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Reducing Sexual Risk Behaviors for HIV/STDs in Women with Alcohol Use Disorders

Diane M. Langhorst,

Addiction & Women's Health: Advancing Research and Evaluation (AWHARE), Virginia Commonwealth University

Y. Joon Choi,

School of Social Work, University of Georgia

Lori Keyser-Marcus, and

Department of Psychiatry, Virginia Commonwealth University

Dace S. Svikis

Department of Psychology, Virginia Commonwealth University

Introduction

The lifestyle of alcohol and drug dependent women often places them at increased risk for psychological and medical problems including HIV/STD infection. Participation in substance abuse treatment has been found to be effective for reducing HIV/STD risks related to substance use and abuse (Metzger, Navaline, & Woody, 2000; Sorenson & Copeland, 2000; Woods et al., 1999), yet research to date has demonstrated a relatively low success rate of treatment alone in reducing sexual risk behaviors in this population (Calsyn, Saxon, Freeman, & Whittaker, 1992; McCusker, Stoddard, Zapka, & Lewis, 1993; Prendergast, Urada & Podus, 2001). Further, while alcohol misuse is frequently a co-morbid condition, much less attention has been paid to its role in promoting patient engagement in sexual risk behaviors. Safer Sex Skill Building (SSB), a 5-session manual driven HIV/STD intervention, was developed primarily for women with illicit drug problems (Schilling, El-Bassel, Gilbert, & Glassman, 1993). A recent NIDA Clinical Trials Network (CTN) study found SSB to be effective in reducing sexual risk behaviors of women at 6 month follow-up (Tross et al., 2008). However, both the NIDA CTN study and the original SSB study, conducted by social work researchers at Columbia University, focused primarily on women in outpatient treatment for drug problems.

The purpose of the present study was to adapt the SSB intervention to fit a new population, women with alcohol use disorders (AUDs). The research was funded by NIAAA (R03: "Modifying Safer Sex Skill Building in Alcohol Abusing Women") and was divided into two phases, based on Rounsaville, Carroll and Onken (2001) staged model for development of behavioral therapies. In Phase 1 researchers from the Addiction & Women's Health: Advancing Research and Evaluation (AWHARE) program modified SSB to include alcohol-specific content. The revised manual was pilot tested, and focus groups were conducted to gather feedback from pilot study participants about the revised manual and the need for further improvements. The manual was then finalized as SSB+A based on focus group feedback and consultant recommendations. The present article will focus exclusively on Phase 2. Phase 1 procedures and results are discussed separately (see Choi, Langhorst,

Meshberg-Cohen, & Svikis, 2011). Specifically, a small randomized clinical trial (RCT) was completed comparing the 5 session SSB+A intervention to a single session standard HIV education (HE) group. To limit extraneous factors and maximize “dose” received (for both SSB+A and HE), the study was conducted in a residential substance abuse treatment setting. Women meeting DSM-IV criteria for Alcohol Use Disorders (AUDs) and reporting having intercourse with a male partner in the 180 days prior to treatment admission were eligible. The target population of women was primarily African American, of low SES and at high risk for HIV/AIDS.

Rates of unprotected penetrative intercourse and condom use were assessed at baseline, 60 days and 180 days post-discharge from residential care and compared between women randomized to either SSB+A (5-session experimental group) or the single-session HIV/STD education control group (HE). While Rounsaville et al. (2001) staged model of intervention development limits its focus to effect size estimation in preparation for a larger RCT, the present study examined the hypothesis that women randomized to SSB+A would have better outcomes (e.g., fewer instances of unprotected penetrative intercourse and more instances of penetrative intercourse with condoms) than women assigned to the control group (HE). Four secondary outcome variables were also compared across the three time points to better understand the HIV/STD risks for this group of women.

Women, Substance Use and High Risk Sexual Behavior

The incidence of HIV infection in women has increased from 7% in the mid-eighties to 25% currently (Bryant, Nelson, Braithwaite, & Roach, 2010). The risk is most striking for African American women. Currently, rates of new HIV infections for Black women are nearly four times that of Hispanic/Latino women and almost 15 times that of white women (Centers for Disease Control and Prevention, 2010). African-Americans also have higher mortality rates from HIV/AIDS than other ethnic groups, which may be attributed to disparities in health care and consequent recognition of the disease at later stages (National Institute on Drug Abuse, 2006). HIV disease has consistently been one of the leading causes of death among African-American women (Anderson & Smith, 2005).

Substance use and sexual risk behaviors exhibited by alcohol-and drug-dependent women substantially increase their likelihood of contracting HIV and other sexually transmitted diseases (STDs) (Amaro, Raj, & Reed, 2001; Cohan, 2003; Cook & Clark, 2005; Pulerwitz, Gortmaker, & DeJong, 2000; Theall, Elifson, Sterk, & Klein, 2003). The Centers for Disease Control and Prevention (CDC) estimated that 71% of new AIDS diagnoses in women can be attributed to heterosexual transmission, with injection drug use accounting for 27% of new cases (2005). Impulsivity and trading sex for drugs are often cited as reasons for risky behavior, as well as being in a relationship with an abusive or HIV-infected partner (Schilling et al., 1993). Other studies have demonstrated that elevated HIV risk among women also results from lower education, lower income, and less power in the partner relationship (Amaro & Raj, 2000; Campbell et al., 2009; Logan, Cole, & Leukefeld, 2002; Zierler & Krieger, 1997). Finally, women are vulnerable to the effects of HIV/AIDS in multiple ways. A national study of persons receiving medical care for HIV/AIDS reported that 64% of women had incomes below \$10,000 compared to 41% of men (Bozzette et al., 1998). Even more disturbing is the fact that the majority of infected women are of childbearing age, which may interfere with their ability to manage the multiple requirements of substance abuse treatment (Schuster et al., 2000).

