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Effectiveness of a Cognitive Behavioral Randomized Controlled Trial for People Living with HIV Who are Heavy Drinkers: The Holistic Health Recovery Program (HHRP) Trial in Miami

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Abstract
This study evaluates the impact of an intervention targeting high-risk behaviors among diverse, alcohol-using adults living with HIV ($N=267$) from 2009 to 2013 in Miami, FL. The intervention took place in a group setting for eight sessions over 4 weeks and was compared to a didactic health promotion group. Assessments were conducted pre-intervention, post-intervention, and at 3, 6, and 12 months follow-up. Intervention participants (48% of sample) evidenced greater knowledge about HIV, more condom self-efficacy, and greater intentions to use condoms after participation. This was particularly noteworthy because associations among knowledge about HIV, more condom self-efficacy, and greater intentions to use condoms were negatively associated with intervention status at baseline. Participants also reported fewer heavy drinking days after participating in the intervention than those in the control group. Greater HIV knowledge, more condom self-efficacy and intentions to use condoms predicted more condom assertiveness; greater intentions to use condoms predicted fewer unprotected sexual behaviors. These findings underscore the importance of taking a comprehensive, multi-systemic approach to address risky behaviors in high-risk, diverse populations.

Keywords IMB model · HIV-positive · Alcohol use · Holistic Health Recovery Program (HHRP)

Introduction

To better understand the bio-psychosocial factors that influence HIV transmission, several models of health behavior change have been developed. The Information-Motivation-Behavioral Skills (IMB) model is one such theoretical framework that has effectively predicted HIV risk and preventive behavior in diverse samples and conditions (Fisher & Fisher, 1992). This model incorporates three fundamental determinants of HIV risk reduction: knowledge of HIV/AIDS transmission and information on specific methods for transmission prevention; motivation to change HIV/AIDS risk behavior; and behavioral skills to carry out specific preventive behaviors. The IMB model proposes that the combination of HIV prevention information, motivation efforts, and skills training will influence risky behavior in at-risk populations. The model has shown particular strength in predicting condom use skills, knowledge, intention, and self-efficacy (Malow et al., 2009). The current study assesses the impact of the IMB-based Holistic Health Recovery Program (HHRP) as implemented in a randomized controlled trial of a high-risk sample of alcohol-using HIV-positive individuals in Miami, Florida. HHRP is a group-based, cognitive behavioral intervention to reduce risk behaviors and improve medical and psychosocial functioning, originally developed for injection drug users (Margolin et al., 2003). Many past cognitive behavioral interventions have been found effective in reducing risk in this population.

In studies using the IMB model, measures of self-efficacy for performing specific behaviors are often used, and single or multiple indicators are employed to define motivation. For

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example, to better assess independent markers of motivation within the IMB framework, researchers such as Kalichman et al. have combined pro-condom social norms, condom attitudes, and perceived risk for HIV (Kalichman et al., 2005). In other studies, the motivational component was measured through attitudes toward condom use, perceived social norms and peer influence supportive of condom use, risk perception/perceived susceptibility, and behavioral intentions to use condoms (Kalichman et al., 2008; Robertson et al., 2006). These measures, in concert, provide researchers with useful parameters for measuring and defining motivation, which further assist in determining the factors that influence behavior change.

The IMB model has been tested on a broad range of populations that include college students (Fisher et al., 1994), heroin injectors (Bryan et al., 2000), severely mentally ill adults (Kalichman et al., 2005), and adolescents (Kalichman et al., 2002). While the model has been effective for predicting risk behaviors among a number of different groups, research underscores the importance of critically examining the variables that predict and moderate outcomes of interventions as a means of increasing the effectiveness among specific subgroups (Crits-Christoph et al., 2014; Chandler et al., 2016). The constructs of the IMB model appear to be most predictive when applied to a well-defined population (Fisher et al., 1994).

The current study employs structural equation modeling (SEM) to assess the impact of participation in an intervention that incorporates the IMB components of transmission knowledge, intentions to use condoms, and condom self-efficacy among adult alcohol users with HIV. SEM has been used often to analyze latent variables in longitudinal, between groups research. In turn, these Information and Motivational mediators are used as predictors of Behavioral outcomes, including risky sexual behaviors, heavy alcohol use, and condom use assertiveness.

Methods

Participants

The original baseline sample of the intervention was culturally diverse, predominantly minority, low income, and sexually active ($N=267$; mean age 45 years [SD = 6.9]; 36% female; 73% Black/African American, 14% Hispanic, 9% White, 5% mixed, 1% American Indian/Native/Hawaiian/Pacific Islander, 1% unreported. Six percent had less than an 8th grade education, 34% had some high school, 32% had a high school diploma or GED, and 24% percent had attended college or had a college degree (the remaining 3% did not respond to this question). Seven percent were employed at baseline. Most reported themselves as heterosexual (65.2%); some reported their sexual orientation as homosexual (19.5%), bisexual (8.6%) or reported themselves as unsure or refused to answer (6.7%).

