasoning that both of these dimensions, which tend to be weakly correlated, when combined predict the occurrence of alcohol-related problems (Babor, Longabaugh, Zweben, Fuller, Stout, Anton, & Randall, 1994; Project MATCH Research Group, 1998). The TLFB has good psychometric properties, including test-retest reliability and high content, criterion, and construct validity across multiple related measures (Sobell & Sobell, 2000). Participants were asked to provide a collateral informant who was contacted once by phone to provide information about past daily alcohol and other drug use over the previous month. Collaterals were randomly assigned to be contacted at baseline or one of the follow-up points. These data were compared to the participants’ self-report of past alcohol and other drug use. The PTSD Checklist- Military (PCL-M) asked respondents to self-report how much they have been bothered by 17 PTSD symptoms in the past month on a 5-point scale. The PCL-M is reliable, valid, (Weathers, 1996) and had good internal consistency in this study ($\alpha=.76$). The total score was used as the primary PTSD outcome. The WHOQOL-BREF was used to measure quality of life, life satisfaction, and personal well-being with 26-items assessing the broad domains of physical health, psychological health, social relationships and environmental factors (e.g., finances, safety) (Murphy, Herrman, Hawthorne, Pinzone, & Evert, 2000). This measure is reliable, valid, and has good internal consistency in this study ($\alpha=.85$). The domain scores were used as the QOL outcome measures.

Several self-report measures were administered at pre and post treatment. Changes scores for each measure were computed as mediators of treatment outcome. The Coping Strategies Scale (CSS) – Brief Version (Litt, Kadden, Cooney, & Kabela, 2003) assesses change

processes and skills taught in coping-skills treatment, such as problem solving and dealing with urges to use substances. Twenty-three items are rated on a 4-point scale for how often each strategy is used to help avoid substance use. This measure has good predictive validity, as total coping skills has been found to be related to reduced drinking (Litt et al., 2003) and good internal consistency reliability in this sample (.87). The total coping scale was used in this study. Medical Outcomes Study Social Support Scale (MOS-SSS) measures how often specific types of social support are available to participants, with 19 items rated on a 5-point scale. The measure has construct validity (Sherbourne & Stewart, 1991) and high internal consistency reliability in this sample (.96). The Brief Situational Confidence Questionnaire (BSCQ) (Breslin, Sobell, Sobell, & Agrawal, 2000) measures self-efficacy, that is how confident participants are in their ability to resist heavy drinking across eight high-risk situations on a 0% to 100% scale. The questionnaire has good test-retest reliability (Conditte & Lichtenstein, 1981) and had good internal consistency reliability in our sample (.90). The Future Scale (Hellstrom, Jansson, & Carlsson, 1999) measures expectations about the future on two scales (Explicit and Implicit, 5-items each, rated on 7-point scales) representing the degree that the future is perceived to be comprehensible, manageable, and meaningful. Hellstrom, Jansson, and Carlsson (2000) found an internal consistency of 0.80 for the full Future Scale and the reliability (Cronbach's α) for each subscale was 0.52 and 0.75, respectively. The current study examined only the Explicit Future Scale. Readiness to Change Questionnaire (RTCQ) is a 12-item questionnaire for assignment of hazardous drinkers to pre-contemplation, contemplation, or action stages (Rollnick, Heather, Gold, & Hall, 1992). The measure has good predictive validity with drinking outcomes and adequate internal consistency reliability (.66) in the current sample. The Connor-Davidson Resilience Scale (CD-RISC) measures resiliency, with 25 items rated on a 5-point scale. The scale has high test-retest reliability, convergent validity, and discriminant validity (Connor & Davidson, 2003). Internal consistency reliability in this sample was good at .88.

Intervention

Treatment as Usual (TAU) consisted of the usual VA primary care services, including medical, behavioral health, pharmacy, weight management and social work services. Behavioral health providers are integrated into the primary care team to provide consultation to medical staff and brief assessment and interventions to referred patients. Treatment utilization among the participants was quite low overall, so we compared treatment visits and prescribed psychiatric medications for participants in the web-based intervention group to visits and medications for participants in TAU across the 24-week study period. On average, participants received less than one primary care visit, slightly more than one mental health visit, and less than one psychiatric medication. The experimental and control conditions did not significantly differ in the amount of care they received. Table A1 is a summary of the number of primary care and mental health visits and psychiatric medications participants received as part of treatment as usual during their six months of active study participation.