While it is well documented that the majority of female illicit drug users are polydrug abusers, co-morbid alcohol problems sometimes go undetected (Bauer et al., 2002; Carroll, Rounsaville, & Bryant, 1993; Gossop, Stewart & Rolfe, 2000; Svikis, McCaul, Haug, &

Boney, 1996). This is unfortunate, as the consumption of alcohol can significantly increase frequency of sexual risk behaviors in a variety of ways. In their review of 42 studies, Cook and Clark (2005) found associations between problem drinking and STD risk across a variety of populations and suggested that alcohol consumption may increase STD risk by both its influence on behavior (e.g., perceived sexual arousal, disinhibition) and by direct negative effects of alcohol on the immune system. Tross et al. (2009) found in an outpatient treatment sample that both “any use of alcohol” and “problem alcohol use” were associated with having multiple male partners and having sex while under the influence of drugs or alcohol. They caution that women who use alcohol in addition to other substances may underestimate the influence of alcohol on sexual risk behavior. Bryant and colleagues (2010) point out that alcohol use often is not seriously addressed as a risk factor in HIV prevention studies, and recommend that behavioral research studies more systematically examine the role of alcohol in HIV transmission risk.

Strategies for HIV Prevention

Despite recent progress in prevention, an estimated one quarter of persons living with HIV do not know they are infected and are at risk for developing AIDS and unknowingly transmitting HIV. CDC recommendations include development and improvement of interventions for underserved populations at high risk (2006). Currently, the most effective methods for slowing the spread of HIV/AIDS focus on reducing intravenous drug use (IVDU) and its associated risks (e.g., needle sharing), as well as sexual risk behaviors, which transmit the virus from one person to another (National Institute on Alcohol and Alcoholism, 2002). Studies show substance abuse treatment can effectively reduce risks due to IVDU behaviors. It has been less effective however, with sexual risk behaviors (Calsyn et al., 1992; Metzger et al., 2000; Sorenson & Copeland, 2000). Barriers such as social stigma, relationship with a drug using sexual partner, and lack of child care among others often make it more difficult for women to enroll in substance abuse treatment than men. This is particularly true for ethnic and racial minority women, as well as those with fewer economic or social resources and those affected by multiple psychosocial problems (Comfort & Kaltenbach, 2000; Comfort, Loverro, & Kaltenbach, 2000).

Initial attempts at HIV education/intervention for men and women in substance abuse treatment often consisted of a brief (30–90-minute) single-session HIV education module presented in lecture format. Evaluation of such methods found little or no change in sexual risk behaviors (Logan et al, 2002; Tross et al., 2008). A review of studies of interventions targeting at-risk women indicated that while increasing HIV awareness is a necessary precursor to behavior change (e.g., condom use), it has little behavioral impact by itself. Rather, socio-cultural and contextual factors have been reported as barriers to condom use and sexual negotiation (Exner, Seal, & Ehrhardt, 1997). Many women have difficulties using condoms and report using condoms inconsistently or not at all (Bedimo, Bessinger, & Kissinger, 1998), even though consistent and correct use of male latex condoms greatly reduces the risk of becoming infected with HIV. Reasons for non-use include a lack of trust in the reliability of condoms to protect them, a lack of desire for pregnancy prevention, and the male partner's refusal to use condoms. The CDC (2011) disseminates a compendium of evidence based HIV prevention interventions with a subset of best-evidence and good-evidence HIV risk reduction interventions categorized by key participant and intervention characteristics. Recently added programs targeting at-risk women include: Motivational Interviewing-based HIV Risk Reduction (Weir, et al., 2009), Female Condom Skills Training (FEMIT) (Choi, 2008), and Safer Sex Skills Building (including online manuals) (Tross et al., 2008).

Several comprehensive reviews of HIV intervention and prevention program outcomes found that the most efficacious HIV prevention programs for women were: (1) Specifically directed toward women; (2) culturally relevant; (3) focused on relationship and negotiation skills; (4) involved multiple, sustained contacts; (5) focused on skills that reduce specific sexual risk behaviors; and (6) involved multiple teaching methods including, but not limited to didactic instruction (Ehrhardt & Exner, 2000; Exner et al, 1997; Prendergast et al., 2001; Robin et al., 2004).

Safer Sex Skills Building (SSB) Intervention

The manual-driven HIV/STD safer sex skills building (SSB) intervention incorporates these program recommendations including: (1) Gender specificity of intervention content and technique; (2) use of cognitive, behavioral and affective skills building (in contrast to information only); and (3) relatively sustained dosage. In addition, SSB addresses female–male power issues by focusing on women’s negotiation skills around safer sex and assertiveness training and increasing women’s choices over sexual decision making through male and female condom use skill building. The original clinical trial of SSB (El Bassel & Schilling, 1992) found it to be effective in increasing frequency of condom use for women who enrolled at outpatient drug treatment facilities at 15-month follow-up. A large, multi-site study conducted by the NIDA Clinical Trials Network (CTN) also found SSB to be effective in reducing number of unprotected sex occasions (USO) for women with drug problems at 6 month follow-up (Tross et al., 2008). However, the effectiveness of SSB for modifying sexual risk behaviors in women with AUDs is unknown.

The current pilot RCT explored the effectiveness of SSB+A. Baseline data were collected, and participants were randomly assigned to either: (1) 5-session SSB+A; or (2) 1-session HE group. The intervention was delivered while women were enrolled in residential care with follow-up assessments on unprotected penetrative intercourse occasions and rates of condom use at 60 and 180 days post-treatment discharge. Women with high vulnerability to HIV and other STDs, many of whom belonged to minority groups and experienced various health care disparities were targeted for study participation.