Recruitment

Recruitment took place at 13 Community-Based Organizations (CBOs) located primarily in densely populated, multicultural, low income, urban areas of Miami with high rates of alcohol and other drug abuse, HIV, violence and poverty. The CBOs varied on several key dimensions, including a range of seropositivity rates among their clients; different philosophical approaches to providing HIV/AIDS services, ranging from faith-based to medical models; and differences in the proportion of their clients who are African American, Caribbean Islander and Hispanic. The vast majority of the population served by the CBOs were uninsured and suffering from multiple health disparities.

The inclusion criteria for the study were: being older than 18 years and less than 60 years; HIV-positive and willing to present documentation to confirm serostatus; consumed any amount of alcohol in the previous 3 months; a history of alcohol abuse or dependence within the past 2 years; and at least one episode of unprotected vaginal or anal sex in the past 90 days. Additional criteria included ability to understand and speak English, understanding the informed consent, providing contact information to be located for interviews, planning to be in the area for the following 12 months, and not facing immediate incarceration or residence in a restricted environment. Participants also had to be willing to be randomized to treatment or a control group and to be contacted for follow-up assessments. They also could not currently be exhibiting symptoms of a major psychiatric disorder, including psychosis or suicidality. Based on these entry criteria, 2,634 potential participants were screened and identified, 267 of whom met study criteria. Data analyses were completed on 267 participants. Ten of these did not have initial demographic data recorded due to computer or assessor error, and one study participant did not meet criteria based on the information that was gathered and was therefore subsequently deleted from the sample.

Recruitment staff met with participants, conducted informed consent, and explained the study procedures, including intervention and assessment protocols, follow-up periods, confidentiality, and incentive structure. Staff made particular effort to ensure that clients understood that participation was voluntary and that being in the study was not contingent on participation in any outside treatment activities. To ensure they understood, clients were asked to repeat back the critical elements of informed consent, including what it means to consent voluntarily, procedures for withdrawal, confidentiality, and assessment procedures.

Study Conditions

This study was a prospective randomized controlled trial where participants were assigned to the experimental or control groups. Participants were entered into the study in cohorts of eight of the same gender. Cohorts were assigned to receive either the experimental or control condition according to a computer-generated random sequence. The random sequencing controlled for bias in subject assignments across conditions. The experimental group participated in the HHRP-A intervention program designed to promote risk reduction behaviors among alcohol abusers living with HIV (Fisher et al., 2014). HHRP-A was adapted from the original 12-session intervention, which emerged from the need for secondary behavioral prevention approaches that would engage and retain substance abusers living with HIV, known to be at high risk for neuropsychological problems due to comorbid substance use and HIV infection. The original HHRP was designed for a methadone using population and did not include cognitive remediation techniques. The adaptation of HHRP-A as well as the intervention protocol were guided by consultation with a community advisory board as well as subject matter experts. The primary outcome of HHRP-A was to reduce HIV sexual transmission risk and reduction in alcohol and other drug (AOD) use the secondary outcome was to improve utilization of primary care services and medication adherence. HHRP was the only CDC-recognized intervention for such a population and is still considered a "gold standard" for intervening with HIV-positive IDUs (Jaworski & Carey, 2007).

The HHRP-A intervention manual was adapted for our population of alcohol abusers living with HIV; it was highly structured and involved both didactic presentations of material as well as experiential exercises. Participants attended eight sessions, each lasting two hours, twice a week, for 4 weeks. Intervention content was comprehensive to address the medical, emotional, and spiritual needs of people with HIV/AIDS. Topics addressed by HHRP-A included: (1) strategies for making healthy lifestyle choices including reducing HIV sexual transmission risk behavior; (2) harm reduction skills training; (3) relapse prevention; (4) training to improve emotional, social, and spiritual health, including coping with stigma and grief; 5) techniques to increase medication adherence and improve participation in medical care. Cognitive remediation strategies were incorporated because of the potential for cognitive impairment in this population. Some of these strategies included emphasis on structure and consistency, repetition and review, behavioral games and memory books, as well as ongoing assessment of new learning and retention, with immediate provision of feedback. Each session was co-facilitated by two counselors using a nonjudgmental, motivational enhancing therapeutic style. Intervention counselors attended a two-day training, had at least high school or bachelor's degrees, and were familiar with the population. They were similar in demographic profile to the participants (e.g., Black and Hispanic, different genders). Participants were offered compensation for participating in data collection and intervention sessions in the form of a gift card, ranging from $5-$50 depending upon time commitment.