TAU Plus Thinking Forward—Participants randomized to the enhanced condition were shown how to access the Thinking Forward web-based program at the end of the baseline assessment session. The program was self-directed, with the first module teaching

participants how to use it. The program contained 24 modules housed within a homepage (Figure 1). Modules were self-paced, with each module taking approximately 20 minutes to complete. Participants were asked to complete the 12 “core modules” in the first six weeks of treatment then to re-visit important modules and complete additional modules of their choice during weeks 7-12. Modules included interactive exercises and veteran stories that illustrate common symptoms and coping strategies. They were designed to teach a variety of cognitive behavioral skills, such as identifying, evaluating and challenging negative automatic thoughts related to PTSD symptoms and doing a functional analysis of problematic alcohol or other drug use. Relaxation and emotional centering modules were included to provide specific skills for managing trauma-related distress. Other modules, although not specific to trauma, drew connections between trauma and conditions such as insomnia, pain, and communications problems, and used examples of veterans with PTSD symptoms. Also, included in the program are recurring queries assessing problematic substance use and trauma symptoms, graphs showing progress made in these areas, a printable workbook containing key points and fillable copies of exercises from each program modules, and a resources page see Possemato et al. (2015) for more detail). Participants accessed the program using a unique login and password. Modules were typically completed at home but participants could opt to complete them in a private room at their local VA. The program also had a back-end system, which allowed research staff to track module completion. Participants who did not complete at least one module per week were contacted by research staff once per week for the first 4 weeks and twice per month for weeks 5-12. Participants were prompted to engage in the treatment via phone calls, text messages, and in-person reminders when they were meeting with research staff to complete study assessments. In an attempt to increase participants’ use of the modules, this strategy was changed after enrolling 24 participants to add a daily reminder call for the first three days to complete the first module.

Analytic Plan

Treatment groups were compared for differences on demographic and other baseline characteristics using bivariate correlations, Wilcoxon Rank Sum Tests for non-normal variables, and chi-square tests for categorical measures. Baseline characteristics examined as potential covariates included age, gender, race, ethnicity, education, employment, and combat experiences. One baseline covariate, post-deployment life events was significantly different between treatment conditions and related to most of the outcomes, thus this covariate was included in both primary and mediation analyses as a control. Analyses included all randomized participants independent of early dropout, consistent with an intent-to-treat approach, and were performed using SAS statistical software.

To assess the intervention effects observed during the treatment period (baseline, 4, 8 and 12 weeks), and the durability or emergence of effects during 1- and 3-month post-intervention follow-up period, we used generalized mixed-effects piecewise regression models. Intervention type (Thinking Forward vs. TAU), two time variables (time 1 - effect of time during the treatment period, time 2 – effect of time during the post-intervention period), and their interaction terms (intervention condition-by-time 1 and intervention condition-by-time 2) were specified for the model. Significant time effects reflect an improvement for all

participants on average, and significant interactions reflect an intervention effect (positive changes over time for participants in Thinking Forward relative to TAU). Random intercept and slope were included to account for across time correlations due to repeated measurements. Analyses were conducted with SAS PROC GLIMMIX (SAS Institute Inc., 2015). The current study attempted to address two empirical questions: 1) whether the intervention changed outcomes during the intervention period (baseline to 12 weeks); and 2) whether intervention effects differed between the intervention period and the post-intervention period. Specifically, we were interested in examining potential emergent (i.e., sleeper), or diminishing treatment effects after the active treatment period had ended. Our piecewise model, though less traditional than a straight longitudinal model, allowed us to address these two questions within one modeling framework.

