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### Title

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### Permalink

<https://escholarship.org/uc/item/37179270>

### Journal

AIDS and Behavior, 19(10)

### ISSN

1090-7165

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### Publication Date

2015-10-01

### DOI

10.1007/s10461-015-1004-3

Peer reviewed



# HHS Public Access

Author manuscript

*AIDS Behav.* Author manuscript; available in PMC 2016 October 01.

Published in final edited form as:

*AIDS Behav.* 2015 October ; 19(10): 1752–1762. doi:10.1007/s10461-015-1004-3.

## Evaluation of a Socio-Cultural Intervention to Reduce Unprotected Sex for HIV Among African American/Black Women

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### Abstract

African American/Black (Black) women suffer disproportionately to other women from HIV. An HIV prevention intervention combining two previous evidenced-based HIV intervention programs; “Coping with Work and Family Stress” and “Hip Hop 2 Prevent Substance Abuse and HIV”, was evaluated in a diverse sample of Black women (n=205). Study participants at 10 recruitment sites were assigned non-randomly to either the intervention or comparison group and then surveyed at baseline, immediate posttest, and 6-month follow-up. General Estimating Equation modeling revealed that participants in the comparison group reported less unprotected sex at immediate post-test and the intervention group less unprotected sex at 6-month follow-up. Despite the initial drop in reported unprotected sex in the comparison group, this study suggests that an HIV risk reduction intervention tailored to address Black women’s socio-cultural stress and enhance their coping may reduce their unprotected sex at 6-months.

### Introduction

Females from minority race/ethnicity backgrounds suffer from higher rates of HIV infection than other women. African American/Black (Black) women account for 29 percent of all new HIV infections in the United States (6,100 new cases in 2010). The rate of new HIV infection among Black women is 20 times that of White women and nearly 5 times that of Hispanic women. Most new HIV infections among Black women are attributed to heterosexual contact (87%) [1].

Social (External factors that influence groups of people similarly. e.g., social and cultural norms, social status, and male-female sex ratios) and contextual (External influences on each person’s unique perspective. e.g., intimate partner violence, work and family demands, and social support) factors have been associated with HIV risk among disadvantaged Black

women [2–5], but many of these factors are not addressed in many HIV risk reduction interventions.

A comprehensive literature review published by Logan, Cole, and Leukefeld in 2002 [2] indicated that most HIV risk reduction interventions are based on health behavior theories that do not account for social and contextual factors. They identified 16 evaluated interventions focusing exclusively on women and of these; 10 targeted Black women; 6 had race-culture specific programming targeting Black women's connectedness (i.e., connection to others through identification with gender roles among Black women), mental health, social status, and/or intimate partner violence; and only two showed a significant effect on condom use. More recently, additional theoretically-based interventions that take into account social/contextual factors using the theory of gender and power have shown effectiveness in reducing HIV risk among Black women, defined as greater condom use [6–7]. Also, intervention based on Social Cognitive Theory with culture- and gender-tailored messaging resulted in less unprotected sexual intercourse among Black women [8].

McNair and Prather [9] describe how the unique vulnerability to HIV among Black women lies at the intersection of high levels of stress, poverty, and environmental demands. Stress and poverty can undermine Black women's psychological strength and general effectiveness at handling what are often heavy social, cultural, and contextual demands. Social and contextual vulnerabilities among Black women might be captured in frameworks describing social subordination and oppression [10]. Viewing Black women's sexual vulnerability to HIV through oppression frameworks clearly exposes the ways combinations of lower income, younger age, and other social stratifications can work against Black women's social status and power within heterosexual relationships. Nevertheless, studies using oppression frameworks may not emphasize the mental health needs of Black women and adequately help them to cope with stress to reduce vulnerability to HIV [9].

An intervention specifically aimed at increasing the use of effective coping strategies to address social and environmental demands, and that incorporated Black cultural messaging to enhance learning, was developed and tested in a diverse group of Black women. The intervention was an integration and adaptation of two evidenced-based programs listed on the National Registry of Evidence-Based Programs and Practices (NREPP) of the Substance Abuse and Mental Health Services Administration: *Coping with Work and Family Stress (CWFS)* and *Hip Hop 2 Prevent Substance Abuse and HIV (H2P)*.

*CWFS* was designed both for women and men, age 18 years and over, and from diverse educational, income, racial/ethnic, and occupational backgrounds. In two randomized controlled trials, effectiveness has been demonstrated in reducing perceived work and family stressors, increasing behavioral and reducing avoidance coping strategies, increasing perceived social support, and reducing alcohol and other drug use and psychological symptoms of anxiety, depression, and somatic complaints [11–16]. The *CWFS* intervention is based on a tripartite conceptual model of adaptive coping behavior: attacking the problem, rethinking the problem, and managing the stress. The model is derived from Pearlin and Schooler's [17] hierarchy of coping mechanisms: (a) responses that change the situation, (b) responses that control the meaning of the stressful experience, and (c) responses that

function to control stress after it has emerged. The aim is to teach participants coping strategies for bringing about changes in risk and protective factors for substance abuse, psychological symptoms, and other problem behaviors.