To ensure adherence to manual guidelines, all intervention sessions were audiotaped (with informed consent). A random selection of 20% of audiotapes were evaluated for adherence to guidelines, general interpersonal skills, and directness and clarity of communication. Facilitators met weekly with the research coordinator for the purpose of monitoring treatment fidelity as well as problem-solving clinical issues that may emerge during sessions with participants.

The Health Promotion Comparison (HPC) group focused on educational and didactic methodologies, addressing common health problems such as nutrition, physical fitness, and healthy living. The HPC did not incorporate behavioral skills training or motivational enhancement techniques. The HPC matched HHRP-A in total administration time and format (eight, two-hour sessions). However, the program was condensed and delivered in two days to reduce the risk of cross-group contamination and the potential for enhancing social support that group sessions repeated over time could engender. A standard care HIV education component was included in the HPC because it was considered ethically irresponsible not to include HIV education in a comparison condition, given the high-risk nature of this population.

Assessment

Assessment methods included: (1) CAPI (computer-assisted personal interview); (2) ACASI (audio computer-assisted self-interview) for subjective sensitive topics; and (3) TLFB (Time-line Follow-back), which uses a calendar format to enhance accurate recall, e.g., for alcohol/drug use and number of sex partners. Follow-up assessments were conducted immediately post-intervention, and at 3, 6, and 12-month follow-up. Due to the level of missing data at the follow-ups, a missing data program was used in the analysis. Also, to keep the number of variables and the amount of imputation required to a reasonable level, mean scores from 3 and 6 months were combined and used in the analysis. The 6-month assessment in particular was missing a significant amount of data.

Variables in the Model

Indicators of the latent variables representing the psychosocial and IMB constructs of the model are described below. Due to the large number of variables in the model and the

relatively small sample size, marginally significant items such as demographics were not included. The impact of demographics, including age, ethnicity, and gender were assessed initially but were not significantly associated with the substantive variables and intervention status; thus, they were not included in the final model.

Background predictor Intervention status was a dichotomous variable (0 = no, 1 = yes). Forty-eight percent of the sample was in the intervention group. Background single items taken at baseline were included in the analyses to control for pre-existing propensities and possible associations at baseline between the variables and intervention condition. These included all the measures described below.

Intermediate IMB Constructs

Knowledge about HIV and STD transmission was assessed using ACASI with the Sexually Transmitted Disease Knowledge Questionnaire (STD-KQ) (Song et al., 2015; Jaworski & Carey, 2007). 28-item (one item added for this study) questionnaire which measures awareness of HIV/STD transmission routes, safe and risky behaviors, myths about HIV and other STDs, and behavior-specific prevention information. During validation, the STD-KQ demonstrated internal consistency ($\alpha = .86$) and test–retest reliability ($r = .88$) over a brief period (Song et al., 2015; Jaworski & Carey, 2007). A single sum score was used as an indicator of knowledge about transmission at baseline. The three scores at post-test, 3–6 months, and 12 months were used as indicators of a latent variable representing HIV Knowledge after participation in the intervention or control group.

Condom Self-Efficacy was assessed with ACASI using the Condom Use Self-Efficacy Scale (Kalichman et al., 2005). This scale consists of 28 items such as "I feel confident in my ability to put a condom on myself or my partner." Items were rated on a 0–4 scale ranging from "strongly disagree" to "strongly agree." Coefficient alphas for the scale were .92 (baseline), .93 (post-test), .93 and .94 (3- and 6-month), and .94 (12-month). Means of the items were calculated and used as individual indicators at each time period.

Intentions to use Condoms was assessed with the 7 items from the Behavioral Intentions scale, by Otto-Salaj et al. (1998) and adding an item about drinking ("I will use a condom the next time I have sex even if I've been drinking"). Items were scored from 0 (definitely not) to 5 (definitely yes). Coefficient alphas for the scale were .88 (baseline), .89 (post-test), .93 and .92 (3- and 6-month), and .90 (12-month). Means of the items were calculated and used as individual indicators at each time period.

Outcome Measures

Unprotected Sexual Behavior reports on the percentage of time participants had unprotected sex for both vaginal and anal intercourse in the past month using the TLFB measures (Carey et al., 2001; Weinhardt et al., 1998; Morokoff et al., 1997). The TLFB is a structured interview designed specifically for a substance abusing population that assesses a number of sexual risk behaviors. Questions ask how many times participants had vaginal/anal sex and then assessed how many times they did not use a condom. Percentages were then calculated.

Condom Use Assertiveness was the mean score, adapted from a 6-item subscale of the Sexual Assertiveness Scale (SAS) (Morokoff et al., 1997; Noar et al., 2002). From the SAS scale which specifically addresses assertiveness during sexual activity. A typical item is: "I make sure my partner and I use a condom or latex barrier when we have sex" and "I insist on using a condom or latex barrier if I want to, even if my partner doesn't like them." Items range from 0 (disagree strongly) to 3 (agree strongly). Coefficient alphas for the scale were .74 (baseline), .72 (post-test), .70 and .68 (3- and 6-month), and .71 (12-month). Means of the items were calculated and used as individual indicators at each time period.

