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ORIGINAL PAPER

Cognitive Behavioral Therapy for Trauma and Self-Care (CBT-TSC) in Men Who have Sex with Men with a History of Childhood Sexual Abuse: A Randomized Controlled Trial

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Abstract
To address childhood sexual abuse (CSA) related distress and HIV risk in men who have sex with men (MSM) using cognitive-behavioral therapy for trauma and self-care (CBT-TSC), which is a novel intervention integrating HIV risk reduction with modified cognitive and behavioral therapy strategies for post-traumatic stress. We compared CBT-TSC to HIV voluntary counseling and testing (VCT)-only in an initial 2-arm RCT in 43 HIV-negative MSM at with a history of CSA and HIV risk. Serodiscordant condomless anal/vaginal sex (CAS; CAS with HIV-postive or HIV unknown status partners) and posttraumatic stress disorder (PTSD) symptoms (Davidson Trauma Scale: total score and avoidance, intrusions, hyperarousal subscales) were outcomes immediately post-treatment, and at 6- and 9-month follow-up. At post-treatment, CBT-TSC had decreased odds (approximately 60%) of any CAS and greater reductions in CAS compared to VCT-only. Additionally, the CBT-TSC condition experienced greater reductions in total PTSD and avoidance symptoms. At the follow-up visits, CBT-TSC condition had significant reductions in the odds of any CAS and reductions in CAS. However, for PTSD symptoms, only the avoidance subscale remained significantly different compared to VCT-only. CBT-TSC is a potentially efficacious approach to address HIV risk in MSM with a CSA history, with replication and extension in a larger trial needed. This proof-of-concept trial is the first to integrate the treatment of a commonly occurring mental-health syndemic problem in MSM with a health psychology approach to self-care in MSM.
Trial Registration Clinicaltrials.gov NCT01266122

Keywords Trauma · HIV · Men who have sex with men · Childhood sexual abuse

Introduction

Childhood sexual abuse (CSA) is disproportionately high among men who have sex with men (MSM), with estimated rates ranging between 29.7 and 35.5% [1–4] as compared to 5–10% of the general male population [5]. The presence of CSA in MSM has been found to be associated with higher rates of HIV sexual risk behavior [6–9] and with higher rates of HIV and other sexually transmitted infections (STIs) compared to MSM with no history of CSA [10, 11]. MSM make up the largest number of individuals living with HIV in the United States (U.S.), have the highest number of new

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infections each year, and have not shown declines in new HIV infections in the past decade. Therefore, interventions to reduce HIV risk behavior among populations at highest risk, MSM with CSA histories, are needed [12]. Although HIV prevention interventions in the U.S. for MSM have been modestly successful [13–15] and cost-effective [16], MSM with CSA may be less likely to benefit from traditional HIV-prevention programs [4]. This may be due, in part, to enduring CSA-related posttraumatic stress reactions that incline MSM with CSA histories to avoid aspects of adult sexual situations, thereby interfering with the implementation of proactive sexual health goals [17].

Cognitive and behavioral therapies comprise a rich evidence base for the psychosocial treatment for post-traumatic stress disorder (PTSD). Cognitive therapies involve learning how to be more aware of maladaptive negative thoughts and beliefs related to the traumatic experiences and learning skills to challenge those thoughts and beliefs. One of these approaches, Cognitive Processing Therapy (CPT) [18–21] can help clients to cope more adaptively with the long-term effects of trauma by changing trauma-related appraisals, identifying thinking errors, addressing interfering thoughts, and restructuring negative cognitions about the self and others. Exposure strategies and other behavioral techniques may help patients habituate their levels of distress, provide a functional context for relearning safety, and can increase distress tolerance [22, 23].

If high rates of HIV risk behavior among MSM with CSA are related to enduring posttraumatic reactions to traumatizing CSA experiences that interfere with the complex social, cognitive, and behavioral skills necessary to navigate adult sexual situations successfully [17], then remediating these CSA-related posttraumatic responses [18, 22, 23] with cognitive therapy may help MSM to enact sexual risk reduction strategies more successfully. Specifically, the use of cognitive therapy strategies to target CSA-related traumatic stress symptoms, integrated with behavioral strategies that allow for systematic rehearsals of sexual pro-health behaviors in situ may allow MSM to approach these sexual situations more fully, to more accurately appraise their risk in these situations, and to move more deliberately toward their sexual health goals, even in the presence of distressing thoughts. In this way, it is anticipated that MSM would develop more accurate HIV risk perceptions, increase their condom-use self-efficacy and their use of condoms, and be more prepared to enter into safer sex negotiations with their sexual partners.

