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ORIGINAL ARTICLE



## A Randomized Controlled Trial for Veterans with PTSD and Substance Use Disorder: *Creating Change* versus *Seeking Safety*

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### ABSTRACT

**Background:** Posttraumatic stress disorder (PTSD) and substance use disorder (SUD) co-occur in military veterans and other populations. **Objective:** To conduct a randomized controlled trial to compare a new *past*-focused treatment (*Creating Change*; CC), to a well-established, evidence-based *present*-focused treatment for PTSD/SUD (*Seeking Safety*; SS), on symptoms of both disorders. CC guides patients to process the past through exploration of PTSD/SUD life themes and memories whereas SS focuses on coping skills in the present. **Methods:** Fifty-two male and female veterans with current PTSD/SUD were randomized ( $n = 26$  per treatment) and assessed at baseline, end-of-treatment and 3-month follow-up. They received 17 individual one-hour sessions. **Results:** Intent-to-treat analyses indicated that both conditions improved over time, with no difference between conditions, on PTSD, alcohol use, and drug use (our primary outcomes) as well as mental health symptoms, quality of life, self-efficacy, and SUD cognitions. Effect sizes were medium except for alcohol use, which was large. Change over time reflected improvement from baseline to end-of-treatment, with gains sustained at follow-up, although alcohol use showed continued improvement from end-of-treatment to follow-up. Both treatments evidenced a strong safety profile; and attendance, alliance, and treatment satisfaction were also very strong. **Conclusions/importance:** CC has promise as a PTSD/SUD therapy with strong public health relevance and the potential to fill important gaps in the field. We used minimal exclusionary criteria to obtain a real-world sample, which was severe—predominantly substance-dependent with chronic PTSD and additional psychiatric diagnoses. Future research is warranted, especially on nonveteran samples and treatment mechanisms of action.

### KEYWORDS

PTSD; substance abuse; therapy; veterans; trauma

## Introduction

Posttraumatic stress disorder (PTSD) and substance use disorder (SUD) co-occur at substantial rates and present major clinical challenges (Ouimette & Read, 2014). Compared to either disorder alone, PTSD/SUD is associated with worse outcomes, lower functioning, more aggression, worse health problems, and greater suicidality and co-occurring psychiatric conditions (Barrett, Teesson, & Mills, 2014; Gros, Szafranski, Brady, & Back, 2015; Ouimette & Read, 2014; Seal et al., 2011). Military veterans in particular have elevated rates of PTSD/SUD. Among current era veterans with SUD, for example, 63% to 76% have PTSD (Seal et al., 2011).

SUD treatment has traditionally not addressed PTSD and, vice versa, PTSD treatment has not addressed SUD (Najavits, 2002). This split reflects different workforces, funding streams, and systems of care for PTSD versus

SUD. Moreover there have been reports that treating both together could harm patients by evoking painful trauma material before stabilizing the SUD (Najavits, *in press*). Thus PTSD clinical trials have generally excluded SUD and related complexities such as suicidality (Bradley, Greene, Russ, Dutra, & Westen, 2005).

As a response to these splits, co-occurring disorders therapies began to arise in the early 1990s (Silverman, Najavits, & Weiss, 2016). Such therapies address SUD in relation mental health disorders. The goal is *integrated care* (treating both disorders at the same time, by the same clinician) rather than traditional *sequential care* (treating SUD until sustained abstinence is achieved and only then addressing co-occurring disorders).

Among co-occurring disorders, PTSD in particular raises challenges as it sometimes worsens rather than improves with substance abstinence (Ouimette &

Read, 2014) as long-hidden trauma memories and emotions erupt, sometimes leading to substance relapse in a classic downward spiral. Specialized models for PTSD/SUD treatment thus arose (Najavits & Hien, 2013b). Seeking Safety (SS) (Najavits, 2002) became the most empirically studied model. It is a *present-focused* approach, teaching coping skills for both disorders. The model became popular in SUD treatment programs as it can be delivered by any provider, in group or individual modality, for any trauma type and any substance type. It does not require training or certification other than in research trials. Over 45 published articles on SS studies evidence positive findings (Lenz, Henesy, & Callender, 2016; Najavits & Hien, 2013b).

In contrast to present-focused models, *past-focused* models guide the patient to explore painful trauma emotions and memories so as to process them. Currently, past-focused approaches are evidence-based only for PTSD, not for the comorbidity of PTSD/SUD. Past-focused approaches include, for example, Prolonged Exposure (PE) and Eye Movement Desensitization and Reprocessing (EMDR). In recent years, there have been several attempts to adapt such models to address SUD as well. However, even with such adaptations, four RCTs in PTSD/SUD samples using such past-focused models (all versions of exposure therapy) found none superior at end-of-treatment on either PTSD or SUD compared to a less emotionally intense therapy or to treatment-as-usual (Foa et al., 2013; Mills et al., 2012; Sannibale & et al., 2013; van Dam, Ehring, Vedel, & Emmelkamp, 2013). Dropout has also been more of a concern than in present-focused models (Najavits, 2015). In general, with more complex clients past-focused methods do not outperform present-focused methods (Gerger, Munder, & Barth, 2014).

We compared two integrated models for PTSD/SUD: *Creating Change* (CC), a past-focused model (Najavits, 2014, in press) and SS, a present-focused model (Najavits, 2002), in a sample of veterans with current PTSD/SUD. CC is designed to offer the same positive features of SS, including a warm, supportive tone; its flexibility; its format; and its applicability to the broadest possible range of PTSD/SUD populations, staff, and settings. Given both the appeal and efficacy of SS, a past-focused model such as CC that draws on the strengths of SS could provide a potentially helpful new model.

However with the various evidence-based past-focused treatments that already exist a natural question is whether there is really a need for another model. CC was developed to address several gaps in the field, which relate not solely to the need for effective models, but also to the need for models that will be sensitive to public health considerations (cost, workforce capacity, etc.) and

appealing to clinicians and clients. Several key features are described below but for a more complete description of CC see Najavits (2014).