Heavy Alcohol Use was assessed by a TLFB measure (Carey et al., 2001) Participants were asked their total number of heavy drinking days (≥ 5 standard drinks) in the past month.

Analysis

The analysis used structural equation modeling (SEM) with latent variables using the EQS structural equations program, Version 6.1. As mentioned above, not all participants had complete data. Thus, the Full Information Maximum Likelihood missing data method available that uses an EM (expectation–maximization) algorithm was employed. In EM, imputation parameter estimates are obtained by iterating an expectation step and a maximization step. Diagnostics indicated that the missing data points were missing completely at random (MCAR) and are reported below.

An initial confirmatory factor analysis (CFA) assessed the adequacy of the hypothesized measurement model and the associations among the latent variables constructed with post-intervention variables, pre-intervention single-item variables, and intervention status. Additional relations were considered for addition to the model for fit improvement and were based on results of the LaGrange Multiplier Test (LM Test). Then a directional latent variable model positioned intervention status as a predictor of the intermediate IMB constructs of knowledge, intentions to use condoms, and condom self-efficacy. In turn, the IMB constructs were

modeled to predict unprotected sexual behavior, condom assertiveness, and heavy alcohol use. Additional paths from the intervention directly to the outcomes were possible and were added if suggested by the LM test. The baseline single items were also included as controls on prior associations between the items and intervention status and also served as predictors of their corresponding latent variables assessed after the intervention (e.g., HIV knowledge at baseline and the HIV Knowledge latent variable). Indirect effects of the intervention on the outcome variables as mediated through the intermediate variables were also examined.

Results

Approximately 40% of both the HPC and HHRP groups had less than a high school diploma (Table 1). The majority in both groups were male, Black/African American, reported being heterosexual, and were unemployed. Of the 333 participants randomized, 105 remained in the experimental group and 101 remained in the comparison group at 12 months post-intervention. There were no significant differences between groups on neurocognitive functioning, alcohol use, demographics, or study variables. There were significant differences in knowledge, post-intervention and at 3–6-month follow-up, with the intervention group demonstrating greater knowledge than the control group. Intentions to use condoms was significantly higher in the HHRP group at post-assessment and 3–6 months post, compared to the control group. Condom use assertiveness at 12 months post, was higher in the control group.

Confirmatory Factor Analysis

Table 2 reports summary statistics of the measured variables and the factor loadings of the hypothesized factor structure for the latent variables constructed from the follow-up variables only. All factor loadings were significant ($p \leq .001$). Fit indices for the CFA model were excellent and indicated that the matrices were plausible even though data were missing. Missing data diagnostics based on the Generalized Least Squares tests of the homogeneity of the means, the covariance matrices, and the means/covariances were excellent (p values $> .05$ are desirable): $\chi^2 = 797.72/741$ *df,* (means; $p = .07$); $\chi^2 = 4425.98/4409$ *df,* (covariances; $p = .43$) 5223.71/5150 *df,* (means/covariances; $p = .23$); CFI = .97. For fit improvement, three correlations were allowed among the predictive single-item baseline variables (e.g., intentions to use condoms and HIV knowledge at baseline were correlated significantly [$p \leq .05$]).

Table 2 reports the bivariate correlations among the post-intervention latent variables and intervention status before the directional hypothesized structural equation model was tested. Of particular note, intervention group membership was positively associated with the intermediate latent variable of Intentions to Use Condoms, and the outcome of Condom Assertiveness, and negatively associated with Heavy Alcohol Use. Although not reported in the table, Intervention Status was not significantly associated with any of the pre-test single-item outcome variables (unprotected sexual activity, condom assertiveness, or heavy drinking at baseline). However, intervention status was by chance significantly and negatively associated with the intermediate IMB variables assessed at baseline before the intervention (correlation between HIV Knowledge and the intervention = − .16, $p = .01$; Condom Self-Efficacy = − .14, $p = .05$; and Intentions to Use Condoms − .13, $p = .05$). These associations were retained in the final model to control for any tendency to show less improvement over time due to pre-existing attitudes or behaviors.

As seen in Table 3, HIV Knowledge was positively associated with greater Condom Self-Efficacy, and Condom Assertiveness. Condom Self-Efficacy was significantly and positively associated with Intentions to Use Condoms and Condom Assertiveness. Intentions to Use Condoms was negatively associated with Unprotected Sexual Behavior and positively associated with Condom Assertiveness. Unprotected Sexual Behavior was negatively associated with Condom Assertiveness and positively associated with Heavy Alcohol Use. Condom Assertiveness was negatively associated with Heavy Alcohol Use (Fig. 1).

