Published in final edited form as:

AIDS Behav. 2010 April ; 14(2): 421–430. doi:10.1007/s10461-009-9573-7.

The Impact of Trauma-Focused Group Therapy upon HIV Sexual Risk Behaviors in the NIDA Clinical Trials Network “Women and Trauma” Multi-Site Study

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Abstract

Women in drug treatment struggle with co-occurring problems, including trauma and posttraumatic stress disorder (PTSD), which can heighten HIV risk. This study examines the impact of two group therapy interventions on reduction of unprotected sexual occasions (USO) among women with substance use disorders (SUD) and PTSD. Participants were 346 women recruited from and receiving treatment at six community-based drug treatment programs participating in NIDA's Clinical Trials Network. Participants were randomized to receive 12-sessions of either seeking safety (SS), a cognitive behavioral intervention for women with PTSD and SUD, or women's health education (WHE), an attention control psychoeducational group. Participants receiving SS who were at higher sexual risk (i.e., at least 12 USO per month) significantly reduced the number of USO over 12-month follow up compared to WHE. High risk women with co-occurring PTSD and addiction may benefit from treatment addressing coping skills and trauma to reduce HIV risk.

Keywords

HIV/AIDS; Substance abuse; PTSD; Trauma; Sexual risk

Introduction

A significant concern for women in substance abuse treatment is the risk of HIV infection and AIDS. Gender-specific behavioral pathways between substance use disorders and risk for HIV infection include engaging in unprotected sexual intercourse (Rasch et al. 2000; Semple et al. 2004), reporting a greater number of sexual partners (Santelli et al. 1998) and sexual acts, (Rasch et al. 2000) and exchanging sex for money or drugs (Hoffman et al. 2000). Being under the influence of alcohol or drugs may diminish inhibitions and adversely affect decisions about engaging in safer sex practices. Another ubiquitous risk factor among women with high risk sexual practices and addictive disorders is a history of interpersonal violence and sexual abuse (Cohen et al. 2000; El-Bassel et al. 2001; Maman et al. 2000; Senn et al. 2007). Sexual abuse in particular has been associated with subsequent problems in sexual functioning, ranging from sexual avoidance to impulsive or compulsive sexual activity (Briere and Runtz 1993; Browne and Finkelhor 1986).

HIV interventions for women (Exner et al. 1997) and HIV interventions in substance abuse treatment programs (Prendergast et al. 2001; Wells et al. 1996; Woods et al. 1999) have been shown to be efficacious in reducing sexual risk behavior. However, in a meta-analysis of HIV prevention interventions for women, Logan et al. (2002) found that few interventions address social and contextual risk factors, including childhood and adult victimization, mental health issues, and substance abuse. Further, interventions that failed to account for the specific environment and context in which women negotiate safer sex had poorer condom use outcomes (Logan et al. 2002). A few studies in this review addressed some social and contextual factors but their target populations were not women with a history of trauma or PTSD and substance use disorders (Exner et al. 1997; Nyamathi et al. 1999; Shain et al. 1999). Several reviews (Exner et al. 1997; Logan et al. 2002) indicated that in order for HIV risk reduction interventions to be efficacious for women, they should be gender specific, contain a minimum of four sessions, and focus on skills development. In particular, recommendations for women-focused

interventions include emphasis on communication and relationship power imbalances related to sexual behavior, as well as integrating elements of drug treatment and addressing risk factors such as traumatic stress, low self-esteem, and self-efficacy (Amaro et al. 2007; Exner et al. 1997; Meade and Sikkema 2005; Tross et al. 2008).

Reducing trauma symptoms has been linked to decreases in sexual risk behavior (Gore-Felton and Koopman 2002; Sikkema et al. 2008; Wyatt et al. 2004). Wyatt et al. (2004) explored the efficacy of a cognitive behavioral intervention which included trauma-focused groups on HIV risk reduction in HIV positive women. At 3 months post treatment, women in the cognitive behavioral group reported a 75% reduction in risk behavior versus a 50% reduction in the attention control group. In a qualitative study with HIV positive women who had histories of childhood sexual abuse, Tarakeshwar et al. (2005) found that substance abuse was a common coping mechanism for dealing with distressing symptoms and sexual activity, but that women were not easily able to make these connections. Amaro et al. (2007), in a quasi-experimental study of integrated trauma treatment (including three HIV/AIDS prevention sessions) for women in substance abuse treatment, found that those receiving the trauma-enhanced treatment had significantly fewer sexual risk occasions compared to those in treatment-as-usual. Given the interconnected relationships between trauma history, substance use, and HIV sexual risk behaviors, these studies provide some indication that integrated trauma and substance abuse treatment may reduce sexual risk behaviors.

Strategies used to help women be more successful in negotiating safer sex include increasing self efficacy and self esteem. Both have been shown to be positively associated with a set of mediators (i.e., condom use self efficacy, condom attitudes, partner communication) that predict safer sex behavior (Salazar et al. 2005). Insofar as an intervention targets increasing self efficacy and self-esteem, social cognitive theory (Bandura 1977, 1986) would predict greater behavioral change in sexual risk behavior when compared with HIV prevention interventions based on psychoeducation alone (the kind typically implemented in substance abuse treatment programs; Shoptaw et al. 2002).