*H2P* provides prevention approaches that incorporate elements of popular culture to enhance their effectiveness at helping individuals choose healthy lifestyles and prevent substance abuse and HIV. *H2P* incorporates an “edutainment” approach, utilizing Hip-Hop to provide a fun, interesting, and motivational twist to traditional teaching methods. The strategies use dance, fashion, music, and art to convey prevention information and to promote skill development. *H2P* has been shown to improve: (1) essential and accurate information about HIV/AIDS and drugs, (2) resistance and refusal skills, (3) effective communication and negotiation skills, (4) correct use of condoms and dental dams, (5) resource tapping, (6) healthy alternatives to sex and drugs, and (7) self-efficacy skills [18].

The adapted and integrated *CWFS* and *H2P* approach for reducing HIV risk among Black women was titled: Substance Abuse and HIV Integrated Prevention Services (SHIPS). A first phase evaluation of the implementation of SHIPS with Black women examines the effectiveness of the program in reducing unprotected sex (vaginal, oral, anal) in order to reduce the risk of HIV transmission. It was hypothesized that women who participated in the SHIPS intervention would report less involvement in unprotected sex over time than those in a comparison group.

## Methods

This project was one of several projects across the country conducted as part of a multi-project, Substance Abuse and Mental Health Services Administration initiative researching dual substance abuse and HIV prevention. Data collection and analysis had Institutional Review Board oversight.

### Recruitment and Group Assignment

Participants were recruited through an extensive, multi-pronged effort including: information sessions held at community centers, PTA meetings, and substance use and HIV counseling centers; radio public service announcements; and word of mouth. Women affiliated with 10 program sites in the community expressed interest in participating in the program and were invited to attend an orientation session to obtain specific information about the SHIPS program and participant responsibilities. For those who consented into the study, it was explained that each would be asked to complete a set of measures prior to and at the completion of the program (approximately 3 months later) and again at 6-month follow-up. Within six sites, women were randomly assigned to group. Within four sites, all women were assigned to the treatment group due to the insistence of the sites’ program directors. Participants were thusly assigned to either the Intervention (n=130) or Control (n=75) group. Individuals assigned to the control group were told that they would have the opportunity to participate in the program at the completion of the study. All participants received a \$25 gift card as an incentive for each survey completion.

## Study Sample and Survey Completion

At the orientation for the study and before randomization, women who wanted to participate in the study were assigned, based on their preference, to one of the 8 different area study sites and told when the baseline survey would be administered at their site. At the designated time and place, the women completed the self-administered paper and pencil baseline survey and then were randomized, or assigned, to condition and those in the intervention group were assigned to the one of eight workshop sites that was most convenient for them. The post-test surveys in the intervention group were self-administered by paper and pencil at the resort location of the final weekend retreat whereas the comparison condition completed their post-test at one of the assigned study sites at a particular meeting time. The final 6-month follow-up survey was self-administered by paper and pencil at a single location.

Of the 130 women allocated to the intervention group, 108 (83.1%) completed the post test and 87 (66.9%) completed the 6-month follow-up. Of the 75 allocated to the comparison group, 48 (64.0%) completed the post test and 38 (50.7%) completed the 6-month follow-up. Hence, there was differential completion rate between groups at both follow-up time periods (post-test 83.1% vs. 64.0%,  $\chi^2=9.52$ ,  $p<.002$ ; 6-month follow-up 66.9% vs. 50.7%,  $\chi^2=5.28$ ,  $p<.02$ ).

Of the women who were administered the baseline survey, those who did not complete a subsequent survey were deleted from subsequent analysis because they could not be included in longitudinal analysis. Hence, of those who completed a baseline survey, 20 (15.4%) were dropped from the intervention condition and 14 (18.7%) were dropped from the comparison condition. The study sample was; therefore, comprised of the 171 participants who completed a baseline survey, including 156 who completed a post-test and 125 who completed a 6-month follow-up survey (Figure 1).

Based on the useable sample for longitudinal analysis, the intervention group included 110 participants with a post-test survey completion rate of 98.2% and a 6-month follow-up survey completion rate of 79.1%. The comparison group included 61 participants with a post-test survey completion rate of 78.7% and a 6-month follow-up survey completion rate of 62.3%. Using cross-sectional Chi-Square analysis, the participants in each group differed on some characteristics at baseline and at each follow-up period (Table I).

Of the 171 adult female baseline participants, almost all labeled themselves as African American (90.3%), about half (51.5%) were below the age of 50 years, and the majority (62.5%) reported annual household income of less than \$20,000 (Table I). More than half (59.8%) had had less than a high school education, and about a quarter (27.3%) were engaged in full-time or part-time employment. The vast majority indicated being heterosexual (92.8%), and more than half (61.4%) reported engagement in at least 1 type of unprotected sex in the past 30 days.

## Intervention

SHIPS includes an adapted version of *CWFS* consisting of 12, 1½ hour bi-weekly sessions in community sites, and a 2-day overnight intervention incorporating selected elements from

*H2P*. Like *CWFS* and *H2P*, *SHIPS* was designed to be implemented in a wide range of community settings to be more readily accessible to program participants.