Structural Equation Analysis

The final model after dropping nonsignificant regression paths is presented in Fig. 2. Regression paths are depicted with one-way arrows; double-headed arrows indicate correlations. For readability, the individual regression paths from the baseline single-item variables to their analogous latent variables are not depicted (all were significant predictors). Regression paths were trimmed such that the most minimal nonsignificant paths and correlations are dropped sequentially until none remain in the model. Fit indices were very good and were the same as the ones reported above; the CFI = .99.

Being in the intervention predicted higher scores on HIV Knowledge, and greater Condom Self-Efficacy and Intentions to Use Condoms. Intervention membership also directly predicted less Heavy Alcohol Use. Intentions to Use Condoms predicted less Unprotected Sexual Behaviors. Greater Condom Assertiveness was predicted by more HIV Knowledge, Condom Self-Efficacy, and Intentions to Use Condoms. The intermediate IMB constructs did not predict Heavy Alcohol Use but Unprotected Sexual Behavior was highly associated with Heavy Alcohol Use. Intervention participation had a significant negative *indirect effect* on

Table 1 Demographic and IMB variables: Miami, FL

Question or characteristics	HPC ($n=161$)	HHRP ($n=160$)	p value
What is the highest level of education or schooling you completed?			
Equivalent to 8th grade or less	14 (8.7%)	12 (7.5%)	.92
Some high school, no diploma	54 (33.5%)	60 (37.5%)	
High school diploma or GED	53 (32.9%)	46 (28.7%)	
Some college or technical training	31 (19.3%)	33 (20.6%)	
College degree	8 (5%)	7 (4.4%)	
Any graduate training	1 (0.6%)	2 (1.3%)	
Gender			
Male	109 (64.5%)	110 (67.1%)	.62
Female	60 (35.5%)	54 (32.9%)	
Which do you consider yourself to be?			
Gay, homosexual	32 (19.9%)	28 (17.5%)	.70
Straight, heterosexual	106 (65.8%)	111 (69.4%)	
Bisexual	18 (11.2%)	19 (11.9%)	
None of the above	4 (2.5%)	1 (0.6%)	
Refuse to answer	1 (0.6%)	1 (0.6%)	
Age			
Mean (*SD*)	44.58 (7.6)	44.99 (6.8)	.618
Are you currently employed?			
No	149 (92.0%)	149 (93.1%)	.69
Yes	13 (8.0%)	11 (6.9%)	
Ethnicity			
Non-Hispanic	137 (85.1%)	136 (85%)	.55
Hispanic	24 (14.9%)	24 (15%)	
Race			
American Indian or Alaska Native	1 (0.6%)	2 (1.2%)	.75
Black or African American	123 (71.9%)	121 (72.5%)	
More than one race	13 (7.6%)	7 (4.2%)	
Native Hawaiian or Other Pacific Islander	1 (0.6%)	0 (0%)	
Unknown or Not reported	13 (7.6%)	15 (9.0%)	
White	20 (11.7%)	22 (13.2%)	
Knowledge (mean, SD)			
BL	15.51 (5.3)	15.86 (5.4)	.55
Post	16.77 (4.9)	18.77 (5.1)	.002
3–6-month combined	33.74 (9.1)	37.54 (8.2)	.005
12 months	18.37 (4.5)	18.15 (4.9)	.73
Condom self-efficacy			
BL	27.1 (17.13)	25.86 (17.9)	.52
Post	28.53 (17.13)	24.22 (18.50)	.06
3–6-month combined	44.69 (28.20)	42.33 (31.90)	.52
12 months	29.52 (17.70)	24.94 (21.00)	.10
Unprotected sex in past 3 months			
BL	4.71 (14.72)	2.72 (11.71)	.225
3–6-month combined	4.10 (13.28)	2.00 (10.66)	.20
12 months	1.44 (6.63)	1.10 (5.12)	.65
Alcohol use in past 3 months			
BL	205.28 (296.4)	214.53 (338.6)	.81
3–6-month combined	80.04 (166.41)	57.46 (127.96)	.22
12 months	50.55 (108.8)	65.31 (147.1)	.40
Condom use assertiveness			
BL	6.9 (3.5)	6.5 (3.5)	.30

Table 1 (continued)

Question or characteristics	HPC ($n=161$)	HHRP ($n=160$)	p value
Post	6.4 (3.3)	5.9 (3.6)	.34
3–6-month combined	10.5 (5.5)	9.9 (5.4)	.37
12 months	6.6 (3.1)	5.5 (3.4)	.01
Intentions to use condoms			
BL	26.7 (8.9)	27.9 (7.3)	.16
Post	26.8 (8.2)	30.1 (6.1)	< .0001
3–6-month combined	43.1 (19.8)	48.5 (16.9)	.02
12 months	28.4 (7.8)	29.1 (6.8)	.44