The present study is the first randomized controlled trial to examine the effect of integrated trauma and substance abuse therapy, with a focus on building self efficacy and safe coping behavior, on HIV sexual risk behavior among a diverse sample of women with comorbid substance use disorders and PTSD. The results of this study will add to the limited number of studies that indicate trauma-focused or coping skills interventions can reduce HIV risk behavior in women with trauma histories and substance abuse.

Methods

Participants

This study was conducted within the National Institute on Drug Abuse (NIDA) Clinical Trials Network (CTN). Participants were 346 women from six geographically diverse community-based substance abuse treatment programs in the United States. Each site randomized from 34 to 106 participants (an additional site withdrew early due to low recruitment and the seven cases are not included in this analysis). All participating programs offered outpatient individual and group treatment, reflecting varying orientations and philosophies of addiction treatment.

To be eligible, participants had at least one lifetime traumatic event and met DSM-IV criteria for either full or subthreshold PTSD in the past 30 days. Sub-threshold PTSD differed from full PTSD only in the number of symptom clusters that needed to be present; that is they had to meet criteria B (re-experiencing the trauma), but only had to meet criteria C (avoidance of trauma reminders) or D (hyperarousal) instead of both. Previous research indicates that a subthreshold PTSD syndrome exists, that it can be identified using the above criteria (Hien et

al. 2004), and that it can increase a study's external validity (Schutzwohl and Maercker 1999). Other inclusion criteria were: (1) women 18–65 years of age; (2) alcohol or illicit substance use within the past 6 months; and (3) a current diagnosis of drug or alcohol abuse or dependence.

Women were excluded if they had: (1) impaired mental cognition based on a Mini-Mental Status Exam (Folstein et al. 1975) score <21; (2) significant risk of suicidal/ homicidal behavior; (3) history of schizophrenia-spectrum diagnosis; or (4) a history of active (past 2 months) psychosis. There were no inclusion or exclusion criteria based on HIV serostatus and HIV status was not collected as part of this study. The majority of ineligibility was due to not meeting PTSD or substance use criteria ($n = 97$ of 171, 56.7%) or presenting as a suicide risk ($n = 31$ of 171, 18.1%).

Procedures

Recruitment occurred over a 21-month period in 2004 and 2005. Interested treatment program clients completed a brief assessment to ascertain potential eligibility, followed by a screening assessment to confirm eligibility. A third (baseline) interview was completed to assess additional substance use, PTSD, and social characteristics. Participants were reassessed at 1-week, 3-, 6-, and 12-months post treatment. Independent assessors performing all baseline and follow-up assessments were, to the extent possible, blind to participant's treatment assignment. See Fig. 1 for a diagram of participant flow through the study.

Interventions

After the baseline assessment, female participants were randomized into one of two 12 session group interventions. Treatment consisted of two 90-min sessions per week for 6 weeks. Groups ranged in size from two to eight women and operated with an open, rolling admission so that participants entered the group at any point in the session cycle (i.e., a participant could enter at session three and complete treatment with session two).

Seeking Safety Treatment (Najavits 2002)—Seeking safety treatment (SS), a short-term manualized therapy, applies cognitive-behavioral strategies to the goals of reducing substance use and the negative impact of trauma exposure and was developed for both individual and group modalities. Sessions are structured and include basic education on substance use disorders and PTSD, action skills to prevent drug use and control PTSD symptoms, cognitive restructuring with particular attention to maladaptive thoughts associated with substance use and trauma symptoms, and a focus on relationship issues and developing effective communication skills to build a healthy support network. Session topics are meaningfully connected to participant reports of unsafe behavior and coping skills.

The basic format of each session includes: (1) a check in for the therapist to find out how the participant is doing and identify safe and unsafe coping used since the last session; (2) a session quotation to provide a brief point of inspiration; (3) connecting the session topic and materials to the patient's experience, offering intensive skill rehearsal; and (4) a check out to provide an opportunity for the therapist to reinforce progress and to provide feedback. While SS does not focus on specific HIV risk behaviors or provide any HIV prevention education, discussion about safety and coping may include sexual or drug risk behaviors. For example, in the context of learning to be assertive in relationships, setting boundaries with partners around safer sex may be discussed. The group format allows for women to discuss the application of coping skills in their lives and participants provide support and reinforcement to each other. Seeking Safety was originally developed for women in the community, but has recently been employed in other populations (men, incarcerated individuals, adolescents).

Women's Health Education (Miller et al. 1998)—Women's Health Education is a psychoeducational intervention that focuses on topics such as female anatomy, human sexual behavior, pregnancy and childbirth, nutrition, and diabetes. It also includes a session on risk behaviors associated with sexually transmitted infections and a session on HIV risk exposure and transmission. WHE provides equivalent facilitator attention, expectancy of benefit, and issue oriented focus, but does not provide theory driven techniques such as cognitive behavioral therapy and psychoeducation specific to substance abuse and PTSD. All sessions followed a common format: (1) introduction of topic; (2) review of group rules; (3) review of between session assignments; (4) topic presentation using mini-lecture, video, story-telling and/or text readings; (5) exercises to facilitate group discussion and application of materials; and (6) goal-setting.

