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Pilot Study of *Creating Change*, a New Past-Focused Model for PTSD and Substance Abuse

Lisa M. Najavits, PhD,[1,2] Kay M. Johnson, LCSW-R[1,3,4]

[1]Treatment Innovations, Newton Centre, Massachusetts
[2]Harvard Medical School, Boston, Massachusetts
[3]Formerly of Crime Victims Center, St. Luke's Roosevelt Hospital, New York, New York
[4]Columbia University School of Social Work, New York, New York

Background and Objectives: *Creating Change* (CC) is a new past-focused behavioral therapy model developed for comorbid posttraumatic stress disorder (PTSD) and substance use disorder (SUD). It was designed to address current gaps in the field, including the need for a past-focused PTSD/SUD model that has flexibility, can work with complex clients, responds to the staffing and resource limitations of SUD and other community-based treatment programs, can be conducted in group or individual format, and engages clients and clinicians. It was designed to follow the style, tone, and format of Seeking Safety, a successful present-focused PTSD/SUD model. CC can be used in conjunction with SS and/or other models if desired.
Methods: We conducted a pilot outcome trial of the model with seven men and women outpatients diagnosed with current PTSD and SUD, who were predominantly minority and low-income, with chronic PTSD and SUD. Assessments were conducted pre- and post-treatment.
Results: Significant improvements were found in multiple domains including some PTSD and trauma-related symptoms (eg, dissociation, anxiety, depression, and sexual problems); broader psychopathology (eg, paranoia, psychotic symptoms, obsessive symptoms, and interpersonal sensitivity); daily life functioning; cognitions related to PTSD; coping strategies; and suicidal ideation (altogether 19 variables, far exceeding the rate expected by chance). Effect sizes were consistently large, including for both alcohol and drug problems. No adverse events were reported.
Discussion and Conclusions: Despite study methodology limitations, CC is promising.
Scientific Significance: Clients can benefit from past-focused therapy that addresses PTSD and SUD in integrated fashion. (Am J Addict 2014;XX:1–8)

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Address correspondence to Lisa M. Najavits, 28 Westbourne Rd., Newton Centre, Newton, MA 02459.
E-mail: Lnajavits@hms.harvard.edu

INTRODUCTION

Substance use disorder (SUD) and posttraumatic stress disorder (PTSD) often co-occur. Lifetime U.S. population SUD rates among men with PTSD are 52% alcohol use disorder and 35% drug use disorder; and, among women, 28% and 27% respectively.[1] Subgroups with elevated rates of this comorbidity include criminal justice, military, veterans, adolescents, and the homeless. Moreover, SUD/PTSD clients have worse outcomes than those with either disorder alone; higher rates of subsequent trauma, other Axis I and II disorders, medical problems, suicidality and self-harm, HIV risk, legal problems, and treatment dropout; and lower work functioning.[2] Traditionally, SUD treatment has not attended to PTSD, and specific treatment for it was not provided. However, it is now widely recommended that integrated care (treating both disorders at once) is more likely to promote substance abstinence and other improvements. Indeed, evidence over the past 15 years indicates that working on both disorders simultaneously results in positive outcomes in both, as well as related areas, and no pattern of worsening.[3]

In conceptualizing treatment for this comorbidity, a stage-based approach is widely recommended. From the earliest writing on trauma in the 19th century through the present, stages of trauma recovery have repeatedly been identified, particularly for complex or comorbid patients.[4,5] The stage-based framework has been labeled a "consensus" model because of its central importance for trauma recovery.[6] A recent survey of 50 PTSD experts found that 84% endorsed a stage-based approach to PTSD treatment.[7]