Table 2 Means or percentages, standard deviations, ranges, and factor loadings of measured variables in the Confirmatory Factor Analysis ($N=267$): Miami, FL

Latent and measured variables (possible range)	Mean (SD)/%	Factor loading*
Intervention member	48%	NA**
IMB variables		
HIV Knowledge (0–28)		
Pre-test knowledge	15.61 (5.40)	NA
Post-test knowledge	17.70 (5.15)	.81
Months 3–6 knowledge	17.78 (4.86)	.74
Month 12 knowledge	18.01 (4.60)	.64
Condom self-efficacy (0–4)		
Pre-test self-efficacy	3.07 (0.63)	NA
Post-test self-efficacy	3.06 (0.63)	.83
Months 3–6 self-efficacy	3.04 (0.63)	.87
Month 12 self-efficacy	3.02 (0.70)	.88
Intentions to use condoms (0–5)		
Pre-test intentions	3.92 (1.16)	NA
Post-test intentions	4.07 (1.06)	.84
Months 3–6 intentions	4.00 (1.08)	.70
Month 12 intentions	4.13 (1.06)	.62
Outcome behaviors		
Unprotected sexual behavior percentage (last month)		
Pre-test percentage	29%	NA
Post-test percentage	7%	.57
Months 3–6 percentage	6%	.65
Month 12 percentage	10%	.37
Condom use assertiveness (0–3)		
Pre-test	1.86 (0.59)	NA
Post-test	1.99 (0.56)	.72
Months 3–6	1.94 (0.50)	.68
Month 12	1.99 (0.55)	.61
Heavy alcohol use (days ≥ 5 drinks in the last month)		
Pre-test	4.58 (7.80)	NA
Post-test	1.41 (4.23)	.30
Months 3–6	1.07 (2.74)	.33
Month 12	2.45 (8.97)	.33

*All factor loadings significant, $p \leq .001$. Factor loadings are standardized

***NA* not applicable

Unprotected Sexual Behaviors ($p \leq .001$) mediated through Intentions to Use Condoms and a positive effect on Condom Assertiveness ($p \leq .001$), mediated through all of the IMB constructs.

Table 3 Correlations among post-intervention latent variables and intervention status ($N=267$) (*$p \leq .05$, **$p \leq .01$, ***$p \leq .001$): Miami, FL

Variables	1	2	3	4	5	6	7
1. Intervention member	–						
Intermediate IMB variables							
2. HIV knowledge	.10	–					
3. Condom self-efficacy	− .03	.20***	–				
4. Intentions to use condoms	.31***	− .05	.25***	–			
Outcome variables							
5. Unprotected sexual behavior	− .05	.01	.02	− .23***	–		
6. Condom assertiveness	.20***	.20***	.31***	.62***	− .31***	–	
7. Heavy alcohol use	− .43***	− .05	− .06	− .11	.21**	− .29**	–

Discussion

The intervention had a direct effect on heavy alcohol use among participants in the intervention condition. Other researchers have found that enhancing patient motivation is associated with an improved ability to address alcohol abuse, which has proven to be effective in HIV prevention (Edelman et al., 2016). The literature points to the pivotal role of intervening with alcohol and substance use in reducing transmission risk and improving clinical outcomes among those living with HIV/AIDS (Williams et al., 2016). Although there was a direct effect on alcohol use, constructs other than the intermediate IMB items did not have a significant effect. Therefore, it is possible that other factors, which may not have been assessed or included in the analysis, may have affected the variables of interest.

Despite negative associations at baseline, the intervention was positively associated with the intermediate variables of the IMB model (HIV knowledge, condom self-efficacy, intentions to use condoms) at follow-up. Although the coefficients are not large, they are significant. Importantly, the initial negative associations had to be overcome in order for these findings to become significant.

Substantial literature exists on the importance of IMB factors in HIV prevention, including condom negotiation and related behavioral skills (Fisher, Fisher, Williams & Malloy 1994). In the current study, the role of skills related to condom use, reinforce the importance of skills building components in HIV behavioral intervention and the need to directly address these intermediate variables (Shuper et al., 2014).

The association between heavy alcohol use and unprotected sex in this study is notable and worth discussing. Cumulative evidence demonstrates that high-risk sex is more likely to occur with heavy drinking in a broad range of populations (Fisher et al., 2014). There is also a strong relationship between alcohol use and behavioral intentions to have unprotected sex and the increased likelihood of impulsive decision-making (Mastroleo et al., 2015; Scott-Sheldon et al., 2013). Among persons living with HIV/AIDS, alcohol and other substance use are directly related to, or mediate, the association with unprotected sex (Metrik et al., 2016; Tross et al., 2015). Despite this well-known coincident risk relationship between harmful alcohol use and HIV risk behavior, heavy drinkers may never be exposed to HIV prevention counseling because of these services still remain inadequately linked to either substance abuse or primary care treatment settings (Scott-Sheldon et al., 2013; Wilson & Albarracin, 2015). Thus, risk reduction approaches must be enfolded in implementation strategies that can raise awareness of coincident risk factors and engage vulnerable individuals and their likely providers in integrated care models.