Our mediation analyses focused on outcomes for which we found significant intervention effects during the in-treatment period. Although a significant intervention effect is not a prerequisite for mediation analysis because it is possible for an entire intervention effect to be “transmitted” to the outcome indirectly (Hayes, 2013; MacKinnon, 2008), we did not find this to be the case in our preliminary analyses. Moreover, because there were no significant differences for outcomes that showed intervention effects when comparing the in-treatment to post-treatment periods, our mediation analyses were conducted only for outcomes during the 12 week in-treatment study period. Lastly, because not all putative mediators were assessed at all assessment points, change scores from baseline to 12 weeks for both outcomes and the mediators were used for mediation analysis. We conducted univariate mediation analysis to assess mediated effect individually then multivariable mediation analyses to evaluate mediated effects by all mediators collectively. Significance of the mediated effects was tested using bias-corrected bootstrapping confidence intervals due to an asymmetric distribution. We also inferred mediated effects by comparing “total effect” (treatment effect without mediators) with “direct effect” (intervention effect when mediators were included in the model). If a total effect was significant and a direct effect was non-significant when the mediator was entered into the model, we assumed that this was a demonstration of complete mediation. If the magnitude of effect was smaller for the direct effect than for the total effect, we considered this to be partial mediation (MacKinnon, 2008). All mediation analyses were conducted using a SAS macro suite “PROCESS” (Hayes, 2013).

Finally, chi-square analyses were conducted to examine rates of clinically significant change by treatment group in PTSD symptoms, as determined by a 10 point decrease in score from baseline to 12 week and baseline to 3 month follow-up (10 points is recommended as a minimum threshold for determining whether improvement is clinically meaningful using the PCL; Weathers et al., 2013) and by a change from clinically elevated score (≥ 50) to a non-clinically elevated score (Weather et al., 2013).

Results

Participant characteristics

A total of 217 veterans were assessed in-person and, consistent with the proposed study protocol, 162 were randomized to either Web CBT (N=81) or TAU (N=81); see CONSORT

Diagram for participant progress through the phases of the trial (Figure 2). The overwhelming majority were male (93%) and identified themselves as White (85%) and non-Hispanic (94%). Average age was 34 (SD 8.1, range=22-64). Slightly more than half (52%) had post-secondary education or a trade school certification; 55% reported they were receiving some type of disability and 62% were working full or part time. Almost half (n=78, 48%) met criteria for a current alcohol use disorder. Based on TLFB data the mean (SD) was 24% (SD = 25%) heavy drinking days, 2.79 (SD = 2.55) drinks/day, 47% (SD = 30%) drinking days, and 5.60 (SD = 3.46) drinks/drinking days, and 15% (SD = 31%) drug use days. Most participants (128, 79%) met criteria for diagnostic-level PTSD on the CAPS, with the remainder having subthreshold PTSD symptoms. Means and SD for the major outcomes derived from the TLFB, PCL, and WHO can be found in Table A2. There were no significant baseline differences between treatment conditions on any variable.

Thinking Forward intervention and feedback

Mean number of total modules completed was 8.8 (6.2). Participants provided intervention feedback on seven visual analog scales, ranging from 0 (poor) to 10 (excellent). Seventy-six percent of participants rated the intervention >5 for “interesting”, 82% for “useful”, 74% for “new information learned”, 67% for “clarified misconceptions about PTSD”, 62% for “clarified misconceptions about substance use”, 41% for “easy to understand”, and 89% for overall satisfaction with the program. Over a third of participants (38.3%) completed all 11 core modules, which is consistent with other interventions of this type (e.g., Brief et al., 2013). A figure showing the percent of participants who accessed each module can be found in the online appendix (Figures A1 and A 2).

Collateral reports

Correlations between TLFB self-reports and collateral reports ranged from .57 (percent heavy drinking day) to .66 (percent drinking days) (all p s < .001). These correlations are consistent with other research in the field comparing TLFB to collateral reports (e.g., .42-.68 for DeMarce et al., 2007; .78-.89 for Fals-Stewart 2000). In addition, participants did not underestimate their drinking or drug use, compared to collateral reports. . Across all drinking outcomes, 36.9% of the patients reported more drinking, 23.0% reported the same amount of drinking, and 39.4% reported less drinking than their collateral contact. For percent of drug use days 5.1% reported more drug use, 83.1% reported the same amount of use, and 21.9% less drug use than their collaterals. Mean differences between participant and collateral reports were quite small, ranging from -1.87 (SD=26.45) for percent drinking days to .56 (SD=18.57) for heavy drinking, and the mean difference in estimated percentage of drug use days was 3.14 (SD=19.00).