Methods

Study Site

The present study was conducted at a large nonprofit organization located in Richmond, VA. The program provides residential and outpatient treatment services for adult women with drug and alcohol problems. The facility houses up to 40 women with slots for an additional 14 women with children. Lengths of stay vary from 30–180 days based on clinical (severity of substance abuse disorder) as well as practical/economic (type of insurance) factors. Treatment is delivered through individual and group counseling services with topics such as relapse prevention, re-entry skills, health and wellness, relationship, anger management and conflict management, leadership skills, domestic violence, sexual abuse, parenting and acupuncture.

Study Participants

Study participants were drawn from the population of women enrolled in residential treatment at the study site from October 2007 to July 2008. Inclusion/exclusion criteria were chosen to maximize generalizability of pilot study participants to the overall population of women served by the program. Inclusion criteria were: (1) 18 years or older; (2) DSM-IV diagnosis of lifetime Alcohol Abuse/Dependence (with or without other drug use disorders); and (3) self-report of unprotected penetrative sexual intercourse in the 6 months prior to treatment entry. Women with an acute or chronic mental disorder that interfered with ability

to provide informed consent or who endorsed self-reported knowledge of personal HIV positive diagnosis were excluded from study participation.

Design and Procedures

Recruitment—Recruitment occurred within 14 days of treatment admission. Flyers were distributed to new patients by a Research Assistant. They were also posted in the waiting area and on bulletin boards at the facility. Women interested in learning more about the study met with the Research Assistant in the private on-site research office. Those providing informed consent were scheduled for baseline assessment and screened by a research assistant using the first questions on alcohol use from the DSM-IV Checklist – Alcohol and Drug Abuse/Dependence Module (Helzer et al., 1985) and a single question regarding whether they had intercourse with a male partner in the 180 days prior to treatment admission. Every effort was made to ensure confidentiality of study participants. All study procedures were approved by the Institutional Review Board (IRB).

Baseline assessment—All research staff were trained and certified in conducting assessment measures by an AWHARE team faculty member. To minimize fatigue, baseline assessments were administered over two 45–60 minute assessment sessions. Measures used to acquire the six primary or secondary outcome variables in the present study were: (1) Timeline Follow-back Interview (TLFB; Sobell & Sobell, 1996); (2) Risk Behavior Survey (RBS; Needle et al., 1995; Weatherby et al., 1994); and (3) Addiction Severity Index (ASI; McLellan et al., 1992).

TLFB is a reliable and valid assessment that uses a calendar and other memory aids to facilitate participant recall about their alcohol consumption (Sobell & Sobell, 1996). This approach for summarizing quantity and frequency of drinking over a set time period was later expanded to focus on other drugs as well. More recently, the TLFB has been further modified to measure partner violence (Fals-Stewart, Birchler & Kelley, 2003), employment (Svikis et al., 2011) and specific sexual risk behaviors (Carey, Carey, Maisto, Gordon, & Weinhardt, 2001; Weinhardt et al., 1998). In studies of sexual risk behavior, the TLFB demonstrated good test-retest reliability of .85 – .98 for 30-day period and .81 – .97 for 3-month period (Weinhardt et al., 1998). Likewise, in four studies of sexual risk behavior reviewed by Carey and colleagues (2001), the TLFB had test-retest reliability of .71 – .94 for 1-month recall period and .91 – .94 for 3-month period, with beginning evidence of moderate validity when comparing the TLFB with traditional single item self-report measures.

The RBS is a brief structured interview with established reliability and validity for individuals with substance use disorders. It is widely used to quantify occasions of sexual behaviors and substance use. In a study by Needle et al. (1995), the RBS showed a 30-day test-retest reliability coefficient of .66 – .83 for sexual risk behavior. Days having sex in the last 30 days, number of sex partners in the last 30 days, and the number of times that respondents had vaginal sex in the last 30 days all had coefficient above .80. Only number of sexual partners who were injectors in the last 30 days had coefficient of .66.

The ASI is a semi-structured interview with excellent reliability and validity. It screens for problems in 7 clinical domains (Medical, Employment, Alcohol, Drug, Legal, Family/Social, and Psychological) and is frequently used for both research (to track participant outcomes) and clinical (substance abuse treatment planning) purposes. In a study of 524 male veteran alcoholics and drug addicts, McLellan et al. (1980) reported inter-rater reliability of .918 for the ASI, and its test-retest reliability ranged from .64 to .95 in studies of people with substance abuse problems (Daepfen et al., 1996; Drake, McHugo, & Biesanz, 1995). Other studies reporting ASI development and psychometric properties

include: Fanzese, 2005; Mäkelä, 2004; McLellan et al., 2006; Zanis et al., 1994). Especially, Fanzese and colleagues (2005) reviewed studies of ASI reliability and validity with different samples over a 15 year period and concluded that it is a reliable and valid instrument.

The following measures were also administered, but not examined in the present study. They are part of the Common Assessment Battery (CAB) that identifies key screening and assessment questionnaires and instruments used across multiple sites for NIDA CTN studies including SSB (#0019): Condom Barrier Scale (St. Lawrence et al., 1999); Condom Use Self-efficacy Scale - female version (Marin, Tschann, Gomez, & Gregorich, 1998); Sexual Relationship Power Scale (Pulerwitz et al., 2000); Intervention Exposure Inventory; Biologic Measures collected on-site (Urine Drug Toxicology to test for the presence of 7 drugs and breathalyzer to assess for recent alcohol use); DSM-IV Checklist – Alcohol and Drug Abuse/Dependence Module (Helzer et al., 1985); Reasons for Drinking Questionnaire (RFDQ) (Zywiak, Connors, Maisto, & Westerberg, 2002); and Alcohol Effects Questionnaire (AEQ-2) (Rosenow, 1983).