The current study examines the effects of integrating cognitive and behavioral therapy strategies with traditional HIV risk reduction counseling on the long-term effects of CSA in HIV-negative MSM with a CSA history and existing HIV risk behavior. We hypothesize that this intervention, cognitive-behavioral therapy for trauma and self-care (CBT-TSC), would be more successful than traditional HIV risk reduction counseling and testing alone in both reducing HIV-risk behavior and in reducing long-term trauma-related PTSD symptoms. Because this study took place before documentation of viral suppression as a mechanism for reducing HIV transmission risk [24, 25], as well as the FDA approval and use of pre-exposure prophylaxis (PrEP) [26], HIV-risk behavior was defined as condomless anal or vaginal sex (insertive or receptive) with serodiscordant partners (defined as HIV-positive or unknown status partners), heretofore referred to as "condomless anal sex" (CAS).

Methods

Trial Design and Procedures

This was a two-arm, pilot randomized controlled trial with 1:1 allocation ratio. There were four assessment points: baseline, at the end of the treatment period (approximately 3-months after randomization), and at 6- and 9-month follow-up visits. All participants completed an informed consent process prior to undergoing any study procedures. All procedures were approved by the Institutional Review Board at Fenway Health. The two study arms (described below) were either a 10-session integrated CBT-TSC intervention with HIV voluntary counseling and testing (VCT) *or* VCT alone (VCT-only). Randomization occurred after participants completed a baseline assessment and followed their return for HIV test results and two-sessions of HIV risk reduction counseling. The period of recruitment was 07/2007 to 10/2010, with the 9-month follow-up period extending until 07/2011.

Participants

Participants were recruited via study advertisement—through flyers and online ads—and through referrals from other studies taking place at Fenway Health, a community health center in Boston, Massachusetts. Recruitment materials indicated that the study was seeking individuals with recent risk for HIV and childhood sexual abuse histories.

Inclusion criteria were being a biologically born male who has sex with men, reporting a history of CSA (i.e., sexual contact before the age of 13 with an adult or person 5 years older, or sexual contact with the threat of force or harm between the ages of 13 and 16 inclusive with a person 10 years older). The Clinical Sexual Abuse Interview [27–29] was used to assess CSA. To meet criteria for sexual abuse, there must have been clear force or threat of harm; however, in children (< 13 years) the threat of force or harm is implied by a 5-year age differential between the victim and perpetrator. Participants were not required to meet diagnostic criteria for PTSD. Additional inclusion criteria were that

participants report 2 or more episodes of condomless anal intercourse with serodiscordant partners—partners who are of a different HIV status than the participant [30] or whose status was unknown—within the previous 6 months and test HIV negative as part of the baseline screening.

Exclusion criteria included the following: all episodes of unprotected anal intercourse occurred with only a single, primary HIV-negative partner; evidence of untreated or undertreated significant mental health condition (e.g., bipolar disorder, psychosis); and inability to complete the informed consent process (e.g., substantial cognitive impairment, inadequate English language skills, acute intoxication from drugs and/or alcohol). Data were collected at The Fenway Institute (TFI) at Fenway Health.

Randomization and Participant Flow

Of the forty-six men enrolled in the study, forty-three were randomized. Figure 1 depicts participant flow throughout the study from screening to randomization to follow-up. Participants were randomized to either the experimental intervention, CBT-TSC (n = 23) or the VCT-only comparison condition (n = 20) (both described below). The randomization sequence was generated in blocks of four with a 1:1 allocation ratio. After participants completed the VCT confirming their HIV-negative status, they were then assigned by the study research assistant to one of two study arms based on the randomization table.

Assessment Measures

Demographics Participants completed a self-report standard demographic assessment that included age, ethnicity, education level, and employment status.

Primary outcome: Serodiscordant condomless anal/vaginal intercourse The primary outcome for the current study was condomless anal/vaginal sex with HIV-positive or HIV -nknown status partners. Overwhelmingly, the sexual risk episodes reported were anal intercourse acts with HIV-positive or -unknown status male partners. However, condomless vaginal intercourse acts with serodiscordant women were also included in outcome variable. These data were collected via computer-assisted self-interview (CASI) software to increase the chances of disclosure of sensitive questions. Specifically, participants were asked about the number of times that they had anal/vaginal sex with male/female partners by perceived HIV status of the partner (HIV-negative, HIV-unknown, and HIV-positive) and whether a condom was used. These data were analyzed both in terms of the proportion of men in each condition (at follow-up visits) who engaged in any condomless sex with unknown-status or HIV-positive partners, as well as continuously, with respect to the number of these types of partners with whom they had condomless sex.

Psychiatric Diagnosis (administered by clinician, independent assessor) The Mini-International Neuropsychiatric Interview, 6th edition [31] (MINI-6) was used to assess symptoms and a diagnosis of PTSD. The MINI-6 is a clinician-administered brief structured interview for diagnosing DSM-IV disorders, including PTSD. It has been shown to have high validation and reliability scores comparable to the Structured Clinical Interview for the DSM-IV [31]. A diagnosis of PTSD was not required for entry into the study.