Substance use outcomes during intervention

Significant time effects were seen for both percent of drinking days and percent of heavy drinking days during the in-intervention period (Table 1). In addition, Thinking Forward participants reported significantly greater declines in percent of heavy drinking days compared to TAU participants (Figure 3). Effects were maintained in the post-intervention period, as evidenced by a lack of significant differences between the in- and post-intervention periods (Table 1). Thinking Forward participants showed a greater decline in

percent drug use days compared to participants in TAU, but the difference did not reach statistical significance (as indicated by the treatment by time interactions) during the in- or post-treatment periods.

PTSD outcomes

There was no significant treatment by time effect for either of the two PTSD outcomes (change in PTSD severity and clinically significant change in PTSD symptoms). However, there were significant time effects, as all participants improved over time in PTSD severity during the in-treatment period but tended to reverse trend in the post-treatment period compared to the in-treatment period. Regarding clinically significant change in PTSD symptoms, chi-square analyses did not reveal significant differences between treatment groups in the percent of participants who showed clinically meaningful improvement in PTSD symptoms on the PCL (i.e., 10-point decrease) at either 12 weeks (TAU 31.3% vs. intervention 41.0% improved) or 3 month follow-up (TAU 29.7% vs. intervention 37.5% improved). Chi-square analyses also did not show significant differences between treatment groups in the percentage of participants who moved from reporting clinically significant distress on the PCL (i.e., >50) to no longer reporting clinical levels of distress at 12 weeks (TAU 17.9% vs. intervention 22.2%) or 3 month follow up (TAU 23.4% vs. intervention 17.9%).

Quality of life outcomes

For QOL, all participants reported significant improvements in the social and environmental domains during the treatment period, but improvement in social QOL significantly slowed down during the post-treatment period (Table 1). There was no significant effect of treatment on QOL over time.

Completers analyses

We conducted “completers” analysis, including only intervention participants that completed all 12 mandatory modules (n=31 / 81). That is, we fitted the same piecewise model to compare completers in web-CBT intervention and those who received TAU. The results of this analysis showed similar (though more robust and more pronounced) intervention effects for alcohol use (i.e., percent drinking days, percent heavy drinking days) during the 12 weeks’ treatment period, but, similar to the ITT analysis, there were no significant treatment by time differences for the other outcomes (i.e., drug use, PTSD, QOL). In addition, this enhanced effect was not sustained during the post-treatment period. A table summarizing the completers analyses can be found in the online appendix (Table A3).

Mediation analyses

We conducted mediation analyses for heavy drinking, as it was the only outcome showing significant treatment effects during the in-treatment period. Results of the univariate mediation analysis (Table 2) show that self-efficacy, social support, hope for the future, and coping were partial mediators of the treatment effect on percent of heavy drinking days¹. To

¹Complete mediation is not commonly seen in social behavioral studies

assess the collective mediation effect of all six proposed mediators, we also conducted multivariate mediation analyses. For percent of heavy drinking days, the combined mediators had a partial mediation effect: the total treatment effect -6.79 ($p = 0.085$) became -5.57 ($p = 0.125$) after all mediators were included.

Discussion

The current study examined the efficacy of a web-based CBT intervention for OEF/OIF/OND veterans who presented in VA primary care with diagnostic or subthreshold PTSD and hazardous drinking or drug use. Our results show that the Thinking Forward intervention significantly reduced alcohol use (including heavy drinking) among recently returned combat veterans but did not change self-reported levels of PTSD or quality of life. Our positive findings for alcohol use are consistent with a growing literature supporting the efficacy of web-based interventions for substance misuse (e.g., Bickel et al., 2008; Brief et al., 2013; Kathleen M Carroll, 1998; Marsch, 2011). Also, reductions in heavy drinking correspond to our intervention's approach to target "problem drinking", but not advocate for abstinence from alcohol as a treatment goal. This focus on reducing hazardous substance use, and not focusing on abstinence, may also explain why we did not see a significant treatment effect on percent of drinking days. It seems that participants in the treatment condition showed a "harm reduction" type of effect; they did not drink on fewer days, but they drank less on days when they did drink. As noted earlier, reducing the frequency of heavy drinking days, even when the total number of days in which alcohol is consumed does not change, tends to reduce the likelihood of experiencing alcohol-related problems. Interestingly, the same pattern was seen for percent of drug use days as for heavy drinking (Figure A3). However, this effect was not significant, likely due to the low rates of drug use in our sample.