Our findings strongly reinforce the importance of coupling alcohol use disorder treatment with sexual risk reduction (Maestroleo et al., 2015). Evidence suggests that prevention is more effective when these two interventions become collaborative, co-located or conjoint services (Scott-Sheldon et al. 2016). However, the disconnect between substance use and HIV risk is a persistent characteristic of too many settings and communities in both low and higher income countries, suggesting that the CDC campaign of "Start Talking, Stop HIV" and similar initiatives are incomplete, unless norms shift so that neither HIV or substance use can be talked about without the other (Shneider et al., 2012).

Limitations

Several limitations accompanied this research. The sample size was relatively small, and the level of missing data, although expected in community-based studies, required the use of statistical strategies to accommodate them. Although the indicators were time-ordered, attempts to develop a latent growth model did not result in significant findings. When inspecting the means, initial improvements were observed, especially at post-test, however, there was a significant change over time. It was potentially for this reason that that the latent growth model did not yield significant outcomes.

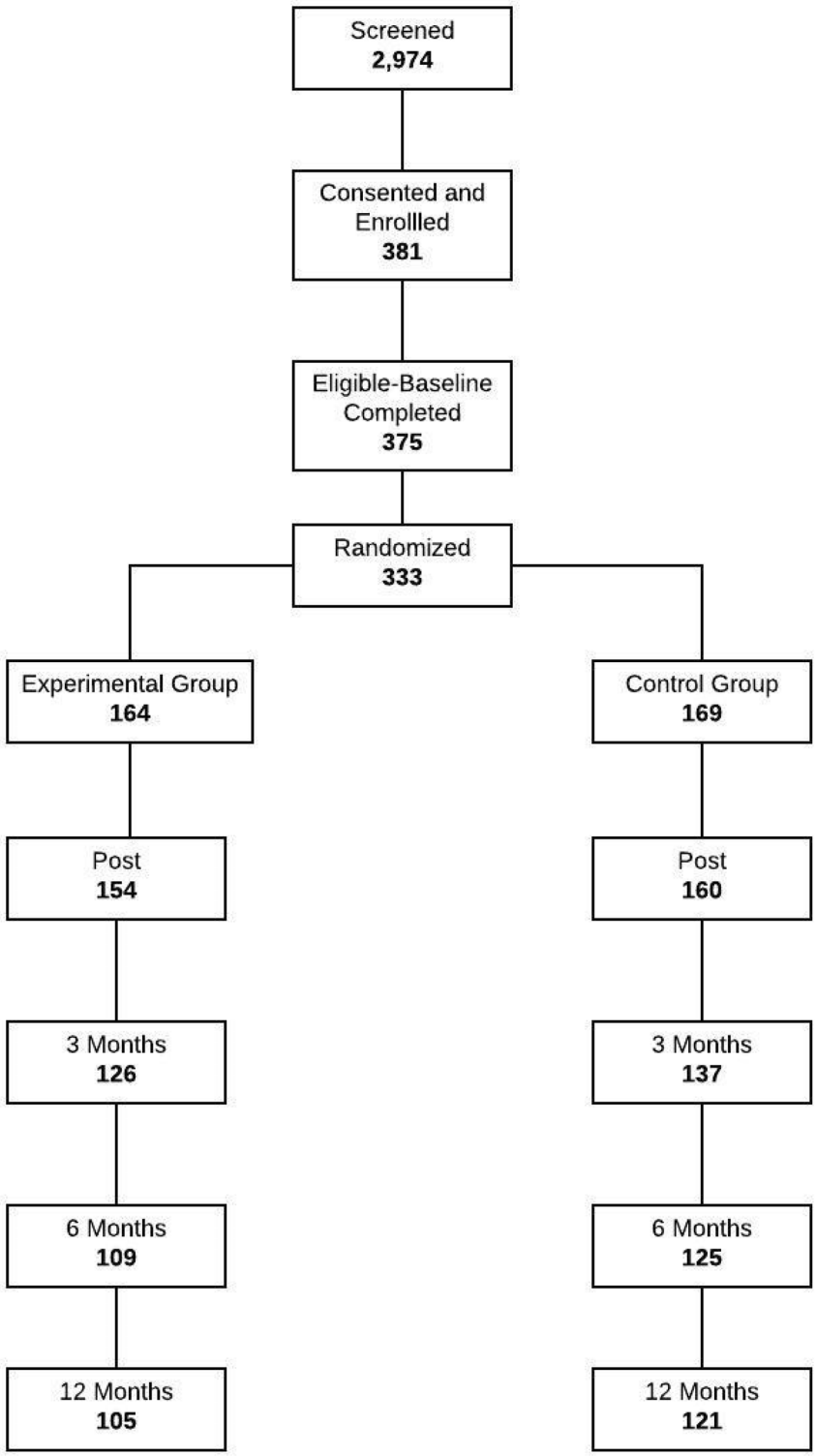

Fig. 1 Participants Flow Diagram: HHRP intervention, Miami, FL

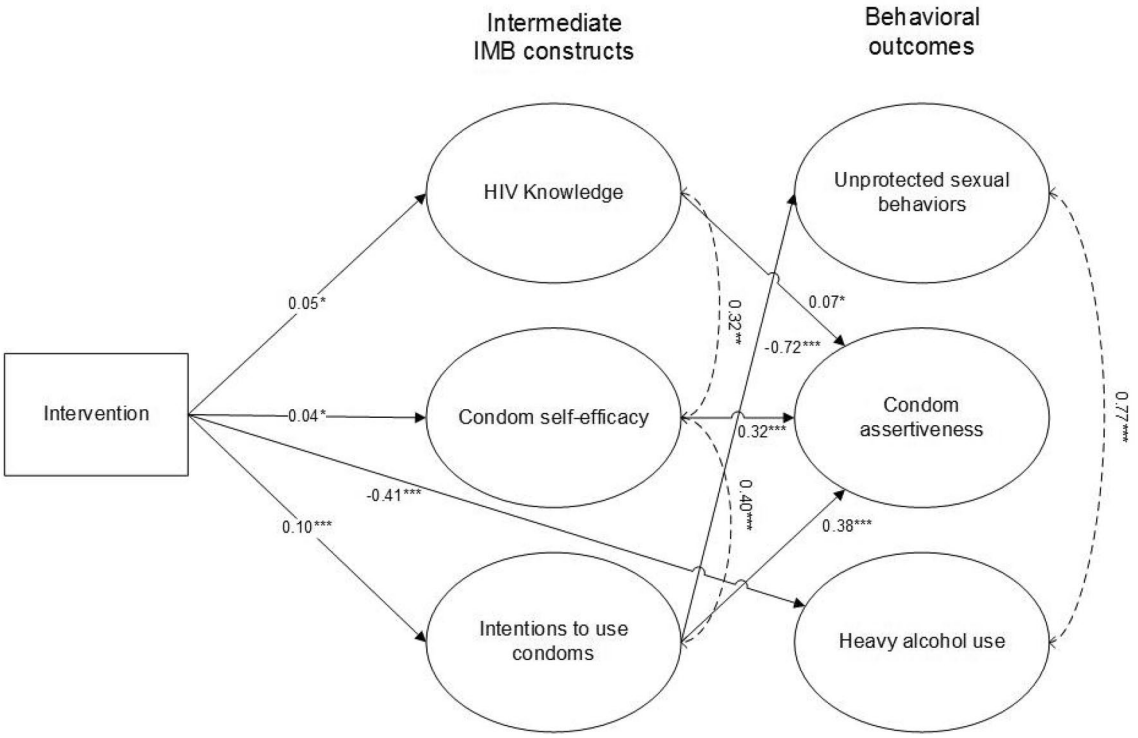