PTSD Symptoms (administered by clinician, independent assessor) The Davidson PTSD Scale [32, 33] is a 17-item self-report measure, based on the PTSD symptom clusters defined by DSM-IV. Each item is rated from 0 to 4 for both frequency and severity of each symptom during the past week. Items are summed for a total score (range 0–136), and subscales of re-experiencing, avoidance, and hyperarousal. The total scale has demonstrated good test–retest reliability (r = .86) and internal consistency (r = .99). The subscales also have high reliability (alpha ≥ .83). This scale was utilized in this study to identify posttraumatic symptoms related specifically to CSA.

Randomization Conditions

Following research team review of their baseline assessments, participants who met eligibility requirements were randomized. Pre-randomization baseline clinical assessments were conducted by study therapists. Follow up clinical assessments were conducted by Independent Assessors who were blind to study condition.

Control condition Participants in both study conditions (CBT-TSC and VCT-only) received HIV/STI voluntary counseling and testing (VCT) at baseline. Individual pretest counseling involved discussion of various points from a checklist following Massachusetts State Department guidelines. Following the delivery of the HIV test results participants discussed their result with the counselor and how the result related to their plans for their sexual health going forward. The VCT procedure is assumed to approximate standard of care, with guidelines from the Centers for Disease Control and Prevention indicating that HIV testing and counseling be integrated into routine medical care [34]. From 2007 to 2010 Massachusetts participated in CDC Expanded HIV Testing Initiative which, among other guidelines, required that 20% of testing efforts made by state health departments focused on reaching high-risk populations, including gay and bisexual men [35].

Participants testing HIV-positive were excluded from the trial and referred for HIV care.

Treatment condition In addition, participants randomized to the experimental intervention received 10 individual