The stages are *safety* (stage 1), *mourning and remembrance* (stage 2), and *reconnection* (stage 3).[4] Each represents a distinct therapeutic task and time perspective.[8] Safety (stage 1) is *present-focused*, emphasizing coping skills and psychoeducation. Mourning and remembrance (stage 2) is *past-focused*, encouraging processing of painful trauma memories and emotions. Reconnection (stage 3) is *future-focused*, building a strong social and work life ahead. There may be

overlap between stages and some clients may not need all three, but overall this stage-based approach is a helpful guide to PTSD recovery. The SUD field too has similar stages although it relies most on present-focused approaches.[9]

Seeking Safety (SS) therapy[9] is the most empirically studied and widely implemented model for present-focused PTSD/SUD treatment.[1] SS is a stage 1, present-focused, cognitive-behavioral therapy (CBT) approach that provides psychoeducation and coping skills to help clients attain safety from PTSD and/or SUD. Example of SS topics include *Safety*, *Asking for Help*, *Honesty*, *Healthy Relationships*, *Community Resources*, *Compassion*, *Creating Meaning*, *Discovery*, *Integrating the Split Self*, *Recovery Thinking*, and *Self-Nurturing*. It builds hope through emphasis on ideals and a compassionate, humanistic approach. It was developed for all levels of care and settings (eg, outpatient, inpatient, residential); all types of trauma and substances; males and females; and group or individual modality. No particular professional degree or training is required to conduct it; and it has even been conducted peer-led. Over 20 SS studies, including pilots, randomized controlled trials (RCTs), and multi-site trials, have shown consistent positive findings.[3] From a public health standpoint, it is one of the most easily implemented models, with low cost, feasibility with vulnerable populations, safety and efficacy, and translation into multiple languages (see www.seekingsafety.org).

Creating Change (CC)[10,11] was developed as a natural next step—a past-focused model for PTSD/SUD. SS and CC are "twins" in that CC was designed to offer the advantages of SS in terms of format; compassionate tone; simple language; integrated approach to PTSD/SUD; flexibility; engagement of clients through exercises and handouts; and emphasis on the clinician role. Yet whereas SS addresses the present, CC focuses on the past. The two models can be used separately or combined (sequentially, concurrently, or alternating).

The rationale for CC is that although clients show positive outcomes from SS, some want to also explore their past. The usual approach is to conduct classic PTSD past-focused models, but none were designed specifically for PTSD/SUD. Such models include Prolonged Exposure (PE),[12] Eye Movement Desensitization and Reprocessing,[13] and Narrative Exposure Therapy.[14] Moreover, in four RCTs conducted thus far with PTSD/SUD clients using such past-focused models (all versions of exposure therapy), remarkably not one showed superiority at end of treatment on either PTSD or SUD compared to less emotionally intense therapy or to treatment-as-usual.[15–18] They have also shown low attendance in some studies.[3,15,17] Historically, PTSD treatment research has consistently excluded SUD clients, particularly those with substance dependence as well as complexities typical of SUD settings: homelessness, suicidal or violent ideation, psychotic and bipolar disorders, domestic violence, and cognitive impairment.[3,19,20] A more extensive description of such exclusions can be found elsewhere.[3,20]

CC was thus designed as a past-focused PTSD/SUD model specifically for SUD settings, with features distinguishing it from existing past-focused PTSD models and SUD models. For example, it encourages clients to process painful SUD memories as well as PTSD memories. It can be conducted in groups, which predominate in SUD treatment, rather than the individual format typical of PTSD models. It has greater flexibility, such as order of session topics, treatment length, dosage, and potential combination with present-focused approaches. It addresses PTSD and SUD simultaneously, and was designed for SUD clinicians, who typically have less training than past-focused PTSD models require. CC was written in 2007 and has been implemented successfully by several programs. A study evaluating a precursor of CC found positive results on multiple domains in an uncontrolled pilot combining it with SS.[21] An RCT comparing it to SS is underway.[22] CC is described in detail elsewhere.[10]

EXAMPLES OF TWO CC TOPICS

Linking Trauma and Addiction

Clients explore how addiction and trauma arose in relation to each other, with emphasis on emotional not just intellectual awareness. Handouts include a trauma and addiction timeline; identifying losses associated with trauma and addiction; family history of trauma and addiction; and recognizing how substances may have "solved" trauma problems.

