

Development of a novel, integrated cognitive-behavioral therapy for co-occurring posttraumatic stress and substance use disorders: A pilot randomized clinical trial

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ABSTRACT

Posttraumatic stress disorder (PTSD) and substance use disorders (SUD) are complex psychiatric conditions that commonly co-occur. No evidence-based, ‘gold standard’ treatments for PTSD/SUD comorbidity are currently available. The present pilot randomized clinical trial was designed to evaluate the feasibility and preliminary efficacy of a novel, integrated cognitive-behavioral treatment approach for PTSD/SUD, entitled Treatment of Integrated Posttraumatic Stress and Substance Use (TIPSS), as compared to standard cognitive-behavioral treatment (CBT) for SUD. The TIPSS program integrates cognitive processing therapy with CBT for SUD for the treatment of co-occurring PTSD/SUD. Both treatment conditions are comprised of 12, 60-minute individual psychotherapy sessions, delivered twice-weekly over six weeks. Primary aims examine whether TIPSS, compared to standard CBT for SUD, reduces: (1) PTSD symptoms and (2) substance use outcomes (i.e., self-report, objective). Secondary aims examine whether (a) trauma- and substance cue reactivity and (b) distress tolerance (i.e., actual or perceived ability to withstand uncomfortable emotional or physical states) are significant mechanisms of change. The study was recently closed to new enrollment. Participants included adults with substance dependence and at least four symptoms of PTSD.

1. Introduction

Posttraumatic stress disorder (PTSD) and substance use disorders (SUD) commonly co-occur [e.g., [1–3]]. The comorbidity is complex, difficult-to-treat, and marked by a more costly and chronic clinical course, when compared to either disorder alone [e.g., [1,4,5]]. To date, there is no consensus regarding ‘best practice guidelines’ for this comorbidity [6,7].

1.1. Study rationale

Based on recent meta-analytic evidence, there is promise in the preliminary efficacy of individualized, integrated, trauma-focused therapy plus evidence-based SUD interventions [6,7]. Most such programs have combined prolonged exposure therapy [PE; [8]], one of the “gold standard” evidence-based therapies for PTSD [9,10], with cognitive-behavioral relapse prevention therapy for SUD [6,7,11,12]. Though promising, available PTSD/SUD treatments are marked by small effect sizes and high rates of attrition [e.g., [13,14]]. Thus, the development of novel PTSD/SUD integrated treatments, based upon evidence-based principles, is imperative.

No studies to date have reported upon the potential efficacy of integrating cognitive processing therapy [CPT; [15,16]], another “gold standard” treatment for PTSD [9,17], with cognitive behavioral therapy (CBT) for SUD [18,19] for the treatment of PTSD/SUD. CPT targets PTSD symptoms through a focus on evaluating and changing trauma-related cognitions, particularly those relevant to five central themes: safety, power/control, intimacy, trust, esteem [15]. Unlike PE, CPT does not include in-vivo or imaginal exposures. CPT is as effective as PE for the treatment of PTSD [16] and may be more effective at targeting trauma-relevant emotions such as guilt [16]. In addition, preliminary studies indicate that CPT for PTSD is similarly well-tolerated by individuals with co-occurring PTSD and alcohol use disorder [20,21], as compared to those with PTSD-only, and leads to significant reductions in PTSD symptomatology regardless of alcohol use disorder diagnosis [20].

1.2. Study aims

We proposed a novel, integrated CBT, the Treatment of Integrated Posttraumatic Stress and Substance Use (TIPSS). The primary purpose

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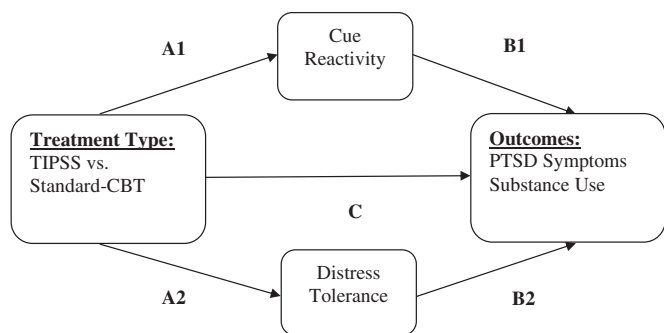


Fig. 1. Conceptual model of RCT depicting study hypotheses. Study outcomes are hypothesized to be affected by changes in individual cue reactivity and distress tolerance. A1 = treatment type will be related to cue reactivity; B1 = cue reactivity will be related to study outcomes; A2 = treatment type will be related to distress tolerance; B2 = distress tolerance will be related to study outcomes; C = treatment types (TIPSS and standard CBT) will be related to study outcomes (PTSD and substance use).