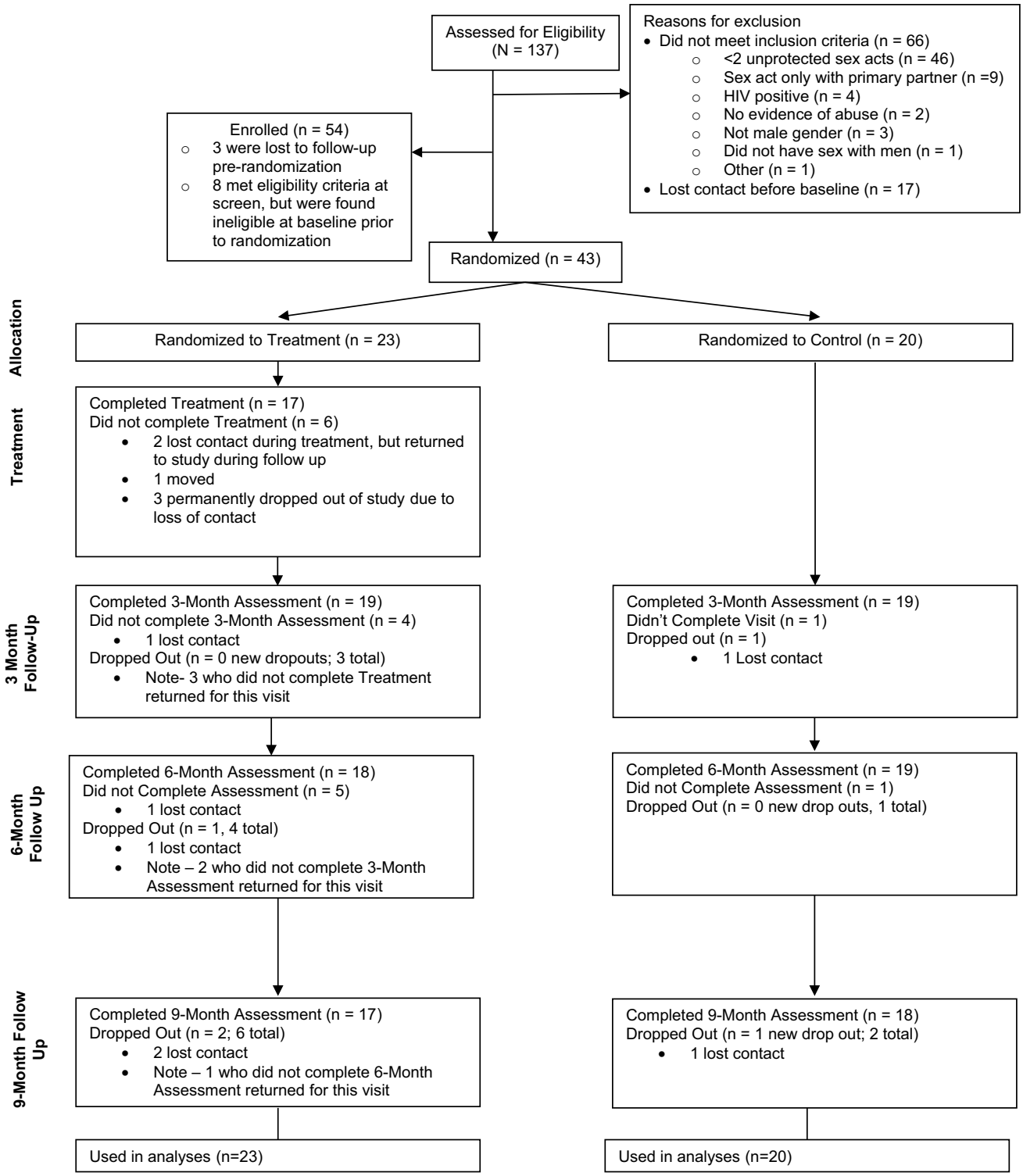

Fig. 1 Participant flow

therapy sessions of CBT-TSC. Sessions 1 and 2 focused on sexual risk reduction counseling, which included identifying motivated targets for sexual behavior change, articulating one's sexual risk limits, recognizing barriers to staying within these limits and strategies for overcoming these barriers. Sessions 3 through 8 were comprised of the integration of cognitive therapy strategies, behavioral techniques, and sexual risk reduction counseling. Sexual risk reduction

strategies were reviewed at the start of each session, and ways in which to integrate the cognitive therapy informed skills [18] in to risk reduction were discussed. Session 3 also involved psychoeducation about the effects of trauma, normalizing symptoms of post-traumatic stress, and a review of existing adaptive coping strategies. Sessions 4 and 5 included identifying a problematic cognitions about self/world related to specific CSA event, describing thoughts and feelings related to the CSA, and generating an impact statement—a written account of the most significant sexual abuse incident (a strategy utilized in CPT) [18]. Sessions 5 through 7 involved learning how to identify cognitive distortions (e.g., self-blame, guilt), and strategies for challenging and changing these unrealistic beliefs. During Sessions 8 through 10 participants were assigned behavioral experiments as homework. Behavioral experiments were enacted in sexual (or social) situations in which negative posttraumatic thoughts about self were likely to emerge and interfere with sexual risk reduction goals. The therapeutic rationale for the behavioral experiments was to provide the functional context in which cognitive restructuring skills could be utilized and to provide the opportunity for rehearsal of adaptive behaviors relevant to participant goals for sexual health. In session, participants planned for the behavioral experiment and anticipated posttraumatic cognitions. The final 3 sessions also focused on consolidating the cognitive therapy skills and discussed areas (e.g. safety, power/control, esteem) that have been most disrupted by the CSA experience (also utilized in CPT) [18]. Every session allocated up to 10 minutes specifically relating the participants' current sexual behavior to posttraumatic responding and integrating the cognitive therapy skill set into the participants' specific sexual risk reduction plan.

Study therapists included clinical psychologists (including the study Principal Investigator (PI; CO)), and pre- and post-doctoral fellows in clinical psychology. Therapist training included a 2-day CPT training with its developer, Dr. Patricia Resick, and completion of approximately 15 h of training with the study PI on administering the adapted study specific cognitive behavioral therapy intervention integrated with HIV risk reduction counseling. Ongoing therapist training also included weekly clinical supervision. As part of clinical supervision study therapists received data-based clinical and treatment adherence feedback from the PI based on audio review of therapy sessions. The PI participated in regular clinical consultation with a consultant clinical psychologist (JCS).

Treatment Fidelity and Therapist Competency

Treatment fidelity was assessed by a doctoral level clinical psychologist from audio recordings. Twenty-four treatment sessions were reviewed (approximately 12% of sessions) using checklists specific to each session ranging from 4 items to 7 items depending on the session (e.g., "Identify barriers to implementing sexual risk reduction goals", "Introduce impact statement and assign as home work", "Provide rationale for behavioral experiments"). Each therapist/session was awarded a percentage score for each session assessed.

Therapist competency was assessed for each non-zero competency item on the checklists (scored from 1 = poor, to 5 = excellent), whereas a score of 1 reflected a brief and cursory consideration of the item and a score of 5 reflected a full interactive, participant-centered consideration of the item including demonstration of therapist skills (i.e., active listening, restatement, clarification, reinforcement). Items that were scored zero for treatment fidelity were also scored zero for therapist competency.

Sample Size and Power Analysis

The study, a-priori, was not powered for efficacy testing, but rather was designed as an incremental project that would progress to a full-scale efficacy trial. However, the goal was to have 40 completers, 20 per intervention arm. This was based on power to detect a categorical outcome of having zero episodes of unprotected anal sex. With 40 participants, this would allow for 80% power at a $p < .05$, two-sided significance test assuming a 40-percentage point difference between the intervention group and the control group (i.e., the intervention group having a 50% response rate and the control group having a 10% response rate). We also sought a "medium" effect on sexual risk assessed continuously as part of evidence for the need for a full-scale RCT of the intervention and informed by previous sexual risk reduction trials with MSM [36, 37].