Knowing and Not Knowing

This topic helps clients face painful truths. More than many disorders, PTSD and SUD engender "knowing and not knowing," or varying levels of truth. This takes many forms reflecting incomplete awareness—fragmented memory, denial, minimization, blackouts, splitting, the "pink cloud," avoidance, the false self, and memory phobia, for example. It is part of PTSD and SUD to block the full brunt of reality, and part of therapy to bring it to light, gently but persistently. The process is also called "facing illusions," "lifting the veil," "owning it," and "trusting truth." Truth is approached in a postmodern sense: a meaningful personal construction that clients build over time, rather than just recounting facts. Memory problems in PTSD and SUD are also explored—how trauma memory differs from normal memory; how substances can impair or evoke memories, etc.

CC offers detailed safety parameters as it addresses more wide-ranging clients and clinicians than prior past-focused models. For example: (a) A Readiness Questionnaire identifies clients' suitability for past-focused work; clinician and setting readiness are also addressed. (b) A written plan documents emergency procedures. (c) The session check-out has optional brief grounding (calming strategies). (d) The client is given

[1] Both SS and CC are relevant to trauma and/or substance abuse broadly, although we will use the term "PTSD/SUD" throughout for simplicity. SS was originally designed for clients with PTSD/SUD diagnoses, but has also been used with those who are subthreshold, have just one disorder or the other, or a history of them. CC too is written with these larger populations in mind.

education about past-focused work before engaging in it. (e) Each session, a self-report scale assesses functioning and recent unsafe behavior. (f) The clinician is instructed on how to handle problems that may arise, such as rage, dissociation, and harmful impulses. (g) The homework ("commitments") promote stabilization (they are present-rather than past-focused) unless the clinician decides otherwise. (h) Therapeutic alliance is measured before moving into intense material. (i) Clients' functioning is emphasized throughout ("one foot in the past and one in the present"). (j) An *advance directive* specifies clients' preferences for additional help. (k) Guidance on how to incorporate SS or other coping-skills approaches is provided. (l) The clinician is the "gatekeeper," monitoring progress and adjusting treatment, with client input.

In this pilot, our goal was to evaluate CC in a small sample of typical PTSD/SUD clients.

METHODS

Participants

Four men and 3 women ($n = 7$) were recruited from a crime victims program that provides mental health treatment for victims of domestic violence and sexual assault. Two additional individuals entered but did not continue (one consented but dropped prior to completing baseline; the other completed the baseline but had mania and was ruled ineligible). No participant was in a controlled environment in the 30 days pre-baseline nor during the study. Inclusion criteria were: PTSD and SUD (current, diagnosed per DSMIV-TR via the MINI Neuropsychiatric Inteview[23]); substance use within 30 days (to obtain a sample with active use); and outpatient. The exclusionary criteria were current bipolar I disorder uncontrolled by medication; and psychosis. Exclusionary criteria were minimal to obtain a generalizable sample. Participants were recruited by word-of-mouth. They were not paid for any aspect of their participation.

Protocol

CC was conducted by four clinicians: three social workers (including the second author), and one psychiatry resident. Consultation was provided as-needed by the first author, the developer of CC, who reviewed audiotapes of full sessions for adherence. CC was conducted weekly in individual format for 17 sessions to cover each of CC's 17 topics.

Measures

Measures were selected for relevance to mental health and SUD outcomes, and psychometric validation. All measures were collected at baseline and end-of-treatment unless noted otherwise. For all measures, higher scores represent worse impairment, unless noted otherwise.