The 12, 1½-hour session version of *CWFS* utilized as part of *SHIPS* was adapted from the original 16, 2-hour session curriculum [11]. Consistent with the original intervention, this program was designed to teach behavioral, social, and cognitive coping strategies to modify work and family risk and protective factors, given the relationship of these factors to psychological symptoms and substance use. The first component of the *CWFS* program trained participants in skills aimed at eliminating or modifying sources of stress to make continuing coping efforts unnecessary. This part of the curriculum included training regarding the identification and analysis of stressful situations and the effective use of problem solving, communication, and social support. The second component of the *CWFS* program offered techniques to modify cognitive and appraisal processes (e.g., cognitive restructuring). These approaches are particularly necessary for stressors that cannot be directly modified. The third *CWFS* component emphasized stress management (e.g., relaxation approaches, exercise) and minimizing the use of avoidance coping (e.g., reinforcing alternatives to the use of alcohol to reduce tension, teaching refusal skills). The stress management approaches taught early-on were practiced for a few minutes at the beginning of each subsequent session for reinforcement purposes. The final *CWFS* session integrated the curriculum material through the creation of participants own personal plan for addressing stressful situations or influences in their lives. Participants were instructed to continue utilizing their plan following the completion of the intervention to extend and maintain positive program effects.

*SHIPS* also incorporated certain aspects of *H2P*. The original *H2P* is a ten 2-hour session substance abuse and HIV prevention curriculum using Hip-Hop culture-based tools and activities such as role plays, interactive media CD-ROM, music and lyrics, art, group discussions, individual and group presentations, and games. Sessions 1–4 offer four interactive substance abuse prevention education and life skills training activities. Sessions 5–10 provide six HIV/AIDS prevention education and life skills training activities. In the *SHIPS* application of *H2P*, a 2-day overnight retreat was conducted following completion of the 12-session *CWFS* intervention. The components of the *H2P* program that were used as part of the overnight intervention were sessions 5–10 that focused on HIV prevention as a supplement to the *CWFS* curriculum that primarily emphasized prevention of substance abuse and psychological symptoms. The workshop sessions included opportunities for *SHIPS* participants to engage in interactive panels, hands-on activities, and small group discussions. This overnight component was designed to allow the participants to reflect on the *H2P* process and think forward on how to incorporate the *H2P* tools into their daily life.

A third component of the *SHIPS* intervention also was provided to the treatment group participants. These participants were offered coordinated access to other services such as: 1) a substance abuse and HIV/AIDS risk assessment; 2) HIV-testing, counseling, referral, and treatment services; and 3) substance abuse counseling and treatment services.

## Participation in Intervention

In regard to the level of participation of the intervention group in the study intervention, the participants attended on average 8 of the 13 activities (12 CWFS intervention sessions and 1, 2-day retreat). The number of participants in each session was: Session 1--Understanding Stress: Multiple Roles and the Stress Cycle (n=110); Session 2--Solving the Problem: Examining Stressful Situations and the Eight Problem-Solving Steps (n=106); Session 3--Solving the Problem: Using Personal Networks (n=104); Session 4--Managing Your Stress: Deep Breathing and Muscle Relaxation (n=103); Session 5--Solving the Problem: Listening and Responding (n=102); Session 6--Solving the Problem: Assertive Communication (n=101); Session 7--Rethinking the Problem: Stress Reassessment (n=97); Session 8--Rethinking the Problem: Self-Talk (n=92); Session 9--Managing Your Stress: Eating Habits and Exercise (n=96); Session 10--:Managing Your Stress: The Chemical Dependency Cycle (n=101); Session 11--Managing Your Stress: Self-Monitoring (n=103); Session 12--Finding Your Plan: Personal Approach to Coping with Work and Family Stressors (n=106). The final 2-day retreat was held at a Forbes 4-star luxury resort in rural West Virginia and it was attended by 87 intervention group members. Facilitators reported covering 90–100% of the intended curriculum across all intervention sessions.

## Measures

A major part of the survey questionnaire consisted of questions from the Substance Abuse and Mental Health Services Administration's National Outcome Measures [19]. The major outcome measure for this study was unprotected sex. In the questionnaire, protected and unprotected sex were defined for participants: "Protected sex is when a latex or polyurethane condom (rubber) is used to cover the penis; a female condom is used to cover the vagina; or a dental dam is used to cover the anus. By unprotected sex, we mean vaginal, oral, or anal sex without a barrier such as a condom or dental dam." Three items were used in this study to measure unprotected sex; "The last time you had oral sex, was it protected or unprotected?", "The last time you had vaginal sex, was it protected or unprotected?", "The last time you had anal sex, was it protected or unprotected?". Response options and their coding for this study included "I have never had anal sex" (coded 0), "Protected" (coded 0), and "Unprotected" (coded 1). The three items were summed to form a 4-point scale: 0=None/protected, 1=1 type unprotected, 2=2 types unprotected, and 3=3 types unprotected. The reliability of the final scale was adequate (Cronbach's alpha=0.70).