Measures

Sociodemographics

Basic demographic data, including age, ethnicity, and race were collected at the screening assessment. Marital status and education were collected at baseline using the *Addiction Severity Index (ASI-Lite)*, revised from the 1997 ASI Fifth Edition; McLellan et al. 1992).

HIV Risk Behavior

Sexual risk behavior was assessed using the *Risk Behavior Survey* (RBS; Booth et al. 1993), an interviewer-administered questionnaire assessing HIV risk behavior defined as sexual activity (vaginal or anal sex) without use of a condom in the past 30 days. Because sexual activities were evaluated on a categorical seven-point scale for frequency (once/irregularly to four or more times per day), data were recalculated to create a continuous variable of vaginal or anal occasions. The number of sexual occasions in the past 30 days was coded 1 = once/irregularly; 2 = less than once per week; 5 = about once per week; 16 = 2–5 times per week; 30 = about one time per day and; or 60 = 2 or more times per day. The proportion of condom use was recoded as 0 = never; 0.25 = less than half the time; 0.5 = about half the time; 0.75 = more than half the time; and 1 = always. Number of occasions was multiplied by one minus the proportion of condom use to derive a continuous variable of number of unprotected occasions in the past 30 days.

Substance Use

Alcohol and substance use data were collected for the prior 30-days using the *ASI-Lite* (McLellan et al. 1992). A single, continuous substance use variable was created using the maximum days of use among five substances (alcohol, heroin, other opiates, cocaine, and amphetamines).

Post Traumatic Stress Disorder

PTSD at baseline was assessed via the *Clinician Administered PTSD Scale* (CAPS; Blake et al. 1995) which measures frequency and intensity of signs and symptoms of PTSD in the past 30 days.

Data Analysis

An intent-to-treat sample was used in all analyses. Participants' demographic and baseline diagnostic characteristics were described by means and standard deviations, or proportions. The differences between the two treatment groups were tested using chi-square (two categorical variables) and two-sample *t*-tests (continuous variables).

Inspection of the data revealed a large number of participants who reported no unprotected sexual occasions (USO) during the 30 days prior to baseline assessment. This suggested a zero-inflated distribution which violates the assumption of normality underlying a standard linear model. Therefore, to assess treatment effect (SS vs. WHE) on USO, we used a zero-inflated negative binomial model with random effects for participants. The zero-inflated negative binomial model is an extension of the widely used zero-inflated Poisson model introduced by Lambert (1992). Although both zero-inflated negative binomial and zero-inflated Poisson models can be used to model count data with excess zeros, the former relaxes the restriction that the variance equals the mean, necessary in a Poisson distribution. Covariates included treatment, time of assessment (3-, 6-, and 12-months post-treatment), baseline sexual behavior [$\log(\text{baseline USO} + 1)$], and pre-selected baseline variables (race/ethnicity, age, marital status, educational level and treatment site). There were no significant differences in sexual risk outcome based on PTSD diagnosis (subthreshold vs. full), or treatment attendance; therefore these variables were not included in the model. Group was not a unit of analysis included in the model.

The predicted numbers of USO in the zero-inflated negative binomial model are the product of the probability of participants with at least one USO (1-) and the frequency of USO given that the participants might have USO (u , mean of the negative binomial distribution). Follow up analyses were planned to test the possible interactions between treatment, baseline USO, and time if initial analyses achieved a confidence level of greater than 90% (i.e., $P < 0.10$). Inference was based on the final models. PROC NLMIXED in SAS was used to conduct the analysis.

Results

Participant Characteristics

Table 1 displays baseline demographics for 346 randomized participants from six treatment sites. The average age of the participants was 39.2 years. About half were Caucasian (46.2%) and one-third (33.5%) African American. Approximately one-third of the sample were married (34.4%) and about half (53.5%) were sexually active. Of those who were sexually active, the vast majority (79.9%) had only one partner.

As specified by study eligibility criteria, all participants met current DSM-IV criteria for either full (80.4%) or subthreshold PTSD (19.6%). The most frequently diagnosed substance use disorder was cocaine use disorder (72.8%), followed by alcohol use disorder (62.0%). The average CAPS total score among all participants was in the severe range (Weathers et al. 2001) with a mean of 62.7 ($SD = 19.5$, range 19–119). The majority of participants experienced physical (93.8%) or sexual violence (89.5%) in their lifetimes. Individual sites differed across many variables, including age, education, marital status, and CAPS total score.

Table 1 also presents HIV risk behaviors at baseline. Almost half the entire sample reported at least one unprotected sexual occasions (USO) in the 30 days prior to baseline (46.1%). Notably, few women (only 1.7%) injected drugs during the 30-day period. There were no significant differences between treatment groups at baseline on sociodemographic factors, drug use, PTSD symptoms, or sexual behavior variables.

The average number of treatment sessions completed was 7.5 ($SD = 3.85$) for Seeking Safety and 6.8 ($SD = 3.94$) for Women's Health. Retention rates were similar at each follow-up assessment point and did not differ by intervention group, baseline USO, substance use or PTSD symptom severity. For participants in the SS group, retention rates for the 1-week, 3-, 6-, and 12-month follow-up visits were 61.3, 62.4, 61.3, and 63.0%, compared to 63.8, 57.2,

61.3, and 63% for WHE. However, 77% of all cases had at least one follow-up assessment (78.6% for SS and 75.7% for WHE).