Substance-Related Measures

The *Substance Use Disorder/PTSD Timeline*[24] identified onset of each disorder at baseline. The *Addiction Severity Index* (ASI[25]) was an interview to assess addiction-related problems (alcohol, drugs, psychiatric, legal, employment, medical, family/social), and sociodemographics. The Beliefs about Substance Abuse Scale (BSAS)[26] assessed thoughts associated with substance use, *scaled* 1 (*totally disagree*) to 7 (*agree totally*). The *Treatment Services Review* (TSR)[27] assessed number of days in the prior 30 that clients used services for alcohol/drugs, medications, group or individual psychotherapy, and self-help. On this measure there is no directionality (higher means more services, which can be interpreted as positive or negative).

Trauma-Related Measures

The *Trauma History Questionnaire* (THQ)[28] assessed lifetime traumas at baseline. *PTSD Checklist—Civilian Version* (PCL)[29] assessed the 17 DSM-IV-TR PTSD criteria, scaled 1 (*not at all*) to 5 (*extremely*). The *Trauma Symptom Checklist-40* (TSC-40)[30] evaluated 40 trauma-related symptoms scaled 0 (*never*) to 3 (*often*), collected monthly. It has a total and six subscales: anxiety, depression, dissociation, sexual abuse trauma index, sexual problems, and sleep disturbance. The *World Assumptions Scale* (WAS)[31] assessed beliefs related to PTSD, with 32 items on a 6-point scale from *strongly disagree* to *strongly agree*.

Other Measures

The *Mini-International Neuropsychiatric Interview* (MINI)[23] was used at baseline for inclusion and exclusion diagnostic criteria. The *Behavior and Symptom Identification Scale* (BASIS-32)[32] assessed functioning (total score and five subscales: relation to self/others, depression/anxiety, daily living/role functioning, impulsive/addictive behavior, and psychosis), with items rated 0–4 (*no difficulty–extreme difficulty*). The *Brief Symptom Inventory* (BSI)[33] evaluated psychopathology, from 0 to 4 (*not at all–extremely*), with two summary scores (global severity index and positive symptom total) and nine subscales (somatization, obsessive-compulsive behavior, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, psychoticism). The *Coping Strategies Inventory* (CSI)[34] measured coping strategies, rated 1–5 (*not at all-very much*), with higher indicating better coping. The *New-Buss Aggression Questionnaire*[35] assessed hostility on a 5-point scale. The *Suicidal Behaviors Questionnaire* (SBQ)[36] assessed frequency of self-harm incidents/ideation. As this measure does not have total or subscale scoring, we analyzed ten items, with varied scaling (*yes/no*; a 5-point scale, *never-very often*; a 6-point scale *none-almost certainly*). The *Clinical Global Improvement Scale* assessed patients' impression of their degree of improvement since starting the treatment, scaled 1–7 *very much improved-very much worse*. The *Helping Alliance Questionnaire* (HAQ)[37] is scaled 1–6, with higher indicating greater alliance. The *Client Satisfaction Questionnaire* (CSQ)[38] is scaled 0–3 *not at all-a great deal*, with higher indicating greater satisfaction. The *End-of-Session Questionnaire*[9] has 8 items, scaled 0 (*not at all*) to 4 (*a great deal*). Higher scores indicate

greater satisfaction. The *Creating Change End-of-Treatment Questionnaire*[10] assesses satisfaction with CC treatment topics and features, *scaled* 0–100% or −3 to 3 (greatly harmful–greatly helpful), with higher indicating greater satisfaction.

Data Analysis

Mixed-effects modeling was our primary approach to account for the clustered data (repeated assessments within individuals). We used Mixed Model Analysis of Variance (MMANOVA), which models all available data for each participant.[39] To address non-normality, square or square-root transformations[40] were applied. For effect sizes, we used Cohen's *D*, interpreted as .8 (large), .5 (medium), and .2 (small). We did correct not for the number of variables tested as this was a small-sample pilot in a new area, and Type II error is as much a risk as Type I. However, we will compare the number significant expected by chance versus the number found.