## Data Analysis

The independent variable in analyses was group (0, 1). Demographic variables assessed in analyses are included in Table 1. Table 1 also indicates the cross-sectional Chi-Square differences between groups at each study time point. Differences between the intervention and control groups in the outcome variable of unprotected sex across three time periods were examined, using generalized estimating equations (GEE; normal distribution, identity link, unstructured correlation matrix). As the time data were correlated longitudinally for each subject, the standard errors of the regression coefficient were empirically adjusted with the method of GEE [20–21]. The GEE was implemented within the generalized linear model (GLM) framework [22] and was computed with the GENLIN subroutine of the SPSS

statistical analysis software, version 21. Demographic variables were examined as possible covariates in analyses, and only variables found significant were retained in the final models. These variables are indicated in the footnotes of Tables 2–4. Statistical significance was set at 5%.

## Results

At baseline, 48% and 50% of the intervention and comparison groups respectively reported unprotected oral sex, 56% and 46% reported unprotected vaginal sex, and 20% and 18% reported unprotected anal sex. Including all three sex behaviors, 64% of the intervention group and 58% of the comparison group reported unprotected sex at baseline (Table I).

### GEE Modeling

The final overall GEE model indicated a significant Time  $\times$  Group interaction effect ( $\chi^2=13.33$ ,  $p<.001$ ) for the outcome variable (unprotected sex) over the three time points (Table II). To better understand whether the difference in group trajectories was over the short-term (from baseline to post-test) and/or long-term (baseline to 6-month follow-up), the GEE models were rerun over these two time intervals. The Time  $\times$  Group interaction effect for baseline to posttest was significant ( $\chi^2=8.34$ ,  $p<.004$ ) due to less unprotected sex in the comparison group (Effect size 1.10) while the treatment group showed little change (Effect size  $-.06$ ) from baseline. The Time  $\times$  Group interaction effect was also significant ( $\chi^2=4.39$ ,  $p<.04$ ) for baseline to 6-month follow-up. In this case, a positive treatment effect was found with those in the treatment group showing a decrease in unprotected sex (Effect size 1.18) while those in the comparison group showed little decrease in unprotected sex (Effect size .25) from baseline (Table II). These analyses of the longer-term trajectories (baseline to 6-month follow-up) revealed that the intervention group reported a decreased risk in unprotected sex by about 33%, while the comparison group showed a reduction of about 9%. Due to the comparison group's decrease in unprotected sex at post-test relative to the treatment group, and the treatment group's decrease in unprotected sex at 6-month follow-up relative to the comparison group, it was considered whether on balance, the comparison group or the treatment group experienced the most benefit from the intervention. The GEE model with the post-test and follow-up scores averaged together as one score, and both with and without covariates in the model, indicated that there was no Time  $\times$  Group interaction thus no difference between the groups (Without covariates:  $\chi^2=2.85$ ,  $p=.091$ ; with covariates:  $\chi^2=3.15$ ,  $p=.076$ ).

Both income and age were found to be significant moderating variables in the GEE modeling. The Time  $\times$  Group  $\times$  Income and the Time  $\times$  Group  $\times$  Age interaction effects were both significant at  $\chi^2=3.88$ ,  $p<.05$ . The GEE models within levels of these variables were thus examined. Within levels of income, group trajectories across the three study times points differed for those earning \$20,000 or less ( $\chi^2=10.50$ ,  $p<.001$ ) but not for those earning more than this amount ( $\chi^2=2.66$ ,  $p<.289$ ) (Table III). Among those earning \$20,000 or less, the comparison group decreased risk from pre-test by 38% at post-test and 18% at 6-months, whereas the intervention group decreased risk by 0% at post-test and 50% at 6-months.



For levels of age, group trajectories across the three study time points differed for those 50 years or less ( $\chi^2=10.30$ ,  $p<.001$ ) and for those older than 50 years ( $\chi^2=6.90$ ,  $p<.04$ ) (Table IV). Among those 50 years or less, the comparison group decreased risk from pre-test by 32% at post-test and increased risk by about 11% at 6-months, whereas the intervention group decreased risk by 0% at post-test and 34% at 6-months. Among those older than 50 years, the comparison group decreased risk from pre-test by 56% at post-test and 38% at 6-months, whereas the intervention group increased risk by 2% at post-test and decreased risk 34% at 6-months.

## Discussion

The findings from this evaluation of the impact of SHIPS on unprotected sex among Black women are mixed. While the baseline to immediate post-test findings showed that the comparison group reduced risk more than the intervention group, the 6-month follow-up findings showed that the intervention group reduced risk more than the comparison group. Furthermore, averaging the unprotected sex scores at post-test and 6-month follow-up and then analyzing the results suggested that neither the treatment group nor the comparison benefited more from the intervention. The inconsistent findings should be considered exploratory rather than confirmatory, and warrant further clarification and/or confirmation in future research.