First, CC offers a past-focused, integrated PTSD/SUD approach that is feasible in SUD settings. There are various past-focused PTSD models for PTSD but although they are evidence-based for PTSD, none are as yet evidence-based for PTSD/SUD. Further, most past-focused PTSD models assume individual modality, as well as a high level of clinician professional background, training and supervision, with a resulting relatively high cost, elements that are often not realistic in SUD treatment settings. The same holds for the PTSD/SUD models developed by Back et al. (2015) and McGovern et al. (2009), both of which are individual modality and require an advanced degree. In this study CC was conducted in individual modality due to its greater feasibility for recruitment in a VA RCT, but CC itself was designed for use equally in individual or group modality.

Second, CC appears to be more integrated in terms of past-focused PTSD/SUD content: guiding clients to process painful SUD memories as well as trauma memories, and exploring the life trajectory of both disorders in relation to each other in detail.

Third, CC provides extensive safety parameters. Until relatively recently, SUD clients were excluded from most past-focused PTSD treatments and research trials (Bradley et al., 2005; Najavits & Hien, 2013a). This was due to legitimate clinical concerns about the risk for negative outcomes such as increased substance use, harm to self or others, treatment dropout, and impaired functioning (Keane, 1995; Pitman et al., 1992; Ruzek, Polusny, & Abueg, 1998; Solomon, Gerrity, & Muff, 1992). It is now known, however, that some SUD clients want to do past-focused treatments and can improve in them—clients who previously were considered unsuitable (Brady, Dansky, Back, Foa, & Carroll, 2001; Coffey, Schumacher, Brimo, & Brady, 2005; Foa, Riggs, & Hembree, 2006; Mills et al., 2008; Najavits, Schmitz, Gotthardt, & Weiss, 2005; Triffleman, Carroll, & Kellogg, 1999). Yet PTSD/SUD clients indeed are more vulnerable than those with PTSD alone: research consistently finds them to have greater impairment and worse outcomes (Najavits et al., 1998; Najavits et al., 2007; Ouimette & Brown, 2002; Riggs, Rukstalis, Volpicelli, Kalmanson, & Foa, 2003). The principle “first, do no harm” is key. CC addresses safety parameters explicitly and in detail, beyond the level in classic PTSD therapies, and in more detail and more explicitly than in other PTSD/SUD models (e.g., Back et al., 2015; McGovern et al., 2009). For example, in CC there are extensive guidelines to evaluate whether clients can tolerate past-focused therapy and for monitoring clients’ safety throughout the treatment.

Fourth, CC addresses broad social and historical contexts—beyond the individual. Many clients with PTSD/SUD feel abandoned or betrayed by society, whether by their own family; authority figures who harmed them; or societal oppression or neglect related to class, race, or other subgroup issues. CC contextualizes PTSD and SUD beyond the individual, including social influences, culture, and institutional responses. Such wider circles play a role—both positive and negative—in the development of PTSD/SUD and also in the recovery process.

Fifth, rather than a primary, repeated focus on the trauma narrative or memories, which is at the core of most past-focused PTSD approaches, CC explores poignant *themes* related to the past. Patients choose what they want to share in terms of the trauma narrative. Each therapy topic guides them to an emotionally evocative aspect of past trauma and/or SUD. For example, *Self-Protection* explores how the client may have developed defenses that allowed them to survive but which now hold them back from growth, such as isolation, overendurance, secrecy, regression, numbness, pretending to look good, etc. In essence, CC, like SS, is a patient-centered approach with a structured session format, rather than a highly sequenced, prescriptive protocol. The goal is to engage, evoke, invite, and create choices. These may be especially important for PTSD/SUD patients in that both disorders represent a loss of control and powerlessness.

CC had shown positive results in two small pilots conducted in individual modality. One had a largely minority, low-income sample with childhood-based PTSD and chronic SUD (Najavits & Johnson, 2014). Significant improvements were found in PTSD and trauma-related symptoms (e.g., dissociation, anxiety, depression, and sexual problems); broader psychopathology (e.g., paranoia, psychotic symptoms, obsessive symptoms, and interpersonal sensitivity); daily life functioning; cognitions related to PTSD; coping strategies; and suicidal ideation. Effect sizes were consistently large, including for both alcohol and drug problems. The other pilot used a precursor of CC (Najavits et al., 2005) with substance-dependent men with childhood-based PTSD. Improvements were found in drug use, trauma symptoms, dissociation, anxiety, hostility, suicidal thoughts and plans, family/social functioning, global functioning, and sense of meaning. Both studies had strong attendance and satisfaction and were notable for having fewer exclusionary criteria than prior exposure-based PTSD studies. Suicidality and self-harm, for example, were not exclusions.

The current study is the first RCT on CC. Our goal was to evaluate how CC, a new model, compares to SS, an existing evidence-based model for PTSD/SUD. SS is currently the most empirically studied model for that

comorbidity and has the strongest outcomes of any model tested for it. We predicted that CC would do at least as well as SS as it shares many of the strengths of the latter, or might exceed it, given that past-focused counseling is sometimes viewed as more emotionally powerful (Najavits, Hyman, Ruglass, Hien, & Read, 2017). In either case there is room for a new model such as CC as implementation science shows that some clients and clinicians have preferences for some models over others, and thus the more choice available, the better (Najavits, Kivlahan, & Kosten, 2011).

## Materials and methods

### Participants

Patients were 52 veterans, male or female, who were included if they were (a) ages 18–65; (b) met DSM-IV criteria for current PTSD and current SUD (DSM-IV was used as recruitment started prior to DSM-5); (c) used a substance within 60 days of baseline; (d) outpatient (outside an institutional setting for at least two weeks before baseline); (e) lived locally; (f) interested in PTSD/SUD treatment; (g) if on psychiatric medication, on a stable regimen for at least four weeks.