RESULTS

Participant Characteristics

See Table 1.

Attendance and Outcomes

Participants attended an average of 16 sessions (SD = 4.43). Clients were allowed to attend sessions over a 6-month time period, to allow time to experience all topics (as the instability of the client population means that some weeks they could not get in for therapy).

See Table 2 for all significant results. Of 63 variables analyzed, 20 (31.75%) evidenced significance ($p < .05$) in the across-time analysis (MMANOVA). Six more variables (9.52%) were trends ($p < .10$). The number significant exceeds the number expected by chance (5% of 63 = 3.15).

Non-significant results were as follows, with effect size in parentheses. With our small sample, effect sizes are important for estimating change, as statistical significance is less likely due to low power. Of the 37 non-significant variables, all but four indicated improvement. The 34 variables (and effect sizes) showing improvement were as follows. ASI composites: medical (1.60), alcohol (1.09), psychiatric (.82), family (.78), and drug (.68). BASIS-32: relation to self and others (1.45), impulsive and addictive behavior (1.09), psychosis (1.08). TSC: sleep disturbance (.80). BSI: phobic anxiety (.12) and somatization (1.30). CSI: engagement (1.00), express feelings (.90), isolation (.72), emotion focused disengagement (.47), work hard to solve problem (.30), disengagement (.29), distraction (.25), problem-focused engagement (.19), wishful thinking (.18), self-blame (.14), cognitive restructuring (.06). New Buss: overall mean (1.02). PCL: criterion B (1.23). SBQ: harm yourself within the next 6 months (.84), harm yourself at any point in the future (.84), thoughts about killing yourself (.76), kill yourself at any future point (.57), if…thinking about killing yourself would you talk to anyone (.41), kill yourself within the next 3 months (.32), drinking immediately before/after suicide attempt/self-injury (.24). WAS: self world (1.25), meaning (.23). Of the remaining four variables, three had neutral results (same mean pre- and post-treatment): on the CSI, problem-focused disengagement, and on the SBQ, two items: intentionally harmed yourself, "and" Do you currently have a plan for what you'd do if you decided to harm/kill yourself? Finally, one variable had a small worsening effect size: ASI employment (.12).

Treatment Variables

Global Improvement

The CGIS, at end of treatment, indicated positive means on global improvement (2.20; SD = .84); PTSD improvement (2.20; SD = .84); and substance abuse improvement (2.0; SD = 1.0).

Alliance

HAQ client means were strong at session 3 (5.53; SD = .19) and end-of-treatment (5.39; SD = .08). Clinician means were also strong at both timepoints (5.07, SD = .35; and 5.00, SD = .07). For both clients and clinicians, session 3 and end-of-treatment were not significantly different, indicating that alliance was consistently high.

Utilization

TSR means (number of days of services in the prior month) were 6.81 (SD = 9.12) alcohol/drug; 4.02 (SD = 2.84) psychotherapy; 5.38 (SD = 8.98) self-help; and all clients reported taking medication. There were no significant differences between intake and end-of-treatment, which can be interpreted positively as clients not increasing treatment utilization. However, the TSR is not an outcome measure per se.

Satisfaction

Clients' End-of-Session Questionnaire had consistently positive results, ranging 2.50–2.99 for the mean across the scale's eight items for all rated sessions ($n = 77$–79 sessions). PTSD helpfulness averaged 2.55 (SD = .66, $n = 78$ sessions); with SUD helpfulness 2.76 (SD = .43, $n = 79$ sessions). Clinicians' End-of-Session-Questionnaire was also consistently positive ranging 2.50–2.99 for the mean across the scale's 8 items ($n = 26$–43 sessions). PTSD helpfulness averaged 2.51 (SD = .64, $n = 39$ sessions) and SUD helpfulness averaged 2.49 (SD = .68, $n = 41$ sessions), indicating CC was perceived helpful for both.