Analyses of Treatment Impact

The zero-inflated negative binomial model predicting unprotected sexual occasions (USO) over the study period is summarized in Table 2. In the non-zero part (negative binomial) of the zero-inflated negative binomial model predicting the number of USO over the entire study period (3-, 6-, and 12-month assessment points; right side of Table 2), there was a significant interaction effect between treatment and baseline USO. The effect of treatment (SS vs. WHE) on USO was statistically different among individuals with higher baseline levels of USO (Adjusted OR = 0.74, CI = 0.55, 1.00, $df = 262$, $P < 0.05$). In the zero inflated part of the zero-inflated negative binomial model predicting USO being zero vs. non-zero over the follow-up period (left side of Table 2), there was a significant main effect of baseline USO, but the interaction effect between treatment and baseline USO was not significant.

Based on the two-part estimation in the zero-inflated negative binomial model, the mean number of USO was the product of the probability of having any USO (logistic regression) and predicted number of USO (Fig. 2). When the two treatment groups had the same low USO at baseline (two times per month, 25th percentile of USO at baseline among cases who had any USO at baseline), the number of unprotected sexual occasions at the 12-month follow-up was 3.45 for SS and 3.22 for WHE. This was not a statistically significant difference. However, when the two treatment groups had high USO level at baseline (at least 12 times per month, equal to the mean USO and comparable to the 57th percentile of USO at baseline among cases who had any USO at baseline), the number of USO at the 12-month follow-up was 4.97 for SS and 8.60 for WHE, a statistically significant difference ($t = 2.07$, $df = 262$, $P = 0.04$).

In the analysis of total sexual occasions, there were no significant main effects of treatment or interactions of treatment with baseline total sexual occasions or time.

Discussion

Our study provides new evidence for the field of HIV prevention, extending results of the impact of trauma treatment among female substance abusers (Amaro et al. 2007). Study findings demonstrated that SS, a trauma-focused cognitive group therapy targeting skills building and self-efficacy in the context of integrated trauma and substance abuse treatment, was significantly more effective in reducing HIV sexual risk for women with higher levels of unprotected sex when compared with a Women's Health Education curriculum which provided specific psychoeducation on HIV risk reduction. Although Amaro et al. (2007) had similar findings, their study examined a 25-session trauma intervention which included three sessions on HIV/ AIDS prevention. Thus the current study provides further evidence of the association between integrated trauma and substance abuse treatment and reductions in sexual risk behavior beyond those expected from traditional HIV/ AIDS prevention content. In a recent meta analysis review of behavioral interventions to reduce HIV sexual risk behaviors, Noar (2008) found that skills training was a moderator of sexual risk reduction. However, whether skills training focusing specifically on HIV risk reduction skills or coping skills focusing on more personal self management skills is more effective is not yet clearly evident. It may be that certain populations, such as women with PTSD, respond better to learning coping skills directly related to their trauma histories.

While brief, user-friendly, skills-building sexual risk reduction interventions are useful, they are only nominally able to address underlying mental health and trauma experiences common among substance dependent women (Tross et al. 2008). The SS curriculum did not directly address HIV risk reduction, but rather focused on developing safe coping skills, communication

and boundary setting, and generally identifying and reducing unsafe behavior. SS has been shown to impact self-efficacy as a mediator of outcomes (Gatz et al. 2007). Improving self efficacy overall may promote increased awareness of and ability to address safety in multiple domains, including sexual risk behaviors. Social action theory (SAT) predicts that an intervention which enhances an individual's ability to self regulate through problem solving, as well as improves social communication and self efficacy, would be superior to one which focuses on imparting information alone (Ewart 1991). Social action theory is a widely applied theoretical model used to explain HIV sexual risk behavior change and is based on three dimensions that influence self-regulatory systems. Our findings provide support for interventions that alter scripted behavior (through safe coping and cognitive therapy) in the context of systemic factors (such as trauma, substance use and social interaction) to more effectively impact sexual risk behavior compared to a health education curriculum with HIV specific content for women with comorbidity engaging in high risk sexual behavior. It is not known from this study whether SS combined with HIV prevention specific content would be associated with additional sexual risk reduction.

In line with previous findings from the trauma literature, about half of our sample (46.5%) reported sexual abstinence in the 30 days prior to baseline. Previous research has suggested the occurrence of subgroups of women with PTSD who differ dramatically in sexual risk behavior; some women with sexual trauma histories avoid sexual activity, whereas others become sexually compulsive (Deliramich and Gray 2008; Myers et al. 2006). Merrill et al. (2003) found that women with childhood sexual abuse histories who used more avoidant coping strategies reported *fewer* sex partners, whereas those using more destructive coping strategies such as alcohol and drug use reported a *greater* number of sex partners. Thus, in the context of substance abuse treatment, as women stop or use substances less, increases in avoidant coping strategies may actually result in less sexual activity. Notably, in the present study, those who were less sexually active, or generally using safer sexual practices, did not appear to be impacted differentially by either treatment, although this may be a result of a statistical floor effect.