of this pilot randomized controlled trial (RCT; Clinical Trials Identifier: NCT02461732) was to evaluate the impact of TIPSS, as compared to Standard CBT for SUD [18,19], on PTSD symptoms and substance use outcomes. Consistent with leading work in integrated treatment development for PTSD/SUD and the limited scope of the pilot trial, which allowed for only a two-arm RCT, standard CBT for SUD was selected as a comparison condition [22]. A related goal was to maintain high levels of generalizability to real-world treatment settings by using broader inclusion criteria (please see Materials and methods). Secondary aims included exploring mechanisms by which TIPSS may improve outcomes. Specifically, cue reactivity and distress tolerance [i.e., perceived or actual ability to withstand emotional or physical distress; 23] were examined as mechanisms of change due to (1) documented associations with PTSD/SUD [e.g., [24–30]], (2) empirical support for cue reactivity as a mechanism of change in PTSD/SUD treatment [25,26,31,32], and (3) theoretical models purporting DT as a pertinent treatment target and change mechanism in PTSD/SUD [33]. Please see Fig. 1 for overview of study aims.

First, we hypothesized that reductions in PTSD symptoms will be greater in TIPSS compared to Standard CBT for SUD because PTSD symptoms would be targeted directly. Second, we hypothesized that substance use outcomes will be improved in TIPSS, as compared to Standard CBT for SUD, as measured by: (a) urine toxicology testing, alcohol breath level analyses, and participants' self-reports of substance use; and (b) longest sustained abstinence, operationalized as the maximum number of days of abstinence for each participant (i.e., UDS, self-report). This prediction is driven by the well-established self-medication model of PTSD/SUD, which posits that individuals with PTSD/SUD use substances in attempt to self-medicate the painful and intense emotionality associated with PTSD [e.g., [24,28,34–37]]. Thus, targeting PTSD is essential to improving SUD outcomes, since PTSD, including subclinical PTSD symptomatology [e.g., [38]], is predictive of

stronger drug cravings [35,39] and withdrawal symptoms [40] as well as a greater tendency to use substances to alleviate negative mood states [e.g., [41–43]]. Third, we hypothesized that TIPSS, as compared to Standard CBT for SUD, will decrease cue reactivity and increase distress tolerance and that this will be associated with improvements in outcomes (see Fig. 1).

2. Materials and methods

2.1. Trial design overview

This study is a RCT designed to compare the efficacy of two CBT interventions: standard CBT for SUD [18,19] and TIPSS, a novel integrated CBT program for PTSD/SUD. Across both conditions, all participants attended 12 (one-hour) treatment sessions, meeting twice per week for 6 weeks. To examine mechanisms of change, four experimental laboratory sessions (baseline + sessions: 4, 8, 12) were conducted in the context of the treatment protocol. At the baseline/screening visit, the laboratory session took place after the otherwise scheduled activities (i.e., assessments). On sessions 4, 8, and 12, the laboratory sessions were scheduled before other activities (i.e., treatment sessions) (see Table 1 for session details). The study was recently closed to new enrollment; and data analyses are being initiated.

2.2. Recruitment and eligibility

Adults interested in treatment for SUD and trauma-related symptoms were recruited via community-based and online strategies (e.g., newspaper ads; Craigslist). Interested individuals called the treatment research clinic, located in a large southern U.S. metropolitan area, and were screened for general eligibility (e.g., age, substance use, English proficiency) via telephone. Potentially eligible individuals were then scheduled for an intake appointment. Inclusionary criteria were comprised of: being 18–65 years old and proficient in English, meeting criteria for current (past month) DSM-IV [44] substance dependence, reporting a history of trauma exposure per DSM-5 PTSD Criterion A [45] and at least four current (past month) DSM-5 PTSD symptoms (PTSD diagnosis not required), and seeking treatment for substance dependence and trauma-related symptoms. The inclusion of subclinical PTSD was informed by extant interventions for PTSD/SUD [e.g., [46]] and driven directly by two major lines of evidence: (1) comparable rates of distress and impairment associated with full versus partial PTSD [e.g., [3,47,48]]; and (2) high rates of subclinical PTSD among SUD populations [e.g., [49–51]]. Exclusionary criteria included: exclusive (only) nicotine dependence, alcohol or opioid dependence requiring detoxification, current or past bipolar I disorder or major psychotic disorder, active (past 6 months) psychotic spectrum symptoms, major unstable medical conditions, current (past month) suicidal or homicidal ideation with intent or plan, pregnancy, or inability to provide verbal and written consent. The study was approved by all relevant institutional review boards, and all study procedures were carried out in

Table 1
Overview of measures and procedures by study session.

Procedure	Treatment sessions												
	Baseline	Week 1		Week 2		Week 3		Week 4		Week 5		Week 6	
		1	2	3	4	5	6	7	8	9	10	11	12
Urine sample & alcohol breath samples	x	x	x	x	x	x	x	x	x	x	x	x	x
Time-line follow-back	x	x	x	x	x	x	x	x	x	x	x	x	x
CAPS-5	x												x
PCL-5	x	x	x	x	x	x	x	x	x	x	x	x	x
Distress tolerance measures	x				x				x				x
Writing trauma, drug, & neutral scripts	x												
Experimental cue reactivity laboratory sessions	x				x				x				x

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