The condition comparisons at both immediate post-test and 6-month follow-up are subject to biases due to several differences between the conditions beyond just the receipt of the study intervention. First, the drop-out rate was higher in the comparison than intervention group. Although the statistical comparisons of conditions controlled for a number of participant characteristics, perhaps the differential drop-out introduced differences between the groups that were not controlled for. Secondly, while the baseline and 6-month follow-up were administered under similar circumstances for both groups, the two groups completed the post-test under different circumstances. Finally, the comparison group reported being significantly less truthful on their surveys at baseline, post-test, and 6-month follow-up than did the intervention group and this could have introduced bias in the measurements<sup>1</sup>.

Specific to the post-test findings, we can think of no reason why the comparison group would experience a reduction in risk as was observed at the immediate post-test suggesting there were reasons other than the study intervention that influenced the group measurements in potentially different ways. Specifically, the post-test findings might have been influenced by the fact that the post-test survey was collected under different circumstances within each condition. The intervention group completed their post-test survey at the end of a 2-day workshop and the comparison group participants, on the other hand, completed their post-test survey at meetings scheduled explicitly for the purpose of conducting the survey. Hence, the post-test differences in survey administration could have introduced bias into the study condition comparisons.

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<sup>1</sup>When asked "How truthful were you when answering the questions? (1=Very truthful to 4=Very untruthful)" the intervention group said they were more truthful than the comparison group at all three study time points (Mean untruthful at baseline =  $1.05 \pm .32$  vs.  $1.19 \pm .55$ ,  $p < .000$ ; at post-test =  $1.15 \pm .54$  vs.  $1.36 \pm .819$ ,  $p < .001$ ; and at 6-month follow-up =  $1.23 \pm .72$  vs.  $1.39 \pm .95$ ,  $p < .05$ ).

The comparison condition in particular may have introduced more bias than the intervention condition for the following reasons: It had a higher drop-out rate, it admitted less truthfulness in the surveys, and the trajectory of its unprotected sex scores from pre- to post-test were counter to expectations and plausible explanations.

The intervention group, on the other hand, appeared less susceptible to bias than the comparison condition for the following reasons: It had lower drop-out rates, reported being more truthful on the study surveys, and its trajectories of unprotected sex conformed more to expectations and plausible explanations.

Hence, the intervention group trajectory of means of unprotected sex scores, showing little pre- to post-test change but a dramatic decrease (about 33%) in unprotected sex at 6-months, may be viewed with more confidence than the comparison group trajectory. Viewed by itself, the drop in unprotected sex at 6-months in the intervention group may be considered preliminary evidence of an intervention effect. It is also quite plausible that this intervention effect was confined primarily to those intervention group participants with \$20,000 or less annual income and below 51 years of age as these results suggest.

That women with lower income were most positively impacted by the intervention is a finding that can also possibly be explained by other research about sexual risk. The intervention focused on women's vulnerability to sexual risk due to life stressors and ability to cope. Lower income women are likely to have more life stressors than higher income women, particularly stressors related to sexual risk [9; 23–24]. Specifically, lower income women may be more vulnerable to wanting to please sexual partners who offer some level of financial security, and this may lead to hesitancy around asserting the use of sexual protection [25]. Hence, the intervention may have addressed the needs particularly common in lower income women and thus reduced their risk-taking.

That younger women were most positively impacted by the intervention is a finding that can be explained by other research about sexual risk. Older women may be more stable in their sexual relationships while younger women may be more susceptible to sexual risk-taking due to more abbreviated relationships, under-developed decision making skills, and susceptibility to social pressure. Furthermore, younger women may have less social support and higher levels of stress contributing greater sexual risk-taking [26]. Hence, the intervention may have had particular relevance to younger women.

Although this study does not identify the mechanism through which the risk reduction intervention reduced unprotected sex among participants, the theoretical framework underlying the intervention suggests that improvement in women's ability to cope effectively with a wide range of life stressors, increase positive social support, improve self-esteem, and engage in healthier lifestyles should all be explored as potential mechanisms for the change. Future phases of the evaluation will examine these mechanisms for sexual risk reduction. Also, further follow-up studies will address whether SHIPS had its intended impact on HIV risk due to substance use. Additionally, future studies could examine whether these study findings generalize to other women, such as those from other race/ethnicities.