The absence of an intervention effect on PTSD symptoms is counter to a recent meta-analysis finding that web-based CBT interventions for PTSD were superior to passive control conditions (Kuester, Niemeyer, & Knaevelsrud, 2016). It is possible that the self-directed nature of the intervention allowed veterans to selectively attend to problems that were less impacted by avoidance symptoms, which is common in people with PTSD. Newman, Szkodny, Llera, and Przeworski (2011) conducted an extensive review and reported that technology-delivered interventions for substance use that were wholly or predominantly self-administered (as is Thinking Forward) showed efficacy, but that some amount of professional contact is important in maintaining and enhancing the gains made in treatment. The addition of therapeutic contact by mental health clinicians or peer support specialists may enhance the intervention's impact on PTSD symptoms. Another possible reason for non-significant PTSD effects is that only four participants used the module, *Overcoming Trauma Through Exposure* module. Exposure has been identified as one of the most efficacious interventions for PTSD (Bradley, Greene, Russ, Dutra, & Westen, 2005). An intervention effect may have emerged if the exposure module had been a core rather than an optional module. It is also important to note that participants in our sample, though experiencing clinically significant distress associated with PTSD, were not enrolled in or seeking treatment for PTSD. Such individuals may have been reluctant to practice or apply the skills

in the program targeting their PTSD, especially as many had high levels of avoidance around their PTSD symptoms.

Regarding intervention acceptability, with the exception of “easy to understand,” the majority of veterans provided positive feedback across several evaluative domains such as useful, interesting, and clarification of PTSD and substance misuse. It's possible that while the overall intervention was engaging, veterans may have had difficulty fully understanding the cognitive therapy sections of the programs despite the use of the concrete examples and exercises. A more fine-grained examination of response to each program section is needed to improve ease of understanding. Even with a slightly lower rating of ease of understanding, adherence to the intervention was consistent with other technology-based interventions (e.g., Bickel et al., 2008; Brief et al., 2013; Kathleen M Carroll, 1998; Marsch, 2011). Most veterans completed the core intervention content, but there was a drop in engagement with the additional (optional) program sections. Differentiating between core content and additional content may somehow imply to users that the additional content is less important, potent, or easier to ignore.

We also failed to find a treatment effect for change in quality of life. This may have been due to a ceiling effect; veterans in our sample reported high levels of quality of life at baseline, so there was not much opportunity to show improvement on this measure. It is possible the measure we chose was not sensitive enough to capture real changes in our generally well sample, as the WHO-QOLBREF was designed to assess quality of life in chronically ill and other medical populations with much greater life interference as our current sample.

Regarding mechanisms of change for the intervention, our results indicate that self-efficacy, social support, coping, and hope for the future served as partial intervening mediators for reductions in heavy drinking. Self-efficacy has been found to mediate the effects of other web-based CBT interventions for substance misuse (eg. Danaher, Smolkowski, Seeley, & Severson, 2008) while social support is a common mediator in a variety of treatments (Magura et al., 2003). The skills building, strengths-based approach of our web-based CBT may have helped to increase self-efficacy in our veteran sample, and our focus on communication and improving relationships may have fostered improved social support. While we anticipated that Thinking Forward would also foster resilience, we did not find support for this.

One limitation of the current study is the use of self-report data to assess our primary outcome of alcohol and drug use (via TLFB). However, significant, positive correlations between veteran self-reports and collaterals, lack of trend for underreporting compared to collaterals, and very small differences in the amount of use reported strengthen the confidence in the validity of self-reported alcohol use. In addition, the TLFB is a widely used and validated method for assessing alcohol use. Another potential limitation to the current study was the inclusion of veterans reporting subthreshold (and not just diagnostic) PTSD. We chose to include veterans with subthreshold PTSD as they have been shown to exhibit significant functional difficulties, similar to those with diagnostic PTSD, but may be less likely to receive treatment due to lack of a formal diagnosis (Jakupcak et al., 2007; Pietrzak et al., 2009b). A third limitation of the current study was that, given the limits of

our data collection, we were unable to clearly establish temporal precedence in our mediational analyses. Finally, our study drop out may be seen as a limitation despite retaining the majority of our sample through the 3-month follow up (76.5%). Our retention rates are consistent with other treatment studies (e.g., Bickel et al., 2008; Brief et al., 2013; Kathleen M Carroll, 1998; Marsch, 2011), and better than other web-based CBT studies of OEF/OIF veterans (~40% retained at 3-month follow up in Brief et al., 2013). We attempted to mitigate the drop out by employing an ITT approach in our analyses but recognize this is still a limitation of the current study.