CC End-of-Treatment Questionnaire

This questionnaire indicated strong positive perception of the treatment ($n = 5$ clients). With scaling 0–100%: How frequently will you use what you learned in this treatment in the future? 86.00 (SD = 21.91); How easy to understand is this treatment? 95.00 (SD = 12.28); How innovative is this treatment 90.80 (SD = 12.28); To what extent would you recommend this treatment to someone else? 92.00 (SD = 13.04). Other items, scaled −3 to 3 were as follows. How helpful is the treatment overall? 3.00 (SD = 0). How helpful is

TABLE 1. Participant Characteristics

Sociodemographics*	Patients ($n = 7$)
Sex	
Male	4 (57.14%)
Female	3 (42.86%)
Average age, years	45.14 (SD = 10.46)
Ethnicity/race	
African-American	2 (28.57%)
Asian/Pacific Islander	2 (28.57%)
Caucasian	2 (28.57%)
Hispanic	1 (14.29%)
Relationship status	
Never married	4 (57.14%)
Divorced	2 (28.57%)
Married	1 (14.29%)
Average formal education, years	13.20 (SD = 2.28)
Income, past 30 days	
Range	$168.50 to $4,000.00
Mean	$2,026.13 (SD = 1,100.93)
Substance use, lifetime years*	
Any alcohol use	27.00 (SD = 13.08, $n = 7$)
Alcohol to intoxication	16.14 (SD = 11.42, $n = 7$)
Heroin	.57 (SD = .79, $n = 3$)
Other opiates/analgesics	1.43 (SD = 2.70, $n = 2$)
Sedatives/hypnotics/tranquilizers	.14 (SD = .38, $n = 1$)
Cocaine	15.00 (SD = 12.22, $n = 7$)
Amphetamines	.57 (SD = .79, $n = 3$)
Cannabis	15.43 (SD = 10.72, $n = 7$)
Hallucinogens	3.43 (SD = 3.69, $n = 6$)
Inhalants	.14 (SD = .38, $n = 1$)
More than one substance per day, including alcohol	20.43 (SD = 10.83, $n = 7$)
Substance use, number of days in past month*	
Any alcohol use	6.29 (SD = 7.14, $n = 6$)
Alcohol to intoxication	3.57 (SD = 6.53, $n = 4$)
Cocaine	1.86 (SD = 3.76, $n = 2$)
Cannabis	6.00 (SD = 8.35, $n = 5$)
More than one substance per day, including alcohol	1.86 (SD = 3.29, $n = 3$)
Trauma types experienced†	
General disaster/accident	7 (100.00%)
Sexual abuse	7 (100.00%)
Physical abuse	6 (85.71%)
Crime	6 (85.71%)
Average age of first trauma, years	5.00 (SD = 1.67)
Average age of PTSD onset, years‡	18.50 (SD = 3.99)
Average age of SUD onset, years‡	18.33 (SD = 6.59)
PTSD/SUD onset‡	
PTSD onset occurred before SUD	2 (33.33%)
SUD occurred before PTSD onset	3 (50.00%)
Both PTSD and SUD occurred at the same time	1 (16.66%)
PTSD/SUD perceived as related	
"PTSD and SUD are related"	5 (83.33%)
"PTSD and SUD are not related"	1 (16.66%)

*From the Addiction Severity Index; †From the Trauma History Questionnaire; ‡From the PTSD/SUD Timeline.