Statistical Methods

Hierarchical Linear Modeling (HLM) with HLM 7.0 software was used to evaluate acute study outcomes immediately post treatment [38]; this included insertive or receptive condomless intercourse sex acts, evaluated as both a categorical variable and as a dichotomous indicator. As the distributions of the continuous measure of sexual risk in the past 6 months were significantly skewed at both baseline and the post treatment follow up, the distributions were categorized into sextiles. This methodology produced distributions that approached normalcy, allowed for the use of sexual risk data from all participants, and provided a depiction of variation in the data. The dichotomous indicator of sexual risk differentiated those who reported any condomless intercourse acts with serodiscordant partners in the previous 6 months from those who did not. Treatment related changes in trauma-related

symptom severity were also evaluated for total symptoms and the avoidant, intrusion, and hyperarousal symptom clusters. HLM was also used to evaluate the maintenance of treatment related changes through 9-month follow-up.

For post treatment and follow-up HLM analyses the *Level 1* HLM model included the Time variable (months since baseline), which provided the structure of the model for the outcome variable of interest. The *Level 2* model tested the significance of the treatment effect, and is estimated from the significance of the slope (gamma coefficient) associated with the random assignment variable (CBT-TSC or VCT-only). In both sets of analyses the pre-randomization levels are controlled for in the estimation of the slopes.

For the HLM models, all continuous measures in the *Level 2* model were centered about their group means, and all dichotomous variables were coded 1/0. Model parameters were estimated using full maximum likelihood estimation with robust standard errors. In all analyses that used HLM, unconstrained models were run to confirm significant individual variation about the slope and intercept before accounting for random assignment. For all analyses, the Type 1 error rate adopted was a p of $< .05$.

Results

Participant characteristics are described in Table 1. In brief, the mean age was 39.19 years of age (SD = 11.07). Approximately 2/3 of the sample reported educational experiences beyond high school. Despite this, more than half of the sample reported earning less than $20,000 per year. The sample was predominantly Caucasian (62%), 25% African American and 7% identifying as Hispanic/Latino. More than 90% of the sample identified as gay or bisexual. Approximately 1/3 (32.6%) of the sample met diagnostic criteria for PTSD, 5 participants in the control condition and 9 participants in the treatment condition met criteria for PTSD (Chi Square (1) = 0.97, $p = .32$). Of the 43 participants randomized, 38 (88%) completed the post-treatment assessment (3-month), 36 (84%) completed the 6-month follow-up, and 35 (81%) completed the 9-month follow-up. Of those assigned CBT-TSC (n = 23), 17 (74%) completed the treatment. There were no significant differences between the study conditions on any of the demographic/background variables.

Fidelity and Competency Results

The mean fidelity rating was 89.05% (SD = 19.67) with a range from 33 to 100%.

Table 1 Demographics and background characteristics

	Control (n = 20) Mean (SD)/%		Treatment (n = 23)		Total (n = 43)		Chi square/t test
Age	39.55	(10.61)	38.87	(11.68)	39.19	(11.07)	0.20
Education							
< High school	2	10.0%	2	8.7%	4	9.3%	
High school grad	5	25.0%	7	30.4%	12	27.9%	
Some college	6	30.0%	3	13.0%	9	20.9%	
College grad+	7	35.0%	11	47.8%	18	41.9%	2.02
Income							
< $20,000	12	60.0%	10	43.5%	22	51.2%	
$20, 001–$40,000	4	20.0%	2	8.7%	6	14.0%	
$40,001–$60,000	2	10.0%	4	17.4%	6	14.0%	
> $60,000	2	10.0%	7	30.4%	9	20.9%	4.10
Race/ethnicity							
African American	7	35.0%	4	17.4%	11	25.6%	
Caucasian	11	55.0%	16	69.6%	27	62.8%	
Hispanic/Latino	1	5.0%	2	8.7%	3	7.0%	
Other	1	5.0%	1	4.3%	2	4.7%	1.88
Sexual orientation							
Gay	11	55.0%	16	69.9%	27	62.8%	
Bisexual	8	40.0%	4	17.4%	12	27.9%	
Unsure	1	5.0%	3	13.0%	4	9.3%	3.06

Interrater reliability was calculated for 10 sessions yielding a Kappa coefficient of 1.0 (df: 9), $p < .001$, with 8/10 total agreements, indicating near perfect agreement.