Exclusion criteria were: (a) any current acute medical condition that could interfere with attendance or affect psychological functioning (e.g., cancer); (b) current bipolar I disorder, schizophrenia or other psychotic disorder, mental retardation, or organic mental disorder; (c) advice by a primary treater or obvious clinical sign (e.g., muteness) that participation was contraindicated; (d) dangerousness (e.g., serious assault history within the past six months); (e) mandated to treatment. Because substance use was a primary outcome participants were excluded if: (f) their only SUD was to a prescribed medication taken only as prescribed (as reduction would not be a valid intervention target); and (g) they had current or planned placement in a setting restricting substance use (e.g., jail). To promote internal validity on PTSD, we excluded anyone in any past-focused PTSD therapy or integrated PTSD/SUD therapy such as SS. Exclusionary criteria were minimal to obtain a typical outpatient veteran PTSD/SUD sample. We did not exclude based on suicidality, self-harm, personality disorder, drug use disorder, homelessness, recent substance use, or severe dissociation.

Power calculations for sample size determination were based on detecting a 0.6 effect size, which lies between a medium effect size (0.5) and large effect size (0.8) (Cohen, 1992). The calculation was based on the first pilot study of CC (Najavits et al., 2005), using six repeated assessments of the *ASI Drug Composite* (pretreatment, month 1, month 2, month 3, month 4, month 5 or end of

treatment). A compound symmetry design was modeled for the 6 repeated measures, which resulted in a pooled correlation coefficient of  $r = 0.31$ . The within-subject correlation was set slightly higher at  $r = .40$  due to the small sample size of the original pilot. Based on the pilot study data, with a within-subject correlation of 0.40, 26 subjects per condition achieves 82.7% power if 10% of the sample is unavailable/missing after baseline and if all participants are available for assessment after baseline, 26 subjects achieves 86.4% power.

### Procedures

Procedures were approved by our Institutional Review Board and registered at ClinicalTrials.gov (identifier: NCT01274741). Participants were recruited via clinicians, flyers, and word-of-mouth over three years.

Screening occurred by telephone or in-person, followed by an in-person appointment for baseline assessment of self-reports and diagnostic interview. Randomization (two blocks of 26 generated by the study statistician), was by nonblinded study staff.

### Study treatments

CC and SS are cognitive-behavioral therapies (CBT) with interpersonal elements, designed for PTSD/SUD. Both have a check-in, inspirational quotation, handouts, and check-out. They can be conducted in groups or individually; and for this study were conducted individually in 17 weekly 1-hour sessions.

CC is past-focused and described elsewhere (Najavits, 2014, in press). It had 17 topics, each an exploratory theme relevant to both disorders, such as *Choose a Path*, *Transform Pain*, *Tell Your Story*, *See Clearly*, *Honor Your Body*, *The Larger Context*, and *Balance Dark and Light*.

SS is present-focused and described elsewhere (Najavits, 2002). It consists of up to 25 topics, each a coping skill relevant to both disorders, such as *Asking for Help*, *Compassion*, *Taking Good Care of Yourself*, and *Recovery Thinking*. In this study only 17 topics were conducted to keep dosage identical to CC and because evidence on SS shows that it produces positive outcomes in fewer than 25 sessions, indeed as few as 12 (Najavits & Hien, 2013). The 17 topics were selected by the first author (the SS treatment developer) and were identical for all patients.

Patients could attend nonstudy therapies and supports including 12-step self-help groups, except for current PTSD or PTSD/SUD evidence-based therapy models (see exclusionary criteria).

There were five study clinicians (four psychologists, one social worker; four were female, one was male). They

were trained via in-person training and case supervision. Although training is not required for routine clinical implementation, training and fidelity assessment using developer-approved standards are required for research studies that will be published (per [www.seekingsafety.org](http://www.seekingsafety.org), section Training).

### Measures

Assessments occurred at baseline, end-of-treatment, and 3-month follow-up unless noted otherwise. Patients received \$40 for each of these assessments and \$3 for a weekly urinalysis/breathalyzer. Follow-up assessments were conducted blind to treatment condition by staff assessors for the interview-based primary outcomes (*Addiction Severity Index* and the *Mini Neuropsychiatric Interview PTSD module*). On all measures, higher scores reflect worse pathology unless noted otherwise. Psychometrics for each measure are provided in the citation provided. Participants were assessed at all time points regardless of treatment attendance (intent-to-treat design). Primary and secondary outcome measures are noted below.

### SUD and addiction

We obtained DSM-IV SUD diagnosis on the *Mini Neuropsychiatric Interview* (Sheehan et al., 1998) alcohol use disorder and substance use disorder modules; and substance use severity on the primary outcomes *Addiction Severity Index-Lite (ASI)* (McLellan, Cacciola, Carise, & Coyne, 2005) alcohol composite and drug composite. Urinalysis / breathalyzer testing occurred weekly. *Beliefs about Substance Use* (Wright, 1992), a secondary measure, is scaled 1–7 and assesses cognitions associated with SUD continuance (e.g., “Life without using is boring”). At baseline we collected a *Nicotine Screen* (Najavits & Vujanovic, 2010) and *Brief Biosocial Gambling Screen* (Gebauer, LaBrie, & Shaffer, 2010) for descriptive purposes.

### PTSD

We assessed lifetime traumas on the *Trauma History Questionnaire* (Green, 1996) for descriptive purposes. We obtained DSM-IV diagnosis of PTSD on the *Mini Neuropsychiatric Interview* (Sheehan et al., 1998) and PTSD symptoms on the *PTSD Checklist* (Weathers, Litz, Herman, Huska, & Keane, 1993), scaled 1–5; both of these were primary outcomes. Secondary outcomes in this category were the *Trauma Related Guilt Inventory* (Kubany et al., 1996), scaled 1–5, and the *World Assumptions Scale* (Janoff-Bulman, 1989; Elklit, Shevlin, Solomon, & Dekel, 2007) which evaluated trauma-related cognitions, scaled 1–6, with higher scores indicating less pathology.