Our study differs from previous research in several important respects. The sample of treatment-seeking, substance abusing women was selected based on PTSD diagnosis. Previous intervention studies have not focused on women with PTSD as a targeted subpopulation, despite the high prevalence of trauma among women in community drug treatment programs (Bensley et al. 2000; Cohen et al. 2000; Kang et al. 2002). Whereas previous research has focused primarily upon intravenous drug users, those who trade sex for money or drugs, and men who have sex with men (e.g., Bensley et al. 2000; Cohen et al. 2000), the present study focuses on heterosexual risk behaviors, which has become the primary mode of HIV transmission for women (Centers for Disease Control and Prevention 2008).

Several limitations of the study warrant mention. As a study designed to treat PTSD symptoms among women in community drug treatment, the sample met criteria for PTSD or subthreshold PTSD, which limited the range of traumatic stress exposure by excluding those with less severe trauma symptoms. Also, sexual risk information was gathered via the Risk Behavior Survey, an interviewer-administered instrument, not an audio computer-assisted interview, which has been found to increase the validity of sensitive data collection (e.g., Metzger et al. 2000). Similarly, additional data regarding actual or perceived partner risk was not collected as part of this study. Therefore, actual HIV risk for women in this sample was unknown and may have contributed to decisions regarding condom use. Another study limitation involves the fact that two HIV/sexually transmitted disease-related sessions in WHE were part of a longer curriculum of health education; HIV sessions embedded within a more general health intervention may be received differently from free-standing HIV education sessions typically offered in substance abuse treatment settings. Finally, generalizability is reduced by the large number of participants

who were eligible after the initial brief eligibility screen, but who did not attend the full screening interview ($n = 671$). Specific data was not available for why these participants did not attend the screening interview (e.g., may have dropped from substance treatment altogether), but could suggest possible acceptability issues of the study for a sub-population of clients. Although retention rates were lower than desired (approximately 60%), they are reflective of more general substance abuse treatment attrition.

An additional limitation is omission of group level data analysis in the model. It is possible that since the treatments were delivered in rolling groups that changed in membership from session to session, group might exert its own effect upon outcomes. However, since each site ran a single ongoing group for each intervention and did so for the majority of the time using one dedicated therapist (for each intervention), the inclusion of site and intervention in the analysis handles much of the variance. Although innovative statistical methods are being developed to examine relevant questions related to the complexities of group structure under rolling admission designs (Morgan-Lopez and Fals-Stewart 2006), it would be difficult to tease apart group level effects independent from site and intervention in the current analysis.

The current experimental study highlights ways in which cognitive behavioral groups that enhance coping skills, safety, and self-efficacy may indirectly impact risky sexual behavior among women with comorbid trauma and substance use disorders. Future studies could specifically examine the hypothesized mediators and moderators of action that can more fully explain the nature of how trauma-focused interventions can impact HIV risk behaviors. A design that would allow for testing the impact of addressing trauma symptoms directly in contrast to focusing on developing more global coping skills vs. education alone is indicated. In all, findings from the present investigation are encouraging and support new directions for HIV prevention research to explore ways in which behavior therapies can improve symptom management and coping skills for populations with co-occurring PTSD and substance use disorders.

Acknowledgments

The authors wish to acknowledge the work and support of the six Regional Research Training Centers involved in the study and the invaluable commitment of the clients and staff at the seven participating Community-based Treatment Programs. This study was supported by the following grants from the National Institute on Drug Abuse (NIDA): U10 DA13035 (Edward Nunes, PI), U10 DA13714 (Dennis Donovan, PI), U10 DA13038 (Kathleen Carroll, PI), U10 DA13732 (Eugene Somoza, PI), U10 DA13727 (Kathleen Brady, PI), U10 DA013720 (Jose Szapocznik, PI), U10 DA013046 (John Rotrosen, PI), K24 DA022412 (Edward Nunes, PI). Staff from NIDA's Clinical Trials Network collaborated in the design and conduct of the study, assisted with data management and quality assurance during the trial, and provided comments for consideration on this manuscript. The *Clinical Trial Identification Number* is NCT00078156 (NIDA).

References

- Amaro H, Larson MJ, Zhang A, Acevedo A, Dai J, Matsumoto A. Effects of trauma intervention on HIV sexual risk behaviors among women with co-occurring disorders in substance abuse treatment. *Journal of Community Psychology* 2007;35:895–908. doi:10.1002/jcop.20188.
- Bandura A. Self-efficacy: Toward a unifying theory of behavioral change. *Psychological Review* 1977;84:191–215. doi:10.1037/0033-295X.84.2.191. [PubMed: 847061]
- Bandura, A. *Social foundations of thought and action*. Englewood Cliffs, NJ: Prentice-Hall; 1986.
- Bensley LS, Van Eenwyk J, Simmons KW. Self-reported childhood sexual and physical abuse and adult HIV-risk behaviors and heavy drinking. *American Journal of Preventive Medicine* 2000;18:151–158. doi:10.1016/S0749-3797(99)00084-7. [PubMed: 10698246]
- Blake DB, Weathers FW, Nagy LM, Kaloupek DG, Gusman FD, Charney DS, et al. The development of a clinician-administered PTSD scale. *Journal of Traumatic Stress* 1995;8:75–90. doi:10.1002/jts.2490080106. [PubMed: 7712061]