Randomization—Randomization by cohort method was used, as patient admission rates made randomization at individual participant level impractical. Modeled after the NIDA CTN multi-site trial, nine successive cohorts of 3–5 participants each completed baseline assessments during the 2–4 week interval post admission. Each cohort was randomized post-baseline assessment, as a block to either SSB+A or HE by an off-site research team member using a random numbers table.

Interventions—SSB, the experimental condition, consisted of five 90-minute group sessions that included information plus skills building exercises. HE control condition was one information only session representing a treatment-as usual comparison. This study used the SSB and HE manuals (2009) developed for the NIDA CTN study (Protocol 0019). The SSB manual, however was revised in Phase 1 to include additional information and exercises on alcohol, creating SSB+A. The research team was trained and certified in the original SSB intervention by the lead trainer for the CTN study and the first author was certified as a trainer. Both SSB+A and HE groups were co-led by the first and second authors.

While there was a threat of therapist bias since the first and second authors were the group leaders for both the 5-session SSB+A and the single session HE groups, it was minimized by randomization by cohort and careful training and certification in the intervention by the CTN SSB protocol team member with consultation throughout the study. Furthermore, the consistent co-leadership team prevented confounding leader characteristics between the two interventions. In addition to training and consultation, fidelity monitoring procedures included strict adherence of the leaders manuals, flipcharts and participant workbook, as well as leader discussion of an intervention fidelity checklist after each group to review the content and the activities of the sessions. Another fidelity check relating to cross contamination between SSB and HE (and any other STD/HIV prevention education they might have received) was use of the Intervention Exposure Inventory (IEI) at discharge where participant identified if she has been exposed to a list of intervention topics and activities up until that point and what have been the source of exposure for the topics and activities she has been exposed to, which helped researchers discern if cross contamination has occurred.

SSB+A: Modifications to the SSB manual occurred in three forms: 1) Addition of three assessment measures focusing on alcohol use - Timeline Follow-back (Sobell & Sobell, 1992), Reasons for Drinking Questionnaire (Zywiak, Connors, Maisto, & Westerberg, 2002), and Alcohol Effects Questionnaire (Rosenow, 1983); 2) Separation of drug use and

alcohol use questions to make consideration of alcohol use more intentional than in the current SSB intervention; and 3) Changes in participant exercises. Please see Appendix A for SSB intervention components and the modifications made for SSB+A.

HIV/STD Education: The 60 minute single session HE group used a didactic format, flipcharts and a participant workbook of handouts. It consisted of: Discussion of HIV/STD definitions, transmission, pros and cons of testing and counseling, including the availability and location of resources for prevention and treatment. This session reflected current usual care as reported by a survey of community treatment programs (Shoptaw et al., 2002).

Follow-up—Assessments occurred at discharge from residential care, and at 60 and 180 days post-discharge. Follow up assessors were not blind to condition due to resource limitations and the need to travel out of town to conduct interviews, which was done by two of the authors. The discharge interview was scheduled approximately 1 week prior to discharge from the facility and involved: update of patient tracking data using participant locator form, use of a calendar as a memory aid for the follow-up Timeline Follow-back (TLFB) interview, and verification of groups attended and HIV information discussed. Since women stayed in residential treatment for varying amounts of time, the discharge interview in a sense reset the clock for the two follow up appointments. To maximize participation, two phone contacts were made before both the 60 day and 180 day follow-up assessments to schedule the follow-up interviews, and update locator information. The TLFB and the RBS, containing the major outcome variables, were measured for the past 60 days, whereas the ASI was measured for the past 30 days. In several cases, however, the biologic measures could not be collected for practical reasons due to the location where interviews were conducted.

Compensation—All women received a \$25 gift card for completing baseline assessment. Those in the experimental condition also received a \$5 gift card for attending each SSB+A session (up to \$25 in gift cards for attending all 5 sessions). Similarly, those in the control condition received a \$5 gift card for attending the single HE session. In addition, all participants received a \$15 gift card for completing the discharge interview, a \$40 gift card for the 60 day follow-up interview, and a \$40 gift card for the 180 day follow-up interview. Women also received a \$20 gift card for participating in the two telephone contacts between the discharge and the 60 day assessment, and another \$20 gift card for participating in the two telephone contacts between the 60 day and the 180 day assessments. Thus, a woman who participated in all elements of the pilot testing phase of this proposal could earn a total of \$185 in gift cards (SSB+A) or a \$165 (HE) to a local merchant for her time and effort. Gift cards were used instead of cash payments to minimize risk for relapse by study participants and were offered from local merchants (e.g., Dollar General, Target, and Wal-Mart). Bus tickets were provided for participants who needed transportation to and from their follow-up assessments.

Results

Participant Flow

Figure 1 presents participant flow through the course of the study. A total of 38 participants were recruited, and thirty six of the thirty eight women completed baseline assessment and were randomly assigned to either the SSB+A ($n = 19$) or the HE ($n = 17$) groups. Subsequently, one participant was medically unable to participate and three participants left treatment prior to completing the intervention and could not be located. The remaining cohort of 32 participants ($n=17$ for SSB+A group and $n=15$ for HE group) was eligible for receiving interventions. For $N = 32$ who received the interventions and were discharged

from the treatment facility, 8 did not respond to follow-up contacts, leaving a final sample of $N = 24$ ($n=13$ for SSB+A group and $n=11$ for HE group) participants completing at least one of two follow-up interviews (23 participants completed both follow-up interviews). Independent- samples t-test and chi-square tests were conducted to examine participant characteristics measured at baseline and intervention condition between participants who completed follow-up interviews and those who did not. There were no significant differences between these two groups. The results are displayed in Table 1. Rates of follow-up for each intervention condition at each assessment were as follows: (1) SSB+A: 76.5% (13/17) at 60 day and 180 day follow-ups; and (2) HE: 73.3% (11/15) at 60 day follow-up, and 66.6% (10/15) at 180 day follow-up.