TABLE 2. Significant outcome results

Scale[§]	Pre-treatment	End-of-treatment	Univariate F test (fixed effects) F (df)	Effect size Cohen's D
Basis-32[¶]				
Depression and anxiety	1.95 (.69)	1.33 (.86)	10.85 (1, 6)*	2.49 (large)
Daily living and role functioning	2.04 (.75)	1.31 (1.02)	9.35 (1, 6)*	2.31 (large)
Mean score	1.52 (.59)	1.02 (.75)	13.88 (1, 6)**	2.81 (large)
Beliefs About Substance Use[+]				
Mean of all items	2.74 (.66)	2.02 (1.07)	6.62 (1, 5)*	2.10 (large)
Brief symptom inventory[¶]				
Anxiety	1.85 (1.07)	1.00 (.96)	9.08 (1, 6)*	2.27 (large)
Depression	1.90 (1.06)	1.04 (1.12)	12.66 (1, 6)*	2.69 (large)
Interpersonal sensitivity	1.77 (1.11)	.79 (.97)	5.10 (1, 6)†	1.88 (large)
Obsessive-compulsive	2.13 (.89)	1.11 (.85)	16.26 (1, 6)**	3.04 (large)
Paranoid ideation	1.86 (.56)	.89 (.76)	16.84 (1, 6)**	3.31 (large)
Positive symptom distress index	3.30 (1.90)	1.50 (.64)	19.60 (1, 6)**	2.64 (large)
Positive symptom total	35.14 (10.73)	26.57 (13.10)	7.50 (1, 6)*	1.52 (large)
Psychoticism	.46 (.34)	.25 (.28)	6.05 (1, 6)*	1.82 (large)
Coping strategies[+]				
Emotion-focused engagement*	5.66 (2.33)	6.94 (1.16)	5.20 (1, 6)†	1.72 (large)
Social support	2.74 (1.52)	3.77 (.63)	6.21 (1, 6)*	1.88 (large)
PTSD checklist[¶]				
Criterion C	20.86 (6.36)	15.71 (6.47)	14.44 (1, 6)**	3.68 (large)
Criterion D	15.57 (3.51)	12.14 (3.63)	4.85 (1, 6)†	1.67 (large)
Mean of all items	51.00 (10.49)	40.14 (10.64)	23.71 (1, 6)**	2.87 (large)
Suicidal behaviors questionnaire[¶]				
Thoughts about hurting, but not killing, self	2.14 (.90)	1.43 (.79)	6.25 (1, 6)*	1.89 (large)
Trauma symptom checklist-40[¶]				
Anxiety	1.30 (.67)	.92 (.68)	4.34 (1, 6)†	1.58 (large)
Depression	1.51 (.56)	1.00 (.68)	5.71 (1, 6)*	1.81 (large)
Dissociation	1.50 (.58)	.69 (.63)	25.50 (1, 6)**	3.82 (large)
Sexual problems	1.32 (.93)	.70 (.65)	4.38 (1, 6)†	1.58 (large)
Sexual abuse trauma index	1.59 (.81)	.80 (.77)	8.06 (1, 6)*	2.15 (large)
Mean of all items	1.45 (.55)	.86 (.61)	10.14 (1, 6)*	2.41 (large)
World assumptions scale[+]				
Benevolence	4.16 (.84)	4.59 (1.01)	5.50 (1, 6)†	1.77 (large)
Mean of all items	3.75 (.69)	4.01 (.63)	11.40 (1, 6)**	2.55 (large)

*$p < .05$; **$p < .01$; †trends (<.10); §Scales listed alphabetically. All variables are subscales, except for means across all items as indicated; ¶Higher score indicates more pathology; [+]Higher score indicates healthier level.

the treatment for trauma alone? 2.75 (SD = .50). How helpful is the treatment for substance abuse alone? 2.60 (SD = .55). How helpful is the treatment for trauma and substance abuse? 2.75 (SD = .50). Ratings for CC's 17 topics ranged from 2.50 (SD = .58) to 3.0 (SD = 0), indicating consistently positive views. One suggestion by clients was to reduce the length of handouts.