- Booth RE, Watters JK, Chitwood DD. HIV risk-related sex behaviors among injection drug users, crack smokers, and injection drug users who smoke crack. *American Journal of Public Health* 1993;83:1144–1148. doi:10.2105/AJPH.83.8.1144. [PubMed: 8342724]
- Briere J, Runtz M. Childhood sexual abuse: Long-term sequelae and implications for psychological assessment. *Journal of Interpersonal Violence* 1993;8:312–330. doi:10.1177/08862609 3008003002.
- Browne A, Finkelhor D. Impact of child abuse: A review of the research. *Psychological Bulletin* 1986;99:66–77. doi: 10.1037/0033-2909.99.1.66. [PubMed: 3704036]
- Centers for Disease Control and Prevention. HIV and AIDS in the United States: A picture of today's epidemic. 2008. Retrieved September 8, 2008, from http://www.cdc.gov/hiv/topics/surveillance/united_states.htm.
- Cohen M, Deamant C, Barkan S, Richardson J, Young M, Holman S, et al. Domestic violence and childhood sexual abuse in HIV-infected women and women at risk for HIV. *American Journal of Public Health* 2000;90:560–565. doi:10.2105/ AJPH.90.4.560. [PubMed: 10754970]
- Deliramich A, Gray M. Changes in women's sexual behavior following sexual assault. *Behavior Modification* 2008;32:611–621. doi:10.1177/0145445508314642. [PubMed: 18310604]
- El-Bassel N, Witte S, Wada T, Gilbert L, Wallace J. Correlates of partner violence among female street-based sex workers: Substance abuse, history of childhood abuse, and HIV risks. *AIDS Patient Care* 2001;15:41–51. doi:10.1089/10872910146 0092.
- Ewart C. Social action theory for a public health psychology. *The American Psychologist* 1991;46:931–946. doi:10.1037/0003-066X.46.9.931. [PubMed: 1958012]
- Exner T, Seal D, Ehrhardt A. A review of HIV interventions for at-risk women. *AIDS and Behavior* 1997;1:93–124. doi:10.1023/B:AIBE.0000002972.61606.99.
- Folstein MF, Folstein SE, McHugh PR. Mini-mental state: A practical method for grading the cognitive state of patients for the clinician. *Journal of Psychiatric Research* 1975;12:189–198. doi: 10.1016/0022-3956(75)90026-6. [PubMed: 1202204]
- Gatz M, Brown V, Hennigan K, Rechberger E, O'Keefe M, Rose T, et al. Effectiveness of an integrated trauma-informed approach to treating women with co-occurring disorders and histories of trauma. *Journal of Community Psychology* 2007;35:863–878. doi:10.1002/jcop.20186.
- Gore-Felton C, Koopman C. Traumatic experiences: Harbinger of risk behavior among HIV-positive adults. *Journal of Trauma & Dissociation* 2002;3(4):121–135. doi:10.1300/ J229v03n04_07.
- Hien DA, Cohen LR, Litt L, Miele GM, Capstick C. Promising empirically supported treatments for substance-using women with PTSD: A randomized clinical trial comparing seeking-safety with relapse prevention. *The American Journal of Psychiatry* 2004;161:1426–1432. doi:10.1176/appi.ajp. 161.8.1426. [PubMed: 15285969]
- Hoffman J, Klein H, Eber M, Crosby H. Frequency and intensity of crack use as predictors of women's involvement in HIV-related sexual risk behaviors. *Drug and Alcohol Dependence* 2000;58:227–236. doi:10.1016/S0376-8716(99)00095-2. [PubMed: 10759033]
- Kang S, Deren S, Goldstein MF. Relationships between childhood abuse and neglect experience and HIV risk behaviors among methadone treatment drop-outs. *Child Abuse and Neglect* 2002;26:1275–1289. doi:10.1016/S0145-2134(02)00412-X. [PubMed: 12464301]
- Lambert D. Zero-inflated Poisson regression, with an application to defects in manufacturing. *Technometrics* 1992;34:1–14. doi:10.2307/1269547.
- Logan TK, Cole J, Leukefeld C. Women, sex, and HIV: Social and contextual factors, meta-analysis of published interventions, and implications for practice and research. *Psychological Bulletin* 2002;128:851–885. doi:10.1037/0033-2909.128.6.851. [PubMed: 12405135]
- Maman S, Campbell J, Sweat M, Gielen A. The intersections of HIV and violence: Directions for future research and interventions. *Social Science and Medicine* 2000;50:459–478. doi:10.1016/S0277-9536 (99)00270-1. [PubMed: 10641800]
- McLellan AT, Alterman AI, Cacciola J, Metzger D, O'Brien CP. A new measure of substance abuse treatment: Initial studies of the treatment services review. *The Journal of Nervous and Mental Disease* 1992;180:101–110. doi: 10.1097/00005053-199202000-00007. [PubMed: 1737971]
- Meade CS, Sikkema KJ. HIV risk behavior among adults with severe mental illness: A systematic review. *Clinical Psychology Review* 2005;25:433–457. doi:10.1016/j.cpr.2005.02.001. [PubMed: 15914265]