### Additional outcome measures

In addition to the measures named above, we obtained the following, all secondary outcomes: the *Coping Self-Efficacy Scale* (Chesney, Neilands, Chambers, Taylor, & Folkman, 2006), rated 0–10; the *Quality of Life Enjoyment and Satisfaction Questionnaire-Short Form* (Endicott, Nee, Harrison, & Blumenthal, 1993) scaled 1–5; the *General Self-Efficacy Scale* (Schwarzer & Jerusalem, 1995), scaled 1–4; the *Global Severity Index of the Brief Symptom Inventory* (Derogatis, 1983) to evaluate broad mental health symptoms, scaled 0–4; and the *Clinical Global Impressions Scale-Patient version* (Guy, 1976) at end-of-treatment and follow-up for perceived improvement or worsening, scaled 1–7. On all except the latter two measures, higher scores indicate less pathology.

The full *Mini Neuropsychiatric Interview* was conducted at baseline for exclusionary diagnoses (current bipolar I disorder, schizophrenia or other psychotic disorders) and to describe co-occurring Axis I disorders. The *Structured Clinical Interview for DSM-IV Personality Disorders* (First, Spitzer, Gibbon, & Williams, 1997) at baseline obtained Axis II disorders. The *SUD-PTSD Timeline* (psychometric information not available) was collected at baseline (Najavits, 1994). Self-harm and suicide were monitored on items from the *Suicidal Behaviors Questionnaire* (Linehan, 1995) for 3-month periods, rated 0–4.

*Treatment satisfaction/alliance* was assessed on the *Client Satisfaction Questionnaire* (Attkisson & Zwick, 1982) at end-of-treatment, scaled 1–4; the *Helping Alliance Scale* (Luborsky, Crits-Cristoph, Margolis, & Cohen, 1983) at session 3 scaled 1–6; and the *Creating Change Feedback Questionnaire* (Najavits, in press) at end-of-treatment scaled 1–7, and administered only to those in the CC condition. On these measures higher scores indicate stronger satisfaction / alliance.

*Nonstudy treatments* were assessed on the *Treatment Services Review* (McLellan, 1989), each month during treatment, end-of-treatment, and follow-up.

*Fidelity* was assessed on the *CC Fidelity Scale* (Najavits, 2007) and the *SS Adherence Scale* (Najavits & Liese, 2003); for psychometrics see (Hien et al., 2009) on randomly selected audiotapes of full sessions, scaled 0–3 with higher indicating stronger fidelity. Each therapist was reviewed until competence was established (all items 2 or higher on the scale), after which at least one session was reviewed monthly, rotating among therapists and patients within caseloads.

For assessment completion see Figure 1, *Participant flow*. At end of treatment there was no significant difference between treatment conditions in assessment completion, but at follow-up there were significantly more in SS who completed them  $\chi^2 = 5.2$ ,  $df = 1$ ,  $p = .02$ .

### Analyses

We used descriptive statistics to characterize the sample, and two-tailed independent samples *t*-tests or chi square tests to compare by study condition at baseline. We tested whether all outcome measures were missing completely at random (MCAR) using Little's test, which was nonsignificant for all outcome variables. To minimize Type I error we analyzed one summary score per variable rather than including subscales except for the ASI, which had two summary scores (the alcohol and drug composites) as that measure has no total score. We used multiple imputation procedures in SPSS version 24 to address missing data so as to include the full intent-to-treat sample; we used the pooled result of 100 imputations. For continuous variables, imputed outcome data were analyzed with two-way mixed analysis of variance (ANOVA). All continuous variables passed Levene's test of homogeneity of variance. Mauchly's test of sphericity was conducted and if significant, Greenhouse–Geisser estimates were used. Effect sizes are reported as partial eta-squared and interpreted as 0.01 (small), 0.09 (medium), and 0.25 (large) (Watson, 2016). For PTSD diagnosis, we used generalized estimating equations with a logit link function to compare likelihood of PTSD remission at end-of-treatment and follow-up, and by treatment condition.<sup>1</sup> All results are reported on the intent-to-treat sample.

## Results

### Participant characteristics

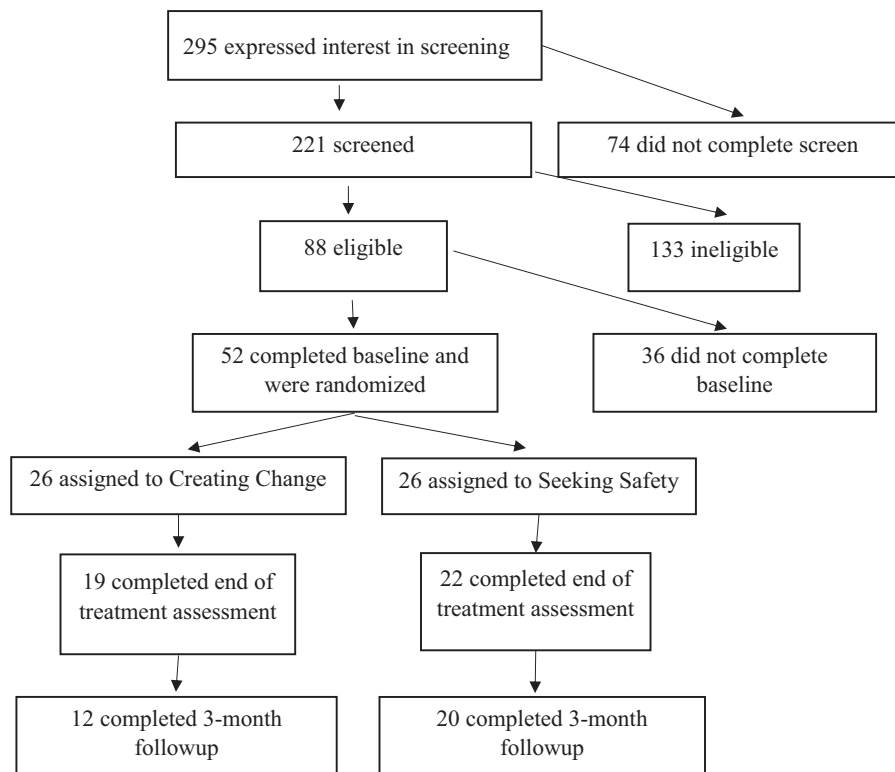
There were no differences between conditions on any baseline characteristics although there was a trend on past-month medical problems with CC patients reporting more than double that of SS patients (see Table 1).