This study has a number of limitations. In regard to generalizability, the sample consisted of a convenience sample of African American women in one geographic region in the Northeast and may not be representative of other samples of African American women or non-African American women. Nevertheless, the sample was diverse across many characteristics and did include women from a number of disparate venues and from different types of communities. In regard to internal validity of the study, the intervention and comparison group design did not comprise a complete random assignment to group. While women at a majority of sites were randomized to group following their consent to participate, women at 4 of the 10 community sites were assigned as a whole to the treatment group. The two groups did in fact differ on age and employment status at baseline. Hence, differences in outcomes observed between groups could be due to other factors beyond the intervention although these and a number of other important sample characteristics were controlled in the analysis. Additionally, attrition was high in this study, particularly in the comparison group, and differential attrition between conditions was observed at both follow-up study time points which could have introduced biases that contribute to the findings. Another potential limitation is that women's self-reported behaviors may be susceptible to bias. It was noted, for example, that the intervention group completed the immediate post-test at the end of a two-day weekend retreat and the comparison group completed the immediate post-test at a group meeting at their "site". The women in the retreat could have been more confident in reporting their socially undesirable (unprotected sex) behaviors, or could have been more aware of their sexual risk behaviors. We note the unexpected trend toward reduced risk in the responses in the comparison group at immediate post-test and believe differences in survey administration may have contributed to differences in self-reported data. Unlike at post-test, the 6-month follow-up survey was administered under the same circumstances for both groups at a single location. Hence, the only surveys completed under similar circumstances for both groups were at baseline and 6-month follow-up. As we have footnoted in the discussion, the women in the comparison group said they were less truthful on the survey than the intervention group at each study time point which could also have influenced the findings. Another limitation of the study pertains to the measurement of "last time unprotected sex" during post-tests. The same questionnaire was administered at each time point, and the post-test questionnaires did not specify time period of unprotected sex to capture the behavior since the intervention. It is plausible that the "last time unprotected sex" might have captured pre-intervention and post-intervention behaviors during the post-test assessments thus introducing potential error to the measurements. Additionally, the actual measures of the outcomes in this study, as well as our combination of those measures into one overall outcome measure, may not conform to any standardization of outcomes found in the HIV prevention trial literature. Furthermore, missing data was also a concern in understanding the internal validity of the study, although the GEE analysis, which uses all available data, tends to decrease the sensitivity of the analysis to missing data.

In summary, this evaluation of an administration of SHIPS, a multi-session intervention based on an adaptation of two science-based programs, CWFS and H2P, revealed several potential biases when comparing the study groups. For example, the comparison group had higher drop-out and reported being less truthful on the study surveys. Also, the comparison

group in this study appeared to have a reduction in unprotected sex from pre-test to immediate post-test counter to expectations and without plausible explanation. Nevertheless, findings also indicated a drop in unprotected sex from pre-test to 6-months in the intervention group leading to less unprotected sex than the comparison group at 6-months. With less opportunity for bias identified in the intervention group than the comparison group, the study offers preliminary evidence that SHIPS may reduce the risk of unprotected sex through six months of follow-up among Black women, particularly among those less than 51 years old and with annual income of less than \$20,000 per year. The specific mechanisms for the observed risk reduction must be further explored. The findings support the premise, however, that delivery of a multi-session program aimed at improving women's coping skills regarding social and environmental demands, and incorporating cultural messaging tailored to Black women in addition to sexual risk education, may reduce unprotected sex among Black women.