Conclusions

The current study demonstrated that a web-based CBT intervention was effective in reducing heavy drinking among OEF/OIF/OND veterans with symptomatic PTSD and hazardous substance use. The impact of the intervention on heavy drinking was mediated by intervening increases in social support, self-efficacy, coping, and hope for the future during the 12-week intervention period. These findings indicate that a web-based, self-management intervention may be useful for engaging and providing treatment to difficult to reach veterans with behavioral health and substance use needs. This type of web-based intervention could be made easily accessible to the many thousands of veterans who need treatment, but are reluctant or unable to receive traditional mental health or substance use treatment. Future research is needed to investigate if adding professional support to web-based treatments may boost their effectiveness in treating PTSD and to determine which aspects of the current treatment are essential to generate the desired improvements in PTSD and substance use outcomes.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Highlights

- A web-based CBT intervention significantly decreased binge drinking in a sample of OEF/OIF veterans with symptomatic PTSD and substance use recruited through VA primary care clinics
- Treatment-related decreases in binge drinking were mediated by intervening increases in coping, social support, self-efficacy, and hope for the future
- Technology-delivered interventions hold promise for providing treatment to difficult-to-reach populations



Figure 1.
Web-based CBT homepage and list of program sections/modules

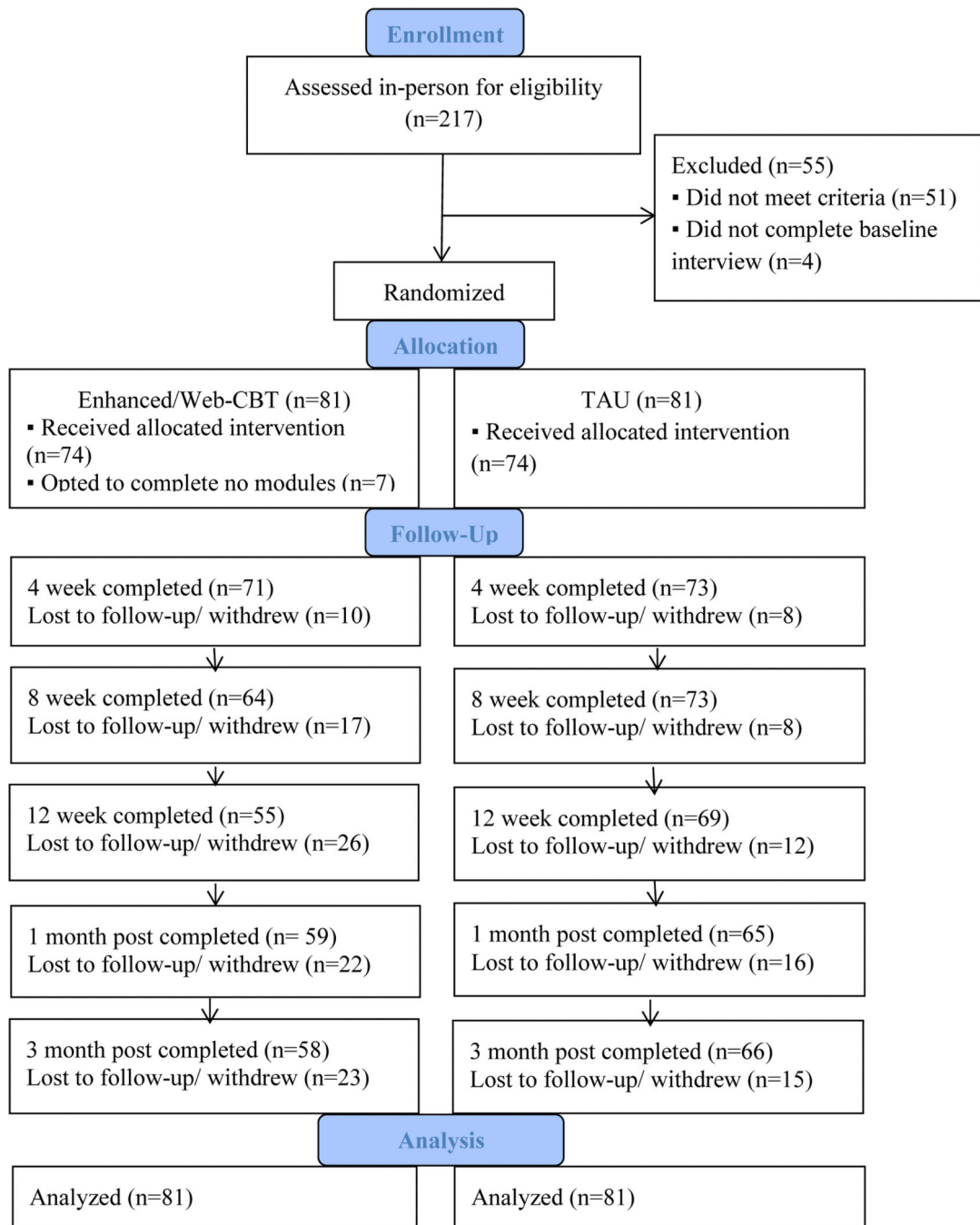
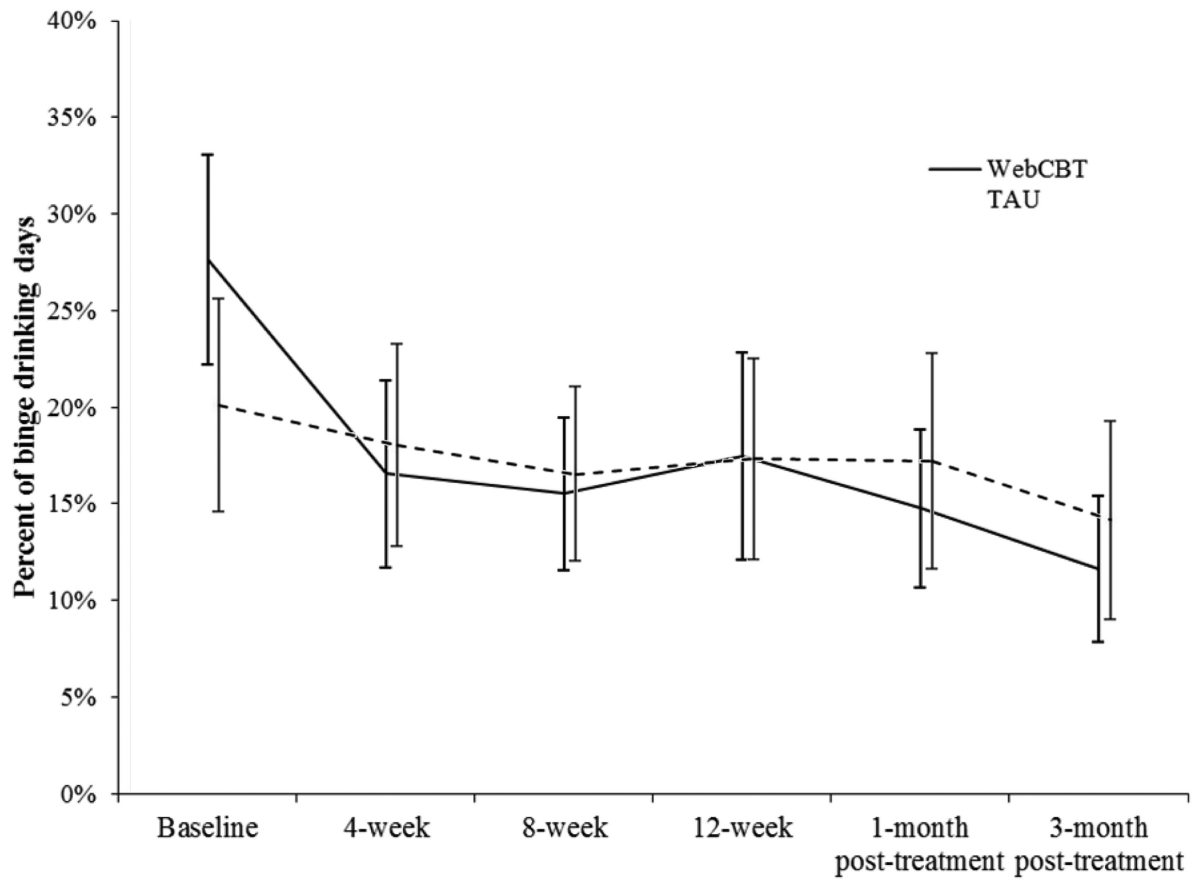