On the *SUD-PTSD Timeline*, for the full sample, PTSD occurred first for most (59.5%), SUD first for 23.8%, both at the same time 14.3%, and “can't say” 2.4%. Most (83.3%) believed their PTSD and SUD were related.

### Attendance

The average number of sessions (maximum 17) was 11.42 for CC and 11.62 for SS ( $SD = 5.36$ ), indicating strong attendance (67% of available sessions for CC and 68% for SS), with no difference between them ( $t = -.12$ ,  $df = 50$ ,  $p = .90$ ). One participant attended no sessions.

<sup>1</sup> We do not report SUD remission as DSM criteria for sustained full remission is based on the past year, which was beyond the timeframe for this study; moreover the standard SUD treatment outcome is reduction in substance use and SUD-related problems.



**Figure 1.** Participant flow.

### Concurrent treatment

On the *Treatment Services Review* there were no differences between conditions at any time point (monthly, end-of-treatment, follow-up) in the number of days patients received services in the prior month on any category of service, and use in all categories was low. Professional treatment ranged from mean = .38 days (SD = .36) to .83 (SD = 1.13); medication from 3.80 (SD = 3.75) to 6.83 (SD = 3.90); and 12-step groups from .92 (SD = 2.79) to 2.57 (SD = 4.44), for CC versus SS, respectively.

### Outcomes

Results are interpreted below only if significant at  $p < .05$  (see Table 2).

#### Primary outcomes

**PTSD and SUD.** All four primary outcomes evidenced improvement over time, with no difference between conditions. On our three continuous outcomes (all but the PTSD diagnosis), so as to understand main effects for time we analyzed pairwise differences from baseline to end-of-treatment, baseline to follow-up, and end-of-treatment to follow-up. All showed improvement from baseline to end-of-treatment and baseline to follow-up, and no deterioration from end-of-treatment to follow-up.

Moreover, on the ASI alcohol composite we found continued improvement from end-of-treatment to follow-up. Effect sizes were medium for the PCL and ASI drug composite and large for the ASI alcohol composite. On PTSD diagnosis the majority remitted at end-of-treatment and follow-up, with no difference between treatments; and no difference in remission rates at end of treatment compared to follow-up, indicating sustained gains.

ASI results are supported by urinalysis/breathalyzer testing. The majority showed concordance (biological testing consistent with ASI). For urinalyses, 75 (18%) were positive on both and 280 (68%) negative on both. When discordance occurred, moreover, about half the time it was nonproblematic (negative urinalysis/positive self-report, i.e., honest self-reporting); this occurred 32 times (8%). Discordance was problematic (positive urinalysis/negative self-report) 27 times (6%), i.e., dishonesty about use. Breathalyzer results showed positive concordance 15 times (3%), negative concordance 195 times (38%); problematic discordance 9 times (2%) and nonproblematic discordance 299 times (57%). The latter is because breathalyzers generally only detect past-24-hours alcohol use.

#### Secondary outcomes

The secondary outcomes are consistent with the pattern of the primary outcomes: improvement over time with no difference between conditions (see Table 2). This

**Table 1.** Participant characteristics at baseline.

	Total sample mean (SD) or percent	CC mean (SD) or percent	SS mean (SD) or percent	Test statistic
Age	48.75 (10.77)	49.04 (9.95)	48.46 (11.72)	$t = .19, df = 50, p = .85$
Gender – male	73.1%	73.1%	73.1%	$\chi^2 = 0, df = 1, p = 1.0$
Education years	14.04 (1.73)	14.17 (1.70)	13.91 (1.78)	$t = .51, df = 44, p = .61$
Race/ethnicity				
Any minority	40.0%	32.0%	48.0%	$\chi^2 = 1.33, df = 1, p = .25$
Hispanic	4.0%			
African-American	30.1%			
Mixed race	3.9%			
Pacific Islander	2.0%			
Caucasian Non-Hispanic	60.0%			
Marital status				$\chi^2 = .23, df = 2, p = .89$
Never married	42.2%	43.5%	40.9%	
Divorced/separated/widowed	42.2%	43.5%	40.9%	
Married	15.6%	13.0%	18.2%	
Employed (full or part-time)	66%	62.5%	69.6%	$\chi^2 = .26, df = 1, p = .61$
Past month days worked	6.72 (11.03)	7.71 (11.71)	5.70 (10.42)	$t = .62, df = 45, p = .54$
Past month medical problems	10.09 (12.71)	13.50 (13.70)	6.36 (10.63)	$t = 1.98, df = 42.89, p = .05$
Months lifetime incarceration	11.83 (31.25)	8.65 (29.01)	15.00 (33.94)	$t = -.59, df = 32, p = .56$
Current SUD diagnoses <sup>1</sup>				
Dependence	94.2%	96.1%	92.3%	$\chi^2 = .35, df = 1, p = .55$
Alcohol	75%	80.8%	69.2%	$\chi^2 = .92, df = 1, p = .34$
Drug	36.5%	30.8%	42.3%	$\chi^2 = .75, df = 1, p = .39$
Cocaine	72.2%			
Cannabis	16.7%			
Heroin	5.6%			
Opiates	5.6%			
Abuse	21.1%			
Alcohol	7.7%			
Drug	13.5%			
Cannabis	9.6%			
Opiates	3.8%			
Cocaine	1.9%			
Two or more SUD diagnoses	32.7%	34.6%	30.8%	$\chi^2 = .09, df = 1, p = .77$
Past-month nicotine use	60.9%	59.1%	62.5%	$\chi^2 = .06, df = 1, p = .81$
Current positive screen for gambling problems <sup>2</sup>	11.5%	16.7%	7.1%	$\chi^2 = .57, df = 1, p = .45$
Trauma				
Lifetime traumas (of 23)	9.88 (4.62)	9.50 (4.61)	10.30 (4.68)	$t = -.60, df = 47, p = .55$
Military combat trauma	32.7%	38.5%	26.1%	$\chi^2 = .85, df = 1, p = .36$
Sexual trauma	55.1%	53.8%	56.5%	$\chi^2 = .03, df = 1, p = .85$
One or more current Axis I disorders other than PTSD/SUD <sup>1</sup>	61.9%	68.4%	58.5%	$\chi^2 = .63, df = 1, p = .43$
Major depression	47.6%			
Panic disorder	19.0%			
Generalized anxiety	33.3%			
Agoraphobia	11.9%			
Obsessive-compulsive	7.1%			
Bulimia	4.8%			
Anorexia	0%			
One or more Axis II disorders	37.0%	39.1%	34.8%	$\chi^2 = .09, df = 1, p = .76$
Paranoid	21.7%			
Borderline	11.5%			
Avoidant	11.5%			
Obsessive-compulsive	7.7%			
Antisocial	6.5%			
Narcissistic	6.5%			