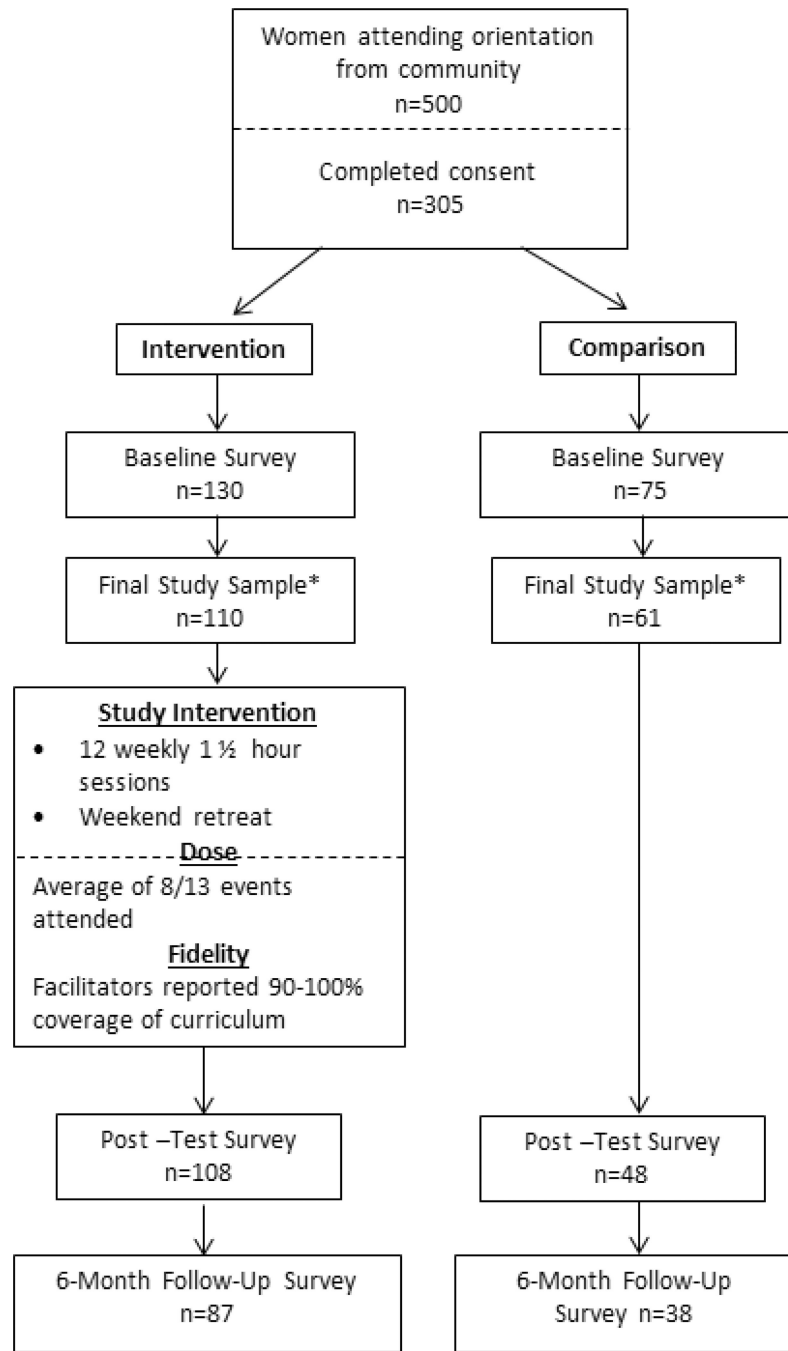
## Acknowledgements

Funding for this project was provided by the Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Prevention (CSAP) through grant SP 15112. The University of Maryland Prevention Research Center evaluators were engaged in this project after the intervention and data collection was completed, and partial support for the evaluation of this project was provided by the Centers for Disease Control and Prevention, Prevention Research Centers Program through cooperative agreement U48DP001929. This study was conducted solely by the authors, and all opinions expressed in this report are theirs and may not represent those of the funding agencies.

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**Figure 1.**  
Study Flowchart

\*The Final Study Sample only included participants who completed the Post-Test and/or the 6-Month Follow-Up Survey.

**Table 1**

Study sample characteristics.

	Baseline		p-value	Post-test		p-value	6-Month Follow-up		p-value
	Intervention (n=110) n(%)	Comparison (n=61) n(%)		Intervention (n=108) n(%)	Comparison (n=48) n(%)		Intervention (n=87) n(%)	Comparison (n=38) n(%)	
<b>Characteristics</b>									
<b>Age (years)</b>			4.6			2.0			2.4
<=50	49(45)	37(63)		46(44)	27(56)		32(38)	20(53)	
51+	59(55)	22(37)		59(56)	21(44)		53(62)	18(47)	
<b>Household Income</b>			1.7			0.5			1.2
<20K	65(66)	30(56)		65(61)	32(67)		52(61)	19(50)	
>20K	33(34)	24(44)		42(39)	16(33)		34(39)	19(50)	
<b>Gender</b>									
Female	110(100)	61(100)		106(100)	47(100)		87(100)	38(100)	
<b>Race/Ethnicity</b>			2.4			2.2			0.9
African American/Black	92(38)	57(95)		92(85)	44(94)		78(90)	36(95)	
Other Race/Ethnicity	13(12)	3(5)		16(15)	3(6)		9(10)	2(5)	
<b>Sexual Orientation</b>			2.8			4.7			7.9
Straight/Heterosexual	101(95)	53(88)		101(95)	40(85)		84(98)	32(84)	
Bisexual/Gay/Lesbian/Uns	5(5)	7(12)		5(5)	7(15)		2(2)	6(16)	
<b>Education</b>			0.7			3			0
<=high school	59(57)	39(64)		63(52)	35(73)		53(62)	23(61)	
>HS grad	44(43)	22(36)		45(42)	13(27)		33(38)	15(39)	
<b>Employment Status</b>			8.4			7.9			6.9
Employed fulltime/part-	28(27)	17(28)		30(28)	13(27)		23(27)	10(26)	
Unemployed/looking/student/	26(25)	26(43)		25(23)	21(44)		15(17)	14(37)	
Disabled	40(38)	12(20)		40(37)	10(21)		40(47)	10(26)	
Retired	11(10)	5(9)		13(12)	4(8)		8(9)	4(11)	
<b>Injection Drug Use Past 30 Days</b>			1.9			0.5			3.9
No	103(100)	53(96)		92(99)	44(100)		81(93)	30(81)	

	Baseline			Post-test			6-Month Follow-up		
	Intervention	Comparison	p-value	Intervention	Comparison	p-value	Intervention	Comparison	p-value
	n(%)	n(%)		n(%)	n(%)		n(%)	n(%)	
<b>Characteristics</b>			$\chi^2$			$\chi^2$			$\chi^2$
Yes	0(0)	1(2)		1(1)	0(0)		6(7)	7(19)	
<b>Oral Sex</b>			0.1			0.2			6.4
None/Protected	55(51)	28(50)		60(59)	28(64)		59(72)	15(47)	
Unprotected	51(48)	28(50)		41(41)	16(36)		23(28)	17(53)	
<b>Vaginal Sex</b>			1.5			9.5			4.5
None/Protected	45(44)	32(54)		43(43)	31(70)		52(65)	21(58)	
Unprotected	57(56)	27(46)		58(57)	13(30)		28(35)	15(42)	
<b>Anal Sex</b>			0.1			6.9			1.4
None/Protected	84(80)	44(82)		76(77)	42(96)		69(89)	28(80)	
Unprotected	21(20)	10(18)		22(22)	2(4)		8(11)	7(20)	
<b>Unprotected Sex Scale</b>			0.8			9.7			7.3
0=None/Protected	39(36)	25(42)		41(40)	23(51)		49(59)	16(44)	
1=1 type Unprotected	23(21)	12(20)		20(19)	13(29)		15(18)	4(11)	
2=2 types Unprotected	29(27)	13(22)		25(24)	9(20)		12(15)	13(36)	
3=3 types Unprotected	16(15)	9(15)		17(17)	0(0)		7(8)	3(8)	



Difference in GEE\* group trajectories of unprotected sex over study time periods considering the baseline (time 1) to post-test (time 2) and to follow-up (time 3).