The mean competency rating was 84.91% with a range from 28.57 to 100%. Interrater reliability was also calculated for 10 sessions yielding a Kappa coefficient of 0.49, (df = 9), $p < .001$, with 6/10 total agreements, indicating moderate agreement.

Post-Treatment Outcomes

Condomless sex with serodiscordant partners For the sample as a whole there was a significant downward slope in the odds of condomless sex ($\gamma_{slope} = -0.30$, t (42) = −4.96, $p < .001$) and the individual variation about the slope was not significant ($\gamma_{slope} = .01$, *Chi Square* = 1.76 (41) $p > .1$).

When adding treatment condition (random assignment), as a predictor to the *Level 2* model, the decrease in odds of condomless sex acts was significantly greater over the treatment period in the CBT-TSC condition ($\gamma_{slope} = -0.51$, t (41) = −2.19, $p = .03$; *OR* = 0.59 *CI* 0.37–0.96) indicating that those in the treatment condition had less than 60% the odds of reporting any condomless sex compared to those in the control condition (see Table 2).

As the distribution of the continuous measure of sexual risk in the past 3 months was significantly skewed at both baseline and the post treatment follow up, the distributions were categorized into sextiles. Using this categorization, there was significant downward slope in sexual risk for all participants ($\gamma_{slope} = -0.42$, t (41) = −7.09, $p < .001$) and significant individual variation about the slope ($\gamma_{slope} = 0.37$, *Chi Square* = 83.49 (36) $p < .001$).

When random assignment was entered into the model, those in the treatment condition experienced a significant decrease in the rates of sexual risk compared to the control condition ($\gamma_{slope} = -0.51$, t (41) = −3.66, $p < .001$).

Davidson Trauma Scale For the Davidson Trauma Scale total score the slope for the group as a whole was not significantly different from zero ($\gamma_{slope} = -.02$, t (41) = 2.43, $p > .1$) although there was significant individual variation about the slope ($\gamma_{slope} = 4.40$, *Chi Square* = 63.40 (36) $p < .01$).

When randomization was entered in to the *Level 2* model there were significantly greater reductions in posttraumatic symptom severity for the CBT-TSC condition relative to the comparison condition for the Davidson Total Score ($\gamma_{slope} = -6.18$, t (41) = −2.47, $p = .018$) and for the Avoidance subscale ($\gamma_{slope} = -3.16$, t (41) = −2.78, $p = .008$) immediately post-treatment. A trend for a difference between the conditions was observed for the Intrusions subscale ($\gamma_{slope} = -1.32$, t (41) = −1.65, $p = .10$). Differences between the conditions for the Hyperarousal subscale were not significant ($\gamma_{slope} = -1.09$, t (41) = −1.17, $p = .25$).

Assessment of Maintenance Effects through 9-Month Follow-Up

The assessment of maintenance effects was undertaken estimating slopes from all available data from baseline, 3-, 6-, and 9-month post baseline assessments. The slope of the change in odds of sexual risk for all participants during the follow-up period was significant ($\gamma_{slope} = -0.15$, t (42) = −3.58, $p < .001$) although individual variation about the slope was not significant ($\gamma_{slope} = 0.04$, *Chi Square* = 25.47 (38) $p > .5$).

Those in the treatment condition maintained their treatment gains over the follow-up period in that the odds of reporting any episodes of condomless sex acts in the previous 3 months in the CBT-TSC condition were approximately one third that of the control condition

Table 2 Means and standard deviations of primary outcomes: unprotected anal intercourse with serodiscordant (HIV positive or status unknown) partners and posttraumatic symptom severity (Davidson Trauma Scale and subscales) across each of the major study time-points

Study condition	Baseline		Post treatment (3 month)		6-month follow-up		9-month follow-up	
	Control	Treatment	Control	Treatment	Control	Treatment	Control	Treatment
Study outcome								
Sexual risk behavior (SRB)	6.40 (8.61)	4.00 (5.60)	5.10 (9.24)	1.0 (4.27)	2.95 (6.15)	0.91 (4.26)	4.29 (8.41)	1.20 (3.90)
% of sample with SRB	0.85 (0.37)	0.87 (0.34)	0.65 (0.49)	0.09 (0.29)	0.50 (0.51)	0.05 (0.21)	0.65 (0.49)	0.13 (0,35)
Davidson total score	37.20 (25.29)	47.09 (21.27)	44.79 (30.31)	32.21 (27.85)	32.21 (27.85)	35.61 (35.26)	45.06 (33.21)	29.69 (26.37)
Avoidance subscale	16.65 (13.27)	21.96 (14.20)	19.79 (15.82)	13.16 (12.92)	19.68 (16.88)	15.28 (13.79)	18.94 (14.25)	11.19 (10.75)
Intrusions subscale	5.85 (7.15)	10.09 (6.82)	10.21 (8.13)	7.37 (7.42)	8.58 (10.25)	5.28 (8.74)	10.67 (11.07)	6.00 (7.56)
Hyperarousal subscale	15.30 (8.74)	16.61 (7.16)	14.79 (9.30)	11.68 (10.50)	16.95 (10.42)	15.06 (16.62)	15.44 (10.72)	12.50 (10.34)

($\gamma_{slope} = -0.37$, t (41) $= -4.81$, $p < .001$; $OR = 0.68$ CI 0.59–0.81).