<sup>1</sup>For diagnoses patients could meet for more than one disorder so rates may total above 100%.<sup>2</sup>All 3 items endorsed. But  $N = 26$  for this measure at baseline (it was added late to the study), so results should be interpreted cautiously.

occurred on the *Global Severity Index*, the *Quality of Life Enjoyment and Satisfaction Scale*, the *General Self-Efficacy Scale*; and *Beliefs About Substance Use*. Pairwise differences for all except the latter also showed the same pattern as the primary outcomes: improvement from baseline to end-of-treatment and baseline to follow-up, and no

deterioration from end-of-treatment to follow-up. *Beliefs About Substance Use* showed improvement from baseline to follow-up but not baseline to end-of-treatment. Effect sizes were medium on all four measures.

There were no differences by treatment or across time on the *World Assumptions Scale*, *Coping Self-Efficacy*



**Table 2.** Intent-to-treat outcomes for creating change (CC) versus seeking safety (SS).

	Baseline mean (SD) [or % if noted]		End of treatment mean (SD) [or % if noted]		3-month follow-up mean (SD) [or % if noted]		Treatment x Time F (df)	Treatment F (df)	Time F (df)	Comparisons for significant effects <sup>2</sup>
	CC	SS	CC	SS	CC	SS				
<i>Primary outcomes</i>										
PTSD Checklist -Total Score	50.37 (14.09)	52.75 (12.41)	45.98 (15.59)	48.83 (16.27)	45.85 (16.67)	42.43 (12.44)	1.59 (2,100) $p = .21$ $\eta_p^2 = .03$	.03 (1,50) $p = .86$ $\eta_p^2 = .001$	7.19 (2, 100) $p = .001$ $\eta_p^2 = .13$ (medium)	Time $a = .047$ $b < .0005$ $c = .114$
Current PTSD diagnosis	100%	100%	40%	46%	34%	41%	See table note <sup>3</sup>	See table note <sup>3</sup>	See table note <sup>3</sup>	See table note <sup>3</sup>
Addiction Severity Index – Alcohol Composite	.31 (.20)	.41 (.21)	.26 (.23)	.21 (.15)	.14 (.13)	.19 (.12)	3.35 (2,78.41) $p = .05$ $\eta_p^2 = .068$	.80 (1,46) $p = .38$ $\eta_p^2 = .017$	21.17 (2,78.41) $p = .0005$ $\eta_p^2 = .315$ (large)	Time $a = .001$ $b = .0005$ $c = .01$
Addiction Severity Index – Drug Composite	.07 (.08)	.05 (.07)	.04 (.06)	.05 (.07)	.05 (.05)	.04 (.06)	1.31 (2,60.34) $p = .27$ $\eta_p^2 = .028$	19 (1,46) $p = .66$ $\eta_p^2 = .004$	4.78 (2,60.34) $p = .02$ $\eta_p^2 = .094$ (medium)	Time $a = .04$ $b = .01$ $c = .99$
<i>Secondary outcomes</i>										
Global Severity Index (Brief Symptom Inventory)	1.22 (.74)	1.40 (.80)	.96 (.73)	1.08 (.78)	1.08 (.87)	1.02 (1.0)	1.03 (2,96) $p = .36$ $\eta_p^2 = .02$	.14 (1,48) $p = .71$ $\eta_p^2 = .003$	6.53 (2,96) $p = .002$ $\eta_p^2 = .12$ (medium)	Time $a = .002$ $b = .01$ $c = .77$
Quality of Life Satisfaction & Enjoyment Scale	2.80 (.75)	3.05 (.85)	3.33 (.71)	3.26 (1.02)	3.30 (.73)	3.44 (.82)	1.40 (2,100) $p = .25$ $\eta_p^2 = .03$	.31 (1,50) $p = .58$ $\eta_p^2 = .006$	12.05 (2,100) $p = .0005$ $\eta_p^2 = .19$ (medium)	Time $a = .001$ $b = .0005$ $c = .38$ $b = .0005$
General Self-Efficacy	2.83 (.51)	2.94 (.46)	3.05 (.42)	3.10 (.45)	2.96 (.45)	3.24 (.42)	2.38 (2,72.90) $p = .10$ $\eta_p^2 = .05$	1.73 (1,49) $p = .194$ $\eta_p^2 = .03$	9.55 (2,72.90) $p = .001$ $\eta_p^2 = .16$ (medium)	Time $a = .005$ $b = .0005$ $c = .50$
Beliefs About Substance Use	48.75 (16.92)	44.73 (20.67)	45.67 (23.68)	37.61 (22.77)	44.78 (22.28)	31.91 (16.53)	1.34 (2,94) $p = .27$ $\eta_p^2 = .03$	.11 (1,47) $p = .10$ $\eta_p^2 = .03$	4.86 (2,94) $p = .01$ $\eta_p^2 = .09$ (medium)	Time $a = .07$ $b = .005$ $c = .20$