**Table II**

Group	Adjusted Means by Time			Unprotected Sex Score Effect Size ( $p^d$ )		
	Baseline Mean (s.e.)	Post-Test Mean (s.e.)	Follow-up Mean (s.e.)	Times 1,2,3	Times 1,2 <sup>1</sup>	Times 1,3 <sup>2</sup>
Comparison	1.11(.16)	0.67(.16)	1.01(.16)	(.001)	1.10 (.004)	.25 (.04)
Treatment	1.20(.11)	1.22(.11)	0.81(.11)	-.06		1.18

\* Note: All five demographic variables, age, gender, employment, education, and income were tested in the GEE model as covariates.

<sup>a</sup> Group  $\times$  Time Interaction,  $\chi^2=13.33$ ,  $p<.001$ .

<sup>1</sup> Considering only time 1 and time 2 in the GEE model,  $\chi^2=8.34$ ,  $p=.004$ .

<sup>2</sup> Considering only times 1 and 3 in the GEE model,  $\chi^2=4.39$ ,  $p=.04$ .

Difference in GEE\* group trajectories of unprotected sex over study time periods by income considering the baseline (time 1) to post-test (time 2) and to follow-up (time 3).

**Table III**

Group	Adjusted Means by Time			Unprotected Sex Score Effect Size (p <sup>d</sup> )		
	Baseline Mean (s.e.)	Post-Test Mean (s.e.)	Follow-up Mean (s.e.)	Times 1,2,3	Times 1,2 <sup>1</sup>	Times 1,3 <sup>2</sup>
\$20K						
Comparison	1.17(.23)	.73(.16)	.96(.21)	(.001)	1.02 (.07)	.46 (.08)
Treatment	1.24(.13)	1.24(.14)	.62(.13)	0	1.72	
>\$20K						
Comparison	1.00(.22)	.55(.26)	1.01(.21)	(.289)	0.94 (.07)	-.02 (.23)
Treatment	1.10(.18)	1.15(.17)	1.13(.17)	-.12	-.07	

\* Note: When all five demographic variables, age, gender, employment, education, and income were tested in the GEE model as covariates, income level was significant in GEE modeling (p<.05)

<sup>a</sup> Group × Time Interaction, for \$20K,  $\chi^2=16.19$ , p<.001; for >\$20K,  $\chi^2=2.48$ , p=.289.

<sup>1</sup> Considering only time 1 and time 2 in the GEE model, for \$20K,  $\chi^2=3.27$ , p<.07; for >\$20K,  $\chi^2=2.66$ , p=.08.

<sup>2</sup> Considering only times 1 and 3 in the GEE model, for \$20K,  $\chi^2=3.11$ , p=.07; for >\$20K,  $\chi^2=1.42$ , p=.23.

Difference in GEE\* group trajectories of unprotected sex over study time periods by age considering the baseline (time 1) to post-test (time 2) and to follow-up (time 3).

**Table IV**

Group	Adjusted Means by Time			Unprotected Sex Score Effect Size (p <sup>d</sup> )		
	Baseline Mean (s.e.)	Post-Test Mean (s.e.)	Follow-up Mean (s.e.)	Times 1,2,3	Times 1,2 <sup>1</sup>	Times 1,3 <sup>2</sup>
50 Years						
Comparison	1.24(.20)	.84(.17)	1.38(.20)	(.001)	.93 (.10)	-.31 (.002)
Treatment	1.20(.17)	1.20(.17)	.79(.16)		0	1.01
>51 Years						
Comparison	.90(.28)	.40(.16)	.52(.18)	(.04)	2.27 (.01)	1.65 (.80)
Treatment	1.20(.13)	1.22(.14)	.82(.15)		-.05	1.02

\* Note: When all five demographic variables, age, gender, employment, education, and income were tested in the GEE model as covariates, age was significant in GEE modeling (p<.05)

<sup>a</sup> Group × Time Interaction, for 50 Years,  $\chi^2=14.64$ , p<.001; for >51 Years,  $\chi^2=6.58$ , p=.04.

<sup>1</sup> Considering only time 1 and time 2 in the GEE model, for 50 Years,  $\chi^2=2.75$ , p<.10; for >51 Years,  $\chi^2=4.02$ , p<.01.

<sup>2</sup> Considering only times 1 and 3 in the GEE model, for 50 Years,  $\chi^2=9.18$ , p<.002, for Age >50 Years,  $\chi^2=0.63$ , p=.80.