When the rate of change in sexual risk over the entire follow-up period was examined using sextile categorization the rate of decline in condomless sex acts over the follow-up period was significant for all participants ($\gamma_{slope} = -0.26$, t (41) $= 2.33$, $p = .03$) and individual variation about the slope was also significant ($\gamma_{slope} = 0.05$, *Chi Square* = 123.56 (38) $p < .001$).

Comparing the randomization conditions across the follow-up period, those in the treatment condition experienced a significantly steeper decrease in sexual risk over time compared to those in the control condition ($\gamma_{slope} = -0.11$, t (41) $= 2.07$, $p = .04$).

Davidson Trauma Scale For the Davidson Trauma Scale total score the slope for all participants over the follow up period was not significantly different from zero ($\gamma_{slope} = -0.07$, t (41) $= -0.12$, $p > .5$) although there was significant individual variation about the slope ($\gamma_{slope} = 4.40$, *Chi Square* = 63.40 (36) $p < .01$).

Over the follow-up period, there was a trend for a statistically significant difference between the randomization conditions on the Davidson Trauma Scale total score ($\gamma_{slope} = -1.63$, t (41) $= -1.61$, $p = .11$). The significant reductions in trauma symptom severity for the Avoidance subscale observed at post-treatment were also evident during the follow-up period ($\gamma_{slope} = -0.88$, t (41) $= -2.15$, $p = .037$). A trend for a meaningful difference between the conditions during the follow-up period was observed for the Intrusions subscale ($\gamma_{slope} = -0.59$, t (41) $= -1.64$, $p = .11$). Differences between the conditions for the Hyperarousal subscale during the follow up period were not significant ($\gamma_{slope} = -0.06$, t (41) $= -0.17$, $p = .87$). The HLM slope estimates and significance tests for the post treatment and follow-up outcomes are presented in Table 3.

Discussion

This study sought to address the high rates of sexual risk for HIV among gay, bisexual, and other MSM with CSA histories by addressing posttraumatic CSA-related symptoms and their association with higher levels of sexual risk taking. Accordingly, we utilized components from an evidence-based treatment for PTSD (i.e., CPT) with behavioral strategies and HIV sexual risk reduction counseling to help MSM with a CSA history decrease their trauma specific distress and improve their sexual health.

The current sample was selected for HIV risk, and all primary and secondary outcome variables were in the expected direction. With respect to condomless anal sex with HIV-positive or -unknown status partners (primary outcome), a greater proportion of participants in the CBT-TSC intervention reported no serodiscordant condomless anal sex post-treatment than those in the VCT-only condition. Participants in the treatment condition also reported fewer episodes of condomless anal sex post treatment than those assigned to VCT-only. The significance of these effects was observed both at the post-treatment outcome assessment and over time during the follow-up period. These results therefore suggest that integrating trauma treatment for CSA-based trauma symptoms with risk-reduction counseling may be an effective strategy for HIV prevention in the context of this co-occurring psychosocial problem, with replication needed with a larger sample.

With respect to posttraumatic symptom severity (secondary outcome), participants in the CBT-TSC intervention condition had lower total scores on the independent-assessor rated Davidson Trauma Scale at the acute (3-month) time point compared to those in the control condition. After analyzing the sub-scales, effects were also present, at post-treatment for the avoidance subscale. During the follow-up period the Davidson Trauma Scale total score maintained a trend toward significance, and the symptoms measured within the avoidance subscale were still significantly

Table 3 Hierarchical Linear Modeling slope parameters and significance tests for change in primary study outcomes, unprotected anal intercourse with serodiscordant (HIV positive or status unknown) partners and posttraumatic symptom severity (Davidson Trauma Scale and subscales) estimates at post treatment and over the follow-up period