Data Analysis

Analyses were performed on 24 participants who completed baseline assessments, received interventions (at least 3 sessions for SSB+A), and completed at least one of the two follow-up interviews (23 out of 24 participants completed both follow-up interviews). The primary outcome variables were the number of unprotected penetrative intercourse (vaginal or anal) occasions and the number of penetrative intercourse (vaginal or anal) occasions with condoms, as derived from the Timeline Follow Back (TLFB) calendar. The following are the primary outcome variables as well as four other variables of interest:

- Alcohol use days in past 60 days (Alcohol Days)
- Penetrative intercourse days in past 60 days (Sex Days)
- Number of penetrative intercourse with condoms in past 60 days (Condoms)
- Alcohol and penetrative intercourse days in past 60 days (Alcohol Sex)
- Drugs and penetrative intercourse days in past 60 days (Drug Sex)
- Number of penetrative intercourse without condoms in past 60 days (No Condoms)

The data collected were the counts of these acts at baseline (0 days) and two follow-up points (60 day post-discharge and 180 day post-discharge). One data point needed to be fixed, as a very high count (453) was recorded for number of sexual acts with condoms in the HE group at baseline, and this large outlier could have skewed modeling results. To remedy this situation, this value was set to the 95% percentile of these counts which was 24, using a process called a 95% Winsorization of a data array (Spjøtvoll & Aastveit, 1982). Analyses were conducted two-tailed at the .05 level of significance.

Independent sample t-test (age and education), chi-square tests (race and monogamy status), and generalized linear mixed model (six outcome variables) were used to examine baseline differences between SSB+A and HE in the 60-day period before baseline. A generalized linear mixed model (GLM) was used to analyze data at 3 time periods (baseline, 60 day and 180 day post-discharge) for the 6 outcome variables. The outcome measures in this study were counts, which follows a Poisson distribution rather than a Normal distribution. A generalized linear model allows for modeling of data with distributions other than the Normal distribution by specifying a link function, which here is the logarithm function. The models were constructed in such a way that a person's own observations over time were allowed to be correlated, which is a flexibility of using mixed models. In the models, the terms included were a group variable, a time variable, and a term allowing for interaction between the two. The interaction term allows for the possibility that the relationship between the two groups depends on which time period is being regarded, or the relationship of time depends on the group. The sample size was too small for rigorous analysis; however, we were interested in seeing whether significant effects exist for group, time, or the interaction between them for a possible future RCT.

Also due to the small sample size, secondary quantitative analysis of data was not feasible. In addition, the AWHARE team wanted to investigate the question, “What were some of the salient characteristics for women in the study who used condoms?” The purpose was to explore if questions for future research might be suggested by the data. Thus, the AWHARE team explored personal characteristics and circumstances of women and their potential relationships with condom use at 3 data points (baseline, 60 day and 180 day follow ups) for the entire sample. Participant characteristics and circumstances extracted from the ASI and the Risk Behavior Survey (RBS) were: (1) Days in alcohol/drug treatment during the last 30 days; (2) probation/parole status; (3) days detained and incarcerated in the last 30 days; and (4) the participant’s number of sexual partners. Days in alcohol/drug treatment, probation/parole status, and days of detention and incarceration were chosen to be examined because we believed that they may work as deterrence to risky behaviors, in this case ‘unprotected sex’. Participant’s number of sexual partners was chosen because several studies found the relationship between reduced condom use and main sexual partners (Exner, Dworkin, Hoffman, & Ehrhardt, 2003; Simon, Walters, & Nero, 2000; Tross et al., 2008).

Baseline Data

With regard to demographic characteristics, almost half of the sample was younger than 40 years (42%) and 83.3% had 12 years of education or less. The majority were African American (70.8%) with the remainder being white. More than half of the sample had been either unemployed or worked irregular part-time jobs in the past three years before baseline, and only three participants (two of them part-time) worked for pay in the past 30 days before baseline. In addition, in the 30 days before baseline seven participants received welfare, and two-thirds (66.7%) received monetary support from their mates, families, or friends. Descriptive statistics on drug use and sexual risk behavior revealed that women in the sample had a mean of 27.7 days of alcohol use, 33.5 days of drug use, 19 days of sex acts, 13.4 days of sex acts with alcohol, 17.1 days of sex acts with drugs, 27.6 sex acts without condoms, and 1.7 sex acts with condoms in the 60-day period before baseline. In sum, the sample consists of primarily African-American, low-income women with substance abuse problems and risky sexual behaviors, which put them at high risk for HIV/AIDS.

As Table 2 and Table 3 show, the 2 groups did not differ on any measures at baseline.

Effects of Intervention on Outcome Measures

The models were fit using a compound-symmetric structure for an individual’s serial correlation. Table 4 describes the fixed-effect tests for the model terms.