Fig. 2 Final model of exposure to HHRP intervention after dropping nonsignificant regression paths. *$p < .05$, **$p < .01$, ***$p < .001$: Miami

Conclusion

This original research examines the primary sexual risk and alcohol use behavioral outcomes of the IMB-based HHRP intervention approach for people living with HIV who abuse alcohol. It is not frequent that behavioral interventions are identified that can reduce sexual risk and heavy drinking in high-risk and hard-to-reach populations such as the one studied (Parry et al., 2017). We describe many of the elements of the intervention, including cognitive remediation strategies, to encourage future opportunities for translation in other communities.

Author Contributions Study Design: JGD, RR, MJ-G, BL, and JS. Data Analysis & Interpretation: JGD, RR, JS, AS, KV, and JA. Manuscript Writing and Revising: JGD, RR, MJ-G, KV, JA, BL, AS, and JS.

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Declarations

Conflict of interest J. G. Dévieux, R. Rosenberg, M. Jean-Gilles, K. Villalba, J. Attonito, B. Lerner, A. Saxena and J. Stein declare that they have no conflict of interest.

Human Rights and Informed Consent All procedures followed were in accordance with the ethical standards of the Review of Internal Research (IRB) at Florida International University and with the Helsinki Declaration of 1975, as revised in 2000 (5). Informed consent was obtained from all participants included in this study.

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