DISCUSSION

This pilot study represents an innovative, promising step in the development of a new behavioral therapy for PTSD/SUD comorbidity. We evaluated *Creating Change*, an integrated *past*-focused approach that follows Seeking Safety (SS), an integrated *present*-focused model. CC draws on successful elements of SS to create a companion model that can be used alone or in combination with SS (or any other model). Both CC and SS are designed for complex clients, broad-ranging clinicians and settings, any substance and trauma type, and individual or group modality.

Study strengths include use of interview-based current diagnoses; psychometrically valid instruments; four clinicians; and minimal exclusionary criteria to obtain a representative sample. Participants were seven men and women outpatients, primarily minority and low-income, with chronic PTSD and

SUD. All experienced childhood trauma (mean age of 5); all had at least 2 traumas and a history of sexual abuse, and most had physical abuse and crime victimization. SUD onset occurred at a mean age of 18, and all used two or more substances per day for an average of over 20 years.

Results were consistently positive despite the small sample. Participants evidenced strong attendance, satisfaction, and alliance, and showed significant improvements on multiple variables (20 of the 63 variables analyzed, 31.75%, exceeding the 5% rate that would be expected by chance). Significant outcomes included PTSD symptoms and trauma-related symptoms; other psychopathology (such as, depression, anxiety, paranoia, psychoticism); coping skills; PTSD cognitions; and suicidal/self-harm variables. Effect sizes were consistently large. Even on non-significant variables, the direction was toward improvement on virtually all variables (important given concerns about conducting past-focused models for SUD clients). Substance use was not significant, but effects sizes were large (alcohol) and medium (drug) on the ASI. With our small sample and relatively few days of use in the month prior to baseline, the effect sizes are a helpful guide for future studies. Alternatively, PTSD reduction may be an important precursor to SUD change.[41] Across 35 psychotherapy studies on PTSD/SUD samples, PTSD has been much more likely to change than SUD by end-of-treatment.[3] Indeed, SS is the only model that has outperformed a control on both PTSD and SUD.[3] Notably too in our CC pilot, substance use did not worsen (a concern expressed in prior literature[15]). However, it may be that a longer dosage is needed for severe SUD clients such as in our sample, who had both highly chronic SUD, and use of multiple substances (CC offered 17 sessions, whereas SS was 25).

Our results are especially promising in light of four recent RCTs for past-focused PTSD treatments conducted in PTSD/SUD samples.[15–18] All four trials found no superiority on either PTSD or SUD at end-of-treatment compared to less-intensive therapies. Treatment attendance has also been a concern in various such studies.[15,17,42] CC thus provides a new option that may be potentially very well-suited to SUD environments. Like SS, a model popular in SUD settings, CC offers a theme-based, gentle approach tailored to SUD clients and clinicians. It offers past-focused exploration skills as a "next step" to the present-focused coping skills of SS. Both models emphasize empowerment, flexibility, group or individual format, and attention to the complex needs of SUD clients.

However, future research is clearly necessary to move CC to more rigorous testing to evaluate efficacy. An RCT with a larger sample and followup period are warranted. Such research could also help identify features of CC that are most important, as well as other questions: Which clients benefit most? Which clinicians and settings are optimal for successful outcomes? What training is necessary? Can readiness for past-focused work be quantified? What treatment topics are essential? How would CC outcomes compare to models developed for PTSD-alone or SUD-alone? What concurrent treatments, including medications and self-help, best augment CC? How much change is possible on SUD versus PTSD? Would a more rigorous CC trial show sustained improvements on SUD?

The goal is thus to move beyond the extremes that have historically guided therapy of PTSD/SUD clients: either none should do past-focused work ("they are too fragile") or all should ("it's helpful for everyone"). The task is to balance these opposites, focusing on how, when, and whether to move into the work with each client.

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Declaration of Interest

Lisa M. Najavits, PhD is the author and developer of *Creating Change*. She is director of Treatment Innovations, which provides training, materials, and consultation related to psychotherapy. Kay M. Johnson, LCSW-R has no interests to declare. The authors alone are responsible for the content and writing of this paper.

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