As is shown in the table above, longitudinal results across 3 time periods (baseline, 60 day and 180 day post-discharge) displayed no group effects on any variables (Alcohol days, Sex days, Alcohol * Sex days, Drug * Sex days, # of sexual acts with condoms, and # of sexual acts without condoms). However, longitudinal results across 3 time periods displayed time effects on several risk variables. That is, the two groups were not significantly different in counts of these acts at three time periods, but the overall counts of the sample were different depending on what time we were considering. This is more clearly shown in the following figure 2. The data points are means estimated from our model. For the variables with significant time effect (Alcohol Days, Alcohol Sex, Drug Sex) baseline counts were much higher than the two follow-ups, but at the second follow up (180 day follow-up) the counts for these three variables were higher than for the first follow-up 60 days post-discharge. This trend was also evident for “No Condoms” and “Sex Days” but was not significant.

More importantly, the interaction term between Group and Time was significant only for sex with condoms ($p = 0.0474$), which was one of two primary outcome measures (see Figure

3). Number of sexual acts with condoms for SSB+A group (Group 1 in Figure 3) was lower than that of HE group (Group 2 in Figure 3) at baseline (0.46 for SSB+A vs. 3.91 for HE) and 60 day follow-up (1.00 for SSB+A vs. 3.73 for HE), but was significantly higher than HE at 180 day follow-up (6.62 for SSB+A vs. 2.35 for HE). That is, SSB+A women had sex with condoms more frequently between 60 day and 180 day post-discharge than HE women did. This represents an effect size (standardized difference between predicted means) of 0.28.

Exploratory Analysis of Participant Characteristics and Condom Use

Correlation analysis was conducted to test bivariate relationships between four variables of participant characteristics (days in alcohol/drug treatment, probation/parole status, days detained or incarcerated, and number of sexual partners) and condom use for the entire sample in this study at baseline, 60 day, and 180 day follow-ups. As Table 5 displays, of the four variables, only number of sexual partners had a positive significant relationship with condom use at 180 day follow-up ($r = .728, p < .01$). That is, the more sexual partners women in the study had, the more they used condoms at 180 day follow-up. On the other hand, the other three variables did not work as deterrence to unprotected sex, which we believed, contributes to more condom use. When we looked at the relationship between condom use and number of partners for SSB+A and HE groups separately at 180 day follow-up, a positive significant relationship was found only for SSB+A group ($r = .789, p < .01$).

Discussion

The present study first modified an intervention for HIV/STD prevention, known to be effective, to include alcohol content (see Choi, Langhorst, Meshberg-Cohen, & Svikis, 2011), using stage 1 of the Rounsaville et al.'s (2001) therapy development research model. It then explored potential effectiveness of the revised intervention (SSB+A) through a pilot clinical trial of women in residential treatment for AUDs who reported engaging in one or more recent sexual risk behaviors in the 60 days before treatment enrollment. Further, it targeted a population of largely African-American, low-income women that continue to experience disparities in health care. Present study findings for sexual acts with condom use were consistent with those reported by Tross et al. (2008) in a multi-site RCT. Specifically, in the present study, HE and SSB+A groups did not differ at 60 day follow-up, but at 180 day follow-up, the SSB+A and HE interventions significantly differed in sex acts with condoms. The number of sex acts with condoms further declined in the HE group whereas the condom use further increased for the SSB+A group favoring the SSB+A intervention over the HE intervention with an effect size of 0.28, which approaches medium effect size.

This finding is encouraging considering the tendency of deteriorated intervention effects over time (Logan et al., 1997; Prendergast et al., 2001). This observed delay of increased condom use among SSB+A participants may be a sleeper effect, which describes the delayed observation of effects of a highly persuasive message (Hovland & Weiss, 1951). The delayed observation of intervention effects have been found in several intervention studies that tested psychotherapy for cocaine dependence (Carroll, Rounsaville, Nich, Gordon, Wirtz, & Gawin, 1994), contraception use in heterosexual couples (Terefe & Larson, 1993), and Tross et al.'s multi-site RCT study on SSB (2008). Additionally, the delays observed could be explained by the time needed to change attitudes regarding condom use and to increase women's negotiation skills around safer sex and assertiveness. Exposure to SSB+A intervention may have shifted women's attitudes regarding condom use, however, skills required to actually negotiate safer sex with partners that eventually lead to condom use may take much longer to acquire (Campbell et al., 2011).

While the increased condom use in SSB+A result was interesting, for the remaining five measures there was no significant difference in the interaction between group and time. The reason the result was restricted to one measure was most likely the small N. Another possibility is that the extensive assessment by itself could have produced therapeutic benefits. Recent research suggests an “assessment effect” or improvement in target behavior as a result of control group assessment, thus blurring the experimental contrast (Kypri, Langley, Saunders, Cashell-Smith, 2007).

Examination of condom use and number of sexual partners indicated that number of sexual partners was related to women’s condom use, with women with more sexual partners reporting more condom use at 180 day follow-up. Considering that heterosexual transmission is becoming the fastest growing mode of contracting HIV among women, especially among AUD and minority women who are at increased risk due to their own and partner’s sexual risk behaviors (Amaro, Raj, & Reed, 2001; Cohan, 2003; Eriksen & Trocki, 1994; Theall, Elifson, Sterk, & Klein, 2003), this result raised questions concerning the condom use decision making processes. Specifically, “How can we better understand the decision-making processes and power dynamics that occur around condom use for “primary partner” and “other partners” as a woman moves through recovery and relapse cycles?”

Programmatic adaptation of this intervention could use qualitative methods to identify and understand, for the population served, relationship power dynamics and the behavior choices within main- partner and multiple- partner relationships, as well as the substance use and condom use decision points and the cues and interconnections between these behaviors. Gaining further insight into impulsivity, risk- reduction and personal safety strategies while tailoring them to the population served, could extend and intensify this intervention in outpatient or residential substance abuse treatment, and women’s shelter settings. Staff members and researchers, with consumer input, could make manual modifications with ongoing qualitative and quantitative evaluation. We recommend use of Fraser and Galinsky’s (2010) 5 step model for intervention research, which outlines the linkage of program design components and evaluation research, includes procedures for cultural and contextual adaptation, and recommends multiple methods of analysis. They emphasize that intervention development and research occurs in a recursive process involving adaptation to new populations, revision and testing.