Figure 2.
CONSORT Flow Diagram



* Error bars represent Standard Deviation from the mean score.

Figure 3.
Percent heavy drinking days by treatment condition

Table 1
Results of the outcome analysis using generalized mixed-effects piecewise regression models

	In-treatment period		Contrast between in- and post-treatment periods	
	Treatment effect ¹		Difference in time effect	
	Estimate (s.e.)	Time Effect ² Estimate (s.e.)	Difference in treatment effect Estimate (s.e.)	Difference in time effect Estimate (s.e.)
Percent of drinking days	-0.93 (1.12)	-1.79 (0.56)**	1.67 (1.84)	0.11 (0.92)
Percent of heavy drinking days	-1.80 (0.79)*	-1.87 (0.40)**	1.89 (1.33)	1.22 (0.66)
Percent of drug use days	-0.27 (0.25)	-0.58 (0.12)**	-0.06 (0.49)	0.27 (0.24)
PTSD severity – mean PCL score	-0.09 (0.50)	-1.57 (0.25)**	0.40 (0.82)	1.73 (0.41)**
QOL - Physical domain	0.75 (0.52)	-0.16 (0.26)	-0.51 (0.91)	0.45 (0.46)
QOL - Psychological domain	0.77 (0.58)	0.41 (0.29)	-0.88 (0.94)	-0.28 (0.47)
QOL - Social domain	1.27 (1.02)	2.47 (0.51)**	-2.00 (1.72)	-2.21 (0.86)*
QOL - Environment domain	0.13 (0.61)	0.94 (0.30)**	0.15 (1.02)	-0.39 (0.51)

Notes:

s.e.= standard error

¹Treatment effect was indicated by treatment type by time interaction, that is, the difference between Thinking Forward and TAU in rate of improvement.

²Time effect represents the outcome for all participants regardless of treatment condition.

* p<.05

** p <.01.

Table 2

Results of mediation analysis for percent heavy drinking days using change scores (from Baseline to 12 weeks) for both outcome and mediators

Mediators	Total effect			Direct effect			Indirect effect [#]		
	Coefficient (s.e.)	p-value		Coefficient (s.e.)	p-value		Coefficient	95% Confidence Interval	
Univariate									
Brief Situational Confidence Questionnaire (BSCQ) ^{*p}	-6.73 (3.78)	0.078		-5.62 (3.74)	0.135		-1.11	(-3.23, 0.14)	
Medical Outcomes Study Social Support Scale (MOS-SSS) ^{*p}	-6.67 (3.78)	0.080		-5.35 (3.43)	0.122		-1.32	(-5.07, 1.55)	
Readiness to Change Questionnaire (RTCQ)	-6.72 (3.74)	0.075		-7.10 (3.74)	0.060		0.37	(-0.40, 3.00)	
The Future Scale ^{*p}	-6.72 (3.74)	0.075		-6.10 (3.73)	0.105		-0.62	(-3.21, 0.25)	
The Connor-Davidson Resilience Scale (CD-RISC)	-7.98 (3.57)	0.027		-8.25 (3.47)	0.019		0.27	(-1.50, 2.33)	
The Coping Strategy Scale (CSS) ^{*p}	-7.06 (3.63)	0.055		-5.69 (3.60)	0.117		-1.37	(-4.90, -0.10)	
Multivariate	-5.99 (4.21)	0.156		-5.47 (3.95)	0.169		-0.51	(-6.16, 4.52)	

Notes: To facilitate interpretation, p-values are shown for total effect and direct effect, and confidence intervals are shown for mediated effect based on convention. s.e.= standard error

*** p <.01.

[†]= total mediation

* p<.05

[#] partial mediation.