- Merrill L, Guimond J, Thosen C, Milner J. Child abuse and number of sexual partners in young women: The role of abuse severity, coping style, and sexual functioning. *Journal of Consulting and Clinical Psychology* 2003;71:987–995. doi: 10.1037/0022-006X.71.6.987. [PubMed: 14622074]
- Metzger DS, Koblin B, Turner C, Navaline H, Valenti F, Holte S, et al. Randomized control trial of audio computer-assisted self interviewing: Utility and acceptability in longitudinal studies. *American Journal of Epidemiology* 2000;152:99–106. doi:10.1093/aje/152.2.99. [PubMed: 10909945]
- Miller, S.; Pagan, D.; Tross, S. Women's health education. In Peer activism for female partners of injection drug users. Columbia University; 1998. Unpublished treatment manual
- Morgan-Lopez AA, Fals-Stewart W. Analytic complexities associated with group therapy in substance abuse treatment research: Problems, recommendations, and future directions. *Experimental and Clinical Psychopharmacology* 2006;14(2):265–273. doi:10.1037/1064-1297.14.2.265. [PubMed: 16756430]
- Myers H, Wyatt G, Loeb T, Carmona J. Severity of child sexual abuse, post-traumatic stress and risky sexual behaviors among HIV positive women. *AIDS and Behavior* 2006;10:191–199. doi:10.1007/s10461-005-9054-6. [PubMed: 16479413]
- Najavits, LM. Seeking safety: A treatment manual for PTSD and substance abuse. New York, NY: Guilford Press; 2002.
- Noar SM. Behavioral interventions to reduce HIV-related sexual risk behavior: Review and synthesis of meta-analytic evidence. *AIDS and Behavior* 2008;12:335–353. doi:10.1007/s10461-007-9313-9. [PubMed: 17896176]
- Nyamathi A, Kington R, Flaskerud J, Lewis C, Leake B, Gelberg L. Two-year follow-up of AIDS education programs for impoverished women. *Western Journal of Nursing Research* 1999;21:405–425. doi:10.1177/01939459922043956. [PubMed: 11512206]
- Prendergast ML, Urada D, Podus D. Meta-analysis of HIV risk-reduction interventions within drug abuse treatment programs. *Journal of Consulting and Clinical Psychology* 2001;69:389–405. doi: 10.1037/0022-006X.69.3.389. [PubMed: 11495169]
- Rasch R, Weisen C, MacDonald B, Wechsberg W, Perritt R, Dennis M. Patterns of HIV risk and alcohol use among African-American crack abusers. *Drug and Alcohol Dependence* 2000;58:259–266. doi: 10.1016/S0376-8716(99)00098-8. [PubMed: 10759036]
- Salazar L, Crosby R, DiClemente R, Wingood G. Self-esteem and theoretical mediators of safer sex among African American female adolescents: Implications for sexual risk reduction interventions. *Health Education & Behavior* 2005;32:413–427. doi:10.1177/1090198104272335. [PubMed: 15851547]
- Santelli JS, Robin L, Brener ND, Lowry R. Timing of alcohol and other drug use and sexual risk behaviors among unmarried adolescents and young adults. *Family Planning Perspectives* 1998;33:200–205. doi:10.2307/2673782. [PubMed: 11589540]
- Schutzwahl M, Maercker A. Effects of varying diagnostic criteria for posttraumatic stress disorder are endorsing the concept of partial PTSD. *Journal of Traumatic Stress* 1999;12:155–165. doi:10.1023/A:1024706702133. [PubMed: 10027149]
- Sample S, Grant I, Patterson TL. Female metham-phetamine users: Social characteristics and sexual risk behavior. *Women and Health* 2004;40:35–50. doi:10.1300/J013v40n03_03.
- Senn T, Carey M, Vanable P. Childhood and adolescent sexual abuse and subsequent sexual risk behavior: Evidence from controlled studies, methodological critique, and suggestions for research. *Clinical Psychology Review* 2007;28:711–735. doi:10.1016/j.cpr.2007.10.002. [PubMed: 18045760]
- Shain RN, Piper JM, Newton ER, Perdue ST, Remos R, Champion JD, et al. A randomized controlled trial of a behavioral intervention to prevent sexually transmitted disease among minority women. *The New England Journal of Medicine* 1999;340:93–100. doi:10.1056/NEJM199901143400203. [PubMed: 9887160]
- Shoptaw S, Tross S, Stephens M, Tai B. NIDA CTN HIV/ AIDS Workgroup. A snapshot of HIV/AIDS-related services in the clinical treatment providers for NIDA's clinical trials network. *Drug and Alcohol Dependence* 2002;66:S163. doi: 10.1016/S0376-8716(01)00205-8.
- Sikkema KJ, Wilson PA, Hansen NB, Kochman A, Neufeld S, Ghebremichael MS, et al. Effects of a coping intervention on transmission risk behavior among people living with HIV/AIDS and a history