(Continued on next page)

Table 2. Continued

	Baseline mean (SD) [or % if noted]	End of treatment mean (SD) [or % if noted]	3-month follow-up mean (SD) [or % if noted]	Treatment x Time F (df)	Treatment F (df)	Time F (df)	Comparisons for significant effects <sup>2</sup>
				$\eta_p^2$ effect size <sup>1</sup>	$\eta_p^2$ effect size	$\eta_p^2$ effect size	
Coping Self-Efficacy Scale	4.81 (.213)	5.25 (1.86)	5.23 (1.99)	.37 (272,36) $p = .63$ $\eta_p^2 = .008$	.80 (1,47) $p = .38$ $\eta_p^2 = .017$	2.72 (272,36) $p = .09$ $\eta_p^2 = .055$	Not applicable
World Assumptions Scale	3.68 (.68)	3.83 (.59)	3.87 (.55)	.32 (2,94) $p = .73$ $\eta_p^2 = .007$	.15 (1,47) $p = .70$ $\eta_p^2 = .003$	1.58 (2,94) $p = .21$ $\eta_p^2 = .033$	Not applicable
Trauma Related Guilt Inventory	2.06 (.68)	1.68 (.63)	1.74 (.72)	6.89 (2,92) $p = .002$ $\eta_p^2 = .13$	1.85 (1,46) $p = .18$ $\eta_p^2 = .039$	1.89 (2,92) $p = .16$ $\eta_p^2 = .039$	Not applicable <sup>4</sup>

Higher scores indicate worse pathology on all measures except Coping Self-Efficacy, General Self-Efficacy, Quality of Life, and the World Assumptions Scale, on which higher scores indicate less pathology.

SPSS  $p$  values of ".000" are listed as <.0005.

<sup>1</sup>Effect size (partial eta squared,  $\eta_p^2$ ) are interpreted as 0.01 (small), 0.09 (medium), and 0.25 (large) per Watson<sup>40</sup>; they are reported to three decimal places to avoid misinterpretation due to rounding.

<sup>2</sup>"a" refers to baseline compared to end of treatment. "b" refers to baseline to 3-month follow-up. "c" refers to end of treatment to 3-month follow-up. Significant results at  $p < .05$  are bolded.

<sup>3</sup>Per the PTSD diagnosis percentages in the table, the majority of patients (60%) in both treatments remitted on PTSD by end-of-treatment, which was sustained at follow-up. Using generalized estimating equations with a logit link function, we compared PTSD remission at end-of-treatment versus 3-month follow-up (i.e., change in PTSD from baseline to each of those time points relative to each other). We found no difference in PTSD remission by treatment condition ( $b = .05$ ,  $SE = .72$ ,  $p = .95$ ), nor between end of treatment and follow-up ( $b = -.44$ ,  $SE = .50$ ), and CC versus SS did not differ in the likelihood of PTSD remission at end-of-treatment versus follow-up ( $b = .42$ ,  $SE = .86$ ,  $p = .62$ ; i.e., there was no interaction between time and treatment). In sum, results for PTSD diagnosis are consistent with the pattern of outcome results reported in the rest of the table: both treatments evidenced improvement from baseline to end-of-treatment, with gains sustained at follow-up.

<sup>4</sup>Box's M test was significant ( $p = .007$ ) so to be conservative the interaction is not interpreted.

Scale, and Trauma Related Guilt Inventory. However we note that the latter had a significant interaction effect but, due to Box's M test being significant for that measure, we took the conservative approach and did not interpret it especially as our sample size was relatively small (fewer than 30 per cell) (Allen & Bennet, 2008).

### Perceived improvement/worsening and safety issues

On the *Clinical Global Improvement Scale*, scaled 1–7 (1 = very much improved, 7 = very much worse), patients perceived improvement at each time point per means at end-of-treatment (CC 2.21, SD = 1.00, SS 2.41, SD = 1.26); and follow-up (CC, 2.40, SD = .68; SS 2.11, SD = .69). There was no interaction of time  $\times$  treatment:  $F(1,42) = 2.10$ ,  $p = .16$ ; and neither time nor treatment were significant: time  $F(1,42) = .11$ ,  $p = .74$ ; treatment  $F(1,42) = .03$ ,  $p = .86$ . This indicates no difference in perceived improvement based on condition and no deterioration from end-of-treatment to follow-up.

To explore iatrogenesis we examined each patient's data for perceived worsening (scoring 5 or higher). Two patients, both in SS, reported 5 (*minimally worse*) at end-of-treatment; none did at follow-up. Throughout the trial there were no adverse events related to either treatment.

On the *Suicidal Behaviors Questionnaire* we found no difference between treatment conditions at any time point on the four items we used: suicide attempts, self-harm events, suicidal ideation, self-harm ideation. There were no suicide attempts at all nor self-harm events except one; and suicidal ideation, and self-harm ideation were low throughout, with means from .08 (SD = .27) to .39 (SD = .85) and .08 (SD = .27) to .38 (SD = .81), respectively.

Overall our safety data indicate that both treatments were safe and not associated with self-harm or suicidal actions or ideation. Patients perceived both treatments as helpful rather than harmful.

### Treatment alliance and satisfaction

All measures of patient alliance and satisfaction were very strong, with no difference between conditions. On the *Helping Alliance Questionnaire* at session 3, scaled 1–6 with 6 representing the strongest positive alliance, means were CC 5.12, SD = .97 and SS 5.27, SD = .51;  $t = -.55$ ,  $df = 32$ ,  $p = .59$ . On the *Client Satisfaction Questionnaire*, scaled 1–4 with 4 representing the strongest satisfaction, means at end-of-treatment results were CC 3.70, SD = .30 versus SS 3.64, SD = .51;  $t = .38$ ,  $df = 30$ ,  $p = .71$ .