The residential treatment setting provided a controlled environment for this small study where attrition was an important issue. The Tross et al. study (2008) demonstrated that an effective “dose” of SSB required attendance at 3 or more of the 5 sessions. Also, residential treatment provides a safe setting for positive behavior change. Because of the complex role that sexual behavior plays in heterosexual relationships, safer sex intervention must include multiple priorities for change in: problem-solving and decision-making skills; communication skills; drug relapse prevention skills; and condom use. On the other hand, a limitation of residential treatment for research is that, in the current fiscal climate, only 8% of drug and alcohol treatment takes place in residential settings (Carise, D., 2010) making it less of a “real world” environment for translational research. One way to use this setting for research is to consider it a “laboratory” to test new interventions and provide the necessary dose for small studies. If the intervention does not demonstrate positive results in a controlled setting, it is unlikely to do so in a more “real world” setting of outpatient or methadone maintenance treatment. We recommend that if the intervention is used in outpatient settings, incentives for group attendance be included as part of the research design to ensure adequate treatment retention.

Limitations of this pilot study include small sample size and self-report measures used for primary outcomes. Self-report measures may be impacted by social desirability response

bias, which could be of particular concern with “private” behaviors (e.g., sex, alcohol/drug use). While studies find good concordance between self-report and more objective measures (Carey et al., 2001), study findings should be interpreted with caution. Another limitation was that the RCT trial design had the risk of threat to independence due to contamination by cross-talk among participants. While several procedures were implemented to minimize the threat of cross-talk, this nonetheless remains a possible limitation. Final limitation was potential response bias based on disappointment of control group members over not being selected to participate in the intervention group. This was addressed directly at consent/randomization, and earnings for study participation were comparable for the intervention and control groups.

Despite limitations, study results have three primary implications. First, while the small sample size does not allow drawing definite conclusions on the effectiveness of the SSB+A intervention for women with AUDs in adopting and maintaining safe sexual behaviors, it affirms the need for further RCT on the SSB+A intervention with a larger sample. This would allow gathering more systematic data to examine why the intervention is having an impact. Using GPower 3.1 (Faul, Erdfelder, Buchner, & Lang, 2009) software, a minimum sample size required for a larger RCT was calculated. Alpha level was set to .05, the effect size was set as 0.28, and a desired statistical power level was expected to be about .80. With these parameters, the recommended sample size for a subsequent RCT is no less than 318. In addition, subsequent RCTs of the SSB+A intervention would benefit from the following recommendations: Using intention to treat analysis of all randomized women in order to avoid various misleading artifacts that can arise in intervention research; audiotaping all sessions, with random selection for independent evaluation for fidelity monitoring and quality control purpose; and blind all assessors to treatment conditions to avoid measurement bias. Another issue for careful consideration in a larger RCT is use of monetary incentives to reinforce attendance so that participants receive an adequate “dose” of the intervention, which is currently a point of discussion in the field. Future studies will need to look carefully at the issue of intervention “dose” as defined by treatment session attendance. Finally, in a Stage II larger clinical efficacy trial, perhaps in an outpatient setting where treatment drop out could be a major issue (Simpson, Joe & Brown, 1997) an attention control group in addition to a treatment-as-usual comparison group would be needed in order to address the problem of imbalance in attention between SSB+A and HE conditions and shed light on engagement and retention differences in the groups.

Second, this study illustrates the critical link between practice and use of a step by step model of intervention research. Focus groups conducted in Phase 1 of the study and feedback from the experimental groups indicated the women responded positively to the empowerment concept that “knowledge is power”, and to role play practice exercises, and to discussing the specific linkages between their alcohol use and drug use and sexual risk behaviors with primary and other partners. The practice experience of two of the authors, who have developed women’s substance abuse programs, and findings from this study support the tentative conclusion that SSB+A is a useful prevention intervention for women with AUDs. We believe the SSB+A addition of specific alcohol content to the SSB intervention, and the results of the pilot clinical trial, if replicated in other real world settings, can add to the knowledge base on the process of intervention adaptation and testing in HIV prevention with AUD women. Third, the methods used in adapting this intervention can be applied to other areas of women’s health research. With further adaptation SSB can be expanded to other vulnerable populations such as homeless women and low income women attending health clinics, such as pregnant women at high risk for HIV/AIDS. The AWHARE team is currently conducting one such study with an OB clinic sample of women at risk for prenatal substance use (including alcohol).

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Appendix A. Outline of SSB* and modifications made for SSB+A

SSB Intervention*	
Session 1	HIV/STD definition, transmission, testing and counseling, treatment and prevention
Session 2	HIV personal risk assessment and awareness building, including triggers for sexual risk, sources of support and ways of seeking help
Session 3	Condom skill building and safer sex problem-solving skill building, including male and female condom demonstration and rehearsal
Session 4	Safer sex negotiation skill building and partner abuse risk assessment and safety planning skill building
Session 5	Wrap-up, review, and Graduation, including practice vignettes focusing on “slip” behavior and resource discussion

Note.

* SSB refers to the CTN version of SSB.