Study outcome/parameter	Post treatment			9-month follow-up		
	γ_{slope}	t (df)	p /OR (CI)	γ_{slope}	t (df)	p /OR (CI)
Condomless anal sex	−0.506	−3.66 (41)	<.001	−0.11	2.07 (41)	.04
Proportion with condomless anal sex	−0.51	−2.19 (41)	0.59 (.37–.96)	−0.37	−4.81 (41)	0.68 (.59–.81)
Davidson total score	−6.18	−2.47 (41)	.02	−1.63	−1.61 (41)	.11
Avoidance subscale	−3.16	−2.78 (41)	.01	−0.88	−2.15 (41)	.04
Intrusions subscale	−1.32	−1.65 (41)	.10	−0.59	−1.64 (41)	.11
Hyperarousal subscale	−1.09	−1.17 (41)	.25	−0.06	−0.17 (41)	.87

improved in the intervention condition compared to the control condition. These findings suggest that the integrated CBT-TSC intervention may have effects on total trauma symptoms, but also these effects may be primarily driven by reductions in trauma-related avoidance. The lack of effects for the intervention on hyperarousal or intrusion subscales may be due to the fact that the majority of the participants did not have diagnostic levels PTSD, and that for many participants, CSA-trauma may have occurred in the distant past and symptoms such as hyperarousal may not have been the most relevant CSA/trauma-related symptoms, or they did not have PTSD at all. Floor effects on PTSD reduced the likelihood of change on the scale. Additionally, the treatment focused on addressing maladaptive CSA-related thoughts and behaviors in the service of reducing sexual risk, rather than reducing PTSD symptoms per se. Thus, the intervention systematically encouraged clients to approach, versus avoid, trauma-related cognitions in the context of sexual situations.

The significant treatment-related changes in both sexual risk behavior and posttraumatic symptom severity may suggest that MSM with a history of CSA may avoid distressing aspects of sexual encounters and therefore avoid safer sex behaviors. In this conceptualization, CSA-related avoidance in adult sexual situations may be driven by avoiding the distress associated with PTSD symptoms, including distress and cognitions about self, which can contribute to increased sensitivity to interpersonal rejection. Such avoidance behaviors, in turn, can interfere with the ability to appraise risk/safety in sexual situations accurately. The integrated CBT-TSC treatment was designed to provide participants with skills to decrease avoidance of distress in adult sexual situations, particularly related to negative posttraumatic cognitions about self. The treatment also provided participants with a method for restructuring these types of cognitions, emphasizing other coping, identifying goals for sexual health, and providing behavioral experiments for rehearsal to achieve these goals.

More comprehensive support for the conceptual model can be evaluated in a full-scale efficacy trial that will allow for a detailed examination of these suggested pathways. The significant finding for the avoidance symptom cluster suggests that men who complete the treatment may well be significantly less avoidant in sexual situations allowing them to reap the benefit in terms of greatly reduced sexual risk behavior. A full-scale efficacy trial will also allow for a more meaningful estimation of treatment effects in comparison to a credible time matched control. This will also allow for comprehensive moderation analysis identifying those who derive most benefit as well as estimating the impact of the intervention for MSM of color who are at increased risk for both CSA [39] and HIV [40].

A limitation of the current study is the small sample size. Accordingly, a future study is needed to more fully evaluate this approach. Additionally, as an initial study, we sought to examine whether the full-fledged intervention fared better than what is currently standard of care, VCT-only. A future evaluation of this approach using a time-matched control group would test whether the specific effects of the intervention fare better than increased attention from a therapist: an explanation that cannot be ruled out on the basis of the current study design. Although the current study evaluated the impact on sexual risk behavior a future full scale efficacy trial could evaluate the impact of the intervention on other sexually transmitted infections in addition to HIV other indicators of risk. The study was also not powered to examine mediators of the intervention effect, and this too should be addressed with a larger sample. Finally, the study was conducted before the FDA approval of PrEP, and before the effects of treatment as prevention were fully known. Thus, a future study examining HIV risk that accounts for advances in biomedical prevention when assessing condomless sex would be indicated.

This trial, however, has important public health implications in that, as an HIV prevention intervention, it specifically integrated an evidence-based psychological treatment for a very common co-occurring psychosocial problem for a sexual minority with an important self-care behavior for HIV risk reduction. Study after study shows that HIV risk, for MSM, occurs in the context of intertwined psychosocial problems, called syndemics [7, 41, 42], and that various syndemics, such as CSA, may interfere with the ability of MSM to benefit from HIV prevention interventions [4, 43].

Previously, some interventions for HIV-positive individuals, including MSM, have been tested using evidence-based approaches and achieved some success addressing certain syndemic problems in the context of increasing adherence (a self-care behavior), [41, 44–46] Additionally, another integrated treatment model has shown promise using a behavioral activation to reduce stimulant use and sexual risk in MSM [47]. However, to our knowledge, Cognitive Behavioral Therapy for Trauma and Self Care (CBT-TSC) is the first intervention to fully integrate the treatment of CSA trauma-related symptoms with HIV risk reduction counseling for MSM.

Sexual minority men can experience multiple psychosocial challenges in adulthood as a result of the sexual minority stress-related developmental vulnerabilities such as CSA [48, 49]. It is likely that these challenges, in part, contribute the devastating disparity for HIV. Our community's success at addressing this disparity will be driven by our ability to develop efficacious and effective treatments to improve the mental health and the sexual health of those most at risk.

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