The *Creating Change Feedback Questionnaire* at end-of-treatment, scaled 1–7, showed all 17 topics received strong ratings, from 5.64 to 6.20. Overall helpfulness of the treatment was 6.73 (SD = .59), for trauma and SUD

6.53 (SD = .74), for trauma alone 6.47 (SD = .91), and for SUD alone 6.33 (SD = .82).

## Discussion

This RCT evaluated, in a sample of military veterans, two therapies for comorbid PTSD and SUD: CC, a new *past*-focused approach, and SS, an evidence-based *present*-focused approach. The pattern of results was consistent: patients in both conditions improved significantly over time with no difference between conditions. This occurred on PTSD, alcohol use, and drug use (our primary outcomes) as well as broad mental health symptoms, quality of life, self-efficacy, and SUD cognitions. Effect sizes were medium except for alcohol use, which was large. Change over time was primarily improvement from baseline to end-of-treatment, with gains sustained at follow-up, although for alcohol use there was continued improvement from end-of-treatment to follow-up. The majority of patients remitted on PTSD diagnosis: 57% at end of treatment and 63% at follow-up, with no differences by treatment condition. On three secondary measures no significant effects were found (Coping Self-Efficacy Scale; World Assumptions Scale; and Trauma Related Guilt Inventory [TRGI]). It is unclear why these did not show improvement over time, but future research may benefit from evaluating these measures with a larger sample size and/or selecting more sensitive measures or ones that may be more directly relevant to the treatments. For example, guilt per se is not the central emotional focus of either CC or SS; rather, all trauma-related emotions are, such as shame, rage, sadness, etc. (That being said, the significant interaction on the TRGI, although not interpretable on our dataset due to the small sample and significant Box's M test, could be interesting to explore in some future study, perhaps matching clients to treatments based on factors such as guilt or other key emotions.)

Our data also indicated that both treatments were safe. There were no adverse events related to either treatment, no increase in suicidal ideation or actions or self-harm, and no pattern of worsening reported by patients. This had been found in numerous trials of SS, but was important to evaluate for CC as it focuses on the past, which is generally more difficult content. Engagement with both treatments was high as early as session 3 on a measure of helping alliance and maintained at end-of-treatment on satisfaction scales. Attendance was very strong, with 67% (CC) and 68% (SS) of available sessions attended. This retention is notable as our sample generally reported low attendance at other professional therapies and 12-step groups throughout the trial. The strong attendance also provides support for the idea that even a severe

PTSD/SUD sample such as ours was able to tolerate a past-focused approach, which may be due to CC's highly flexible, patient-centered style compared to classic exposure therapy. One study clinician called CC "a kinder, gentler approach" to exploring the past.

We were pleased to see that our sample had strong minority representation at 40%, which helps to promote generalizability to diverse populations. The severity of our sample parallels previous SS studies, which have consistently focused on chronic and severe PTSD/SUD patients (Najavits & Hien, 2013b). Our sample had substance dependence, the most severe form of SUD, and a third had two or more SUD diagnoses. There was a substantial rate of drug use disorders, with cocaine dependence the most common. The majority also used nicotine. The rate of lifetime traumas was very high at an average of 10 out of the 23 trauma types assessed. Despite our primarily male sample, sexual trauma was more common than combat trauma. Clinicians should be sure to attend to all trauma types among veterans.

Comorbidity beyond PTSD and SUD was the norm, with 62% meeting criteria for one or more additional psychiatric disorders and 37% meeting criteria for one or more Axis II disorders.

Also of note, we obtained a high rate of veterans screening positive for current gambling problems (11.5%). This rate is consistent with a recent large study of veterans (Westermeyer, Canive, Thuras, Oakes, & Spring, 2013) and reinforces the need to routinely assess for gambling problems, which most clinicians, including VA clinicians, do not do (Cowlshaw, Merkouris, Chapman, & Radermacher, 2014; Newhouse, May 08, 2013).

Strengths of the study design include the relatively minimal exclusionary criteria (a sample of real-world practice); the intent-to-treat design and multiple imputation analyses; blinded raters; and validated measures. Limitations include all of those that accrue to RCTs, such as highly trained clinicians with ongoing monitoring, and patients who volunteered for a research study. Also additional and further out follow-ups would be useful. A larger sample size would allow statistical power for subgroup analyses as well as to better understand assessment completion rates (for example, in this study fewer CC patients completed the follow-up but they also had more medical problems than SS patients, and those issues may be related).

We also did not have a solely treatment-as-usual or no-treatment control arm in this study. However, a meta-analysis of SS (Lenz et al., 2016) found that based on  $n = 1042$  patients in studies comparing SS to waitlist or no-treatment, the average effect size was .56 (medium)

and favored SS. Thus it is unlikely that simply the passage of time created the positive outcomes observed in our study.

CC has promise as a PTSD/SUD therapy with strong public health relevance, given the results of this trial. By having options for both present- and past-focused models, both of which can obtain positive outcomes, clinicians and programs can better customize their offerings based on client needs and preferences. Clients and clinicians may have preferences for one type over another. Yet many questions remain: Might there be added benefit in conducting SS first and then CC, or perhaps using them concurrently? Which clients are most likely to benefit from each treatment? What are the mechanisms of action of each treatment? How do the two treatments compare in their emotional intensity? What characteristics of therapists and settings might promote successful CC outcomes? What training is necessary? Are particular treatment topics essential? How does it fare in group versus individual modality? Further research is warranted.

## Disclosures

Lisa M. Najavits was an employee of VA Boston Healthcare System throughout this project. She developed *Creating Change and Seeking Safety* prior to and outside of her VA employment. Her potential conflict of interest was reviewed by the General Counsel of the Veterans Affairs Central Office and she was cleared to conduct this study prior to starting it. She receives royalties from Guilford Press for *Seeking Safety* and is Director of Treatment Innovations, which provides training and consultation related to various therapy models. Karen Krinsley, Matthew W. Gallagher, Molly E. Waring, and Christopher Skidmore report no competing interests.

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