Modifications for SSB+A

1. Alcohol risk awareness content was added throughout Session 2 to 5 and the following points were highlighted.
 - a. Risks regarding sexual behavior
 - Alcohol alters perception of risk, problem-solving and decision making ability
 - Alcohol interferes with clear, assertive communication about safe sex practices
 - b. Particular risks for low-income and minority women
 - Epidemiological studies of proportion of alcohol vendors in low income areas and marketing to minority communities and women
 - Statistics on percentage of women with moderate to heavy alcohol use
 - c. Medical risks
 - Alcohol compromises immune function increasing susceptibility to HIV and other diseases
 - Differences in men and women in metabolizing alcohol
 - Risks to fetus of alcohol related birth defects (ARBD)
 - Health care disparities: How and where to access help for alcohol treatment
 - d. Other substance use and mental health risks
 - Depression and violence risks related to alcohol

- Alcohol as a trigger for other drug use
2. Addition of “Alcohol Use Context” exercises (completed in group at the end of Session 2)
 - a. Review personal *Timeline Followback* (Sobell & Sobell, 1992) calendar that was filled out at Baseline.
 - b. Identify what was learned from this calendar. Review *Reasons for Drinking Questionnaire* (Zywiak et al., 2002) completed at Baseline.
 - c. Complete *A Roadmap of My Risks* exercise in group. Identify and place risky places, people, thoughts, feelings, occasions related to their alcohol and drug use and unsafe sex to help participants contextualize and individualize the connection between alcohol and drug use and high risk sexual behaviors by looking at the timeline of their alcohol use and drug use and unsafe sex and interconnections among them.
 3. Addition of empowerment and culturally-specific material
 - a. Information as a form of power
 - b. Summary of evidence regarding effectiveness of Safer Sex Skill Building (SSB) and other interventions.
 - c. Allowed participants to change the language of role plays to reflect their daily lives
 - d. Gave an option of closing each session with Serenity
 - e. Prayer instead of WORTH
 - f. Affirmation
 - g. Power and Control Wheel for Women with Substance Abuse (O’Neil, 1996)
 - h. ‘24 things a sista should never apologize for’ (“HypeGyrl Entertainment Blog,” 2007)

Figure 1.

Participant flow chart through the study. *The Tross et al. study (2008) demonstrated that an effective “dose” of SSB required attendance at 3 or more of the 5 sessions.

Figure 2.
Time effects on six outcomes of interest

Figure 3. Interaction between group and time for sex with condoms. Group 1 = SSB+A group; Group 2 = HE group.

Table 1

Baseline Characteristics of Completers and Non-completers for Follow-up Interviews *

Effect	Completers (n = 24) n (%) or Mean (SD)	Non-completers (n = 8) n (%) or Mean (SD)
Age (years) ($p = .169$)	40.9 (8.6)	35.6 (10.7)
Race: n (%) ($p = .283$)		
African American	17 (70.8%)	4 (50.0%)
White	7 (29.2%)	4 (50.0%)
Monogamy status (% yes) ($p = .660$)	16 (66.7%)	6 (75.0%)
Education (years) ($p = .393$)	11.7 (2.2)	10.9 (2.5)
Intervention: n (%) ($p = .838$)		
SSB+A	13 (54.2%)	4 (50.0%)
HE	4(45.8%)	4 (50.0%)

* No significant differences between completers and non-completers on any characteristics

Table 2

Baseline Demographic Characteristics of Participants in SSB+A and HE *

Variable	SSB+A (n = 13)	HE (n = 11)	Total (n = 24)
	n (%) or Mean (SD)		
Age (years) ($p = .536$)	39.9 (7.5)	42.1 (9.9)	40.9 (8.6)
Race: n (%) ($p = 5.497$)			
African American	10 (76.9%)	7 (63.6%)	17 (70.8%)
White	3 (23.1%)	4 (36.4%)	7 (29.2%)
Monogamy status (% yes) ($p = .582$)	8 (61.5%)	8 (72.7%)	16 (66.7%)
Education (years) ($p = .065$)	10.9 (2.5)	12.6 (1.2)	11.7 (2.2)

* No significant difference between SSB+A and HE on any characteristics

Table 3

Baseline Differences between SSB+A and HE on Six Outcome Variables *

Variable	Wald ²	d.f.	p value
Alcohol days	0.00	1	0.9507
Sex days	0.37	1	0.5453
Sex acts with condoms	2.19	1	0.1388
Days of sex acts and alcohol	0.05	1	0.8275
Days of sex acts and drugs	0.40	1	0.5275
Sex acts without condoms	0.63	1	0.4263

* No significant difference between SSB+A and HE on any variables

Table 4

Fixed-Effect Tests for Model Terms

Effect test p-values for model terms			
	Group	Time	Group * Time
Number of Days Alcohol Consumption (Alcohol days)	0.2644	0.0001 ***	0.2992
Number of Days had Sex (Sex days)	0.2125	0.3975	0.8374
Number of Sex Acts with Condoms (Condoms)	0.3351	0.2651	0.0474 *
Number of Days with Alcohol and Sex Acts (Alcohol * Sex)	0.7147	0.0006 ***	0.2798
Number of Days with Drugs and Sex Acts (Drug * Sex)	0.1674	0.0017 **	0.3140
Number of Sex Acts without Condoms (No condoms)	0.1701	0.6245	0.7800

*
 $p < .05$.

**
 $p < .01$.

 $p < .001$.

Table 5

Relationship between Condom Use and Participant Characteristics

Participant Characteristics	Baseline 60 day	60 day follow-up	180 day follow-up
Number of Partners	.290	-.048	.728 *
Days in Outpatient Treatment	-.166	.126	-.076
Probation/Parole Status	-.261	-.158	-.331
Days Detained/Incarcerated	-.118	n.c. **	-.131

* $P < 0.01$

** n.c. – No computation was done because days detained/incarcerated was 0.