- of childhood sexual abuse. *Journal of Acquired Immune Deficiency Syndrome* 2008;47(4):506–513. doi: [10.1097/QAI.0b013e318160d727](https://doi.org/10.1097/QAI.0b013e318160d727).
- Tarakeshwar N, Fox A, Ferro C, Khawaja S, Kochman A, Sikkema KJ. The connections between childhood sexual abuse and human immunodeficiency virus infection: Implications for interventions. *Journal of Community Psychology* 2005;33(6):655–672. doi:[10.1002/jcop.20077](https://doi.org/10.1002/jcop.20077).
- Tross S, Campbell ANC, Cohen LR, Calsyn D, Pavlicova M, Miele GM, et al. Effectiveness of HIV/STD sexual risk reduction groups for women in substance abuse treatment programs: Results of a NIDA clinical trials network trial. *Journal of Acquired Immune Deficiency Syndrome* 2008;48:581–589. doi:[10.1097/QAI.0b013e31817efb6e](https://doi.org/10.1097/QAI.0b013e31817efb6e).
- Weathers FW, Keane TM, Davidson JR. Clinician-administered PTSD scale: A review of the first ten years of research. *Depression and Anxiety* 2001;13:132–156. doi:[10.1002/ da.1029](https://doi.org/10.1002/da.1029). [PubMed: 11387733]
- Wells EA, Calsyn DA, Clark LL, Saxon AJ, Jackson R. Retention in methadone maintenance is associated with reductions in different HIV risk behaviors for women and men. *The American Journal of Drug and Alcohol Abuse* 1996;22:509–521. doi:[10.3109/00952999609001677](https://doi.org/10.3109/00952999609001677). [PubMed: 8911589]
- Woods WJ, Guydish JR, Sorenson JL, Coutts A, Bostrom A, Acampora A. Changes in HIV-related risk behaviors following drug abuse treatment. *AIDS (London, England)* 1999;13:2151–2155. doi: [10.1097/00002030-199910220-00019](https://doi.org/10.1097/00002030-199910220-00019).
- Wyatt GE, Longshore D, Chin D, Carmona JV, Loeb TB, Myers HF, et al. The efficacy of an integrated risk reduction intervention for HIV-positive women with child sexual abuse histories. *AIDS and Behavior* 2004;8(4):453–462. [PubMed: 15690118]

Fig. 1.
Flow diagram of participants through study

Fig. 2.
Predicted values of number of unprotected sexual occasions using a zero-inflated negative binomial model

Table 1

Means, standard deviations, or percentages of baseline demographic and diagnostic characteristics of the randomized sample ($n = 346$) and by treatment assignment

Variables	Total ($n = 346$)	Seeking safety ^a ($n = 173$)	Women's health education ^a ($n = 173$)
Age, years	39.2(9.3)	39.4(9.5)	39.0(9.2)
Ethnicity			
Caucasian	46.2%	47.4%	45.1%
African American	33.5%	32.4%	34.7%
Latina	6.1%	4.1%	8.1%
Other	14.2%	16.2%	12.1%
Marital status			
Married/separated	34.4%	30.6%	38.2%
Never married	37.0%	37.0%	35.3%
Divorced/widow	29.5%	32.4%	26.6%
Education			
<12	26.6%	22.5%	30.6%
=12	31.8%	34.7%	28.9%
>12	41.6%	42.8%	40.5%
Current full PTSD diagnosis	80.4%	76.7%	84.2%
Total CAPS PTSD severity score ^b	62.7(19.5)	61.3(19.4)	64.1(19.6)
Substance use, days in the last 30	5.9(11.0)	6.1(9.7)	5.8(10.1)
Total number of sexual occasions (TSO) at baseline last 30 days	7.5(13.7)	7.6(13.53)	7.5(13.9)
Currently sexually active (TSO>0)	53.5%	54.7%	52.3%
Unprotected sexual occasions (USO) at baseline last 30 days	5.8(11.5)	5.8(10.9)	5.7(12.0)
Having unprotected sexual occasions (USO>0)	46.1%	48.0%	44.2%

PTSD post traumatic stress disorder; *CAPS* clinician administered PTSD scale; *TSO* total number of vaginal or anal sexual occasions with male partner(s); *USO* unprotected vaginal or anal sex occasions with male partner(s)

^a No statistically significant differences between treatment groups on any demographic, diagnostic, or risk factors

^b CAPS total scale possible range = 0–136

Table 2

Adjusted zero-inflated negative binomial model of treatment and interaction effects on unprotected sexual occasions over 3-, 6-, and 12-month follow-up

Covariates ^a	Probability of being zero USO		Number of USO	
	AOR	95% CI	AOR	95% CI
USO (baseline)	0.39**	0.24, 0.63	1.52**	1.22, 1.90
Treatment (SS vs. WHE)	1.54	0.66, 3.57	1.06	0.61, 1.85
Follow up				
3 months (referent)	-	-	-	-
6 months	0.73	0.36, 1.47	1.01	0.77, 1.29
12 months	0.90	0.45, 1.80	1.14	0.87, 1.48
USO (baseline) × treatment (SS vs. WHE)	0.22 [†]	0.04, 1.14	0.74*	0.55, 1.00

USO unprotected vaginal or anal sexual occasions with a male partner, AOR adjusted odds ratio, CI confidence interval. To calculate the odds ratio of the probability of being zero in SS over WHE when baseline USO is 2 = $1/\exp(\log(1.54) + \log(0.22) \times \log(3))$ and when USO is 12 = $1/\exp(\log(1.54) + \log(0.22) \times \log(13))$. To calculate odds ratio of the number of USO in SS over WHE when baseline USO is 2 = $\exp(\log(1.06) + \log(0.74) \times \log(3))$ and when USO is 12 = $\exp(\log(1.06) + \log(0.74) \times \log(13))$

^a Age, racial/ethnic group, education, marital status, and site were controlled in both models

[†] $P < .10$

* $P < .05$

** $P < .01$