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Results from Project GOLD: A pilot randomized controlled trial of a psychoeducational HIV/STI prevention intervention for Black youth

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Abstract

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https://clinicaltrials.gov/ct2/show/NCT03348813?term=mental+health&recrs=e&type=Intr&cond=Hiv&titles=HIV%2FSTI+Prevention+Among+Black+Adolescents+With+Mental+Illnesses&rank=1

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Black youth face significant disparities in HIV/sexually transmitted infection (STI) disease burden—statistics among heterosexual Black youth are concerning. Mental illness and emotion regulation are documented contributors to HIV/STI risk, yet the majority of HIV/STI prevention interventions do not address these factors. Project GOLD was a pilot randomized controlled trial of a psychoeducational HIV/STI prevention intervention designed to address the role of mental illness and emotion regulation in HIV/STI risk among heterosexually-active Black youth aged 14 to 17 (N = 108). Participants were recruited from outpatient mental health treatment programs and general community settings via community partner referrals, face-to-face encounters, flyers and social media. Assessments were conducted pretest, immediate posttest, and at 3-, 6-, and 12-month follow-up. Although there were no statistically significant differences in behavior change from baseline, there were practically significant effect sizes among HIV condition participants when compared to the general health condition (e.g., increased proportion of condom use for vaginal sex at 3 months, fewer sexual partners at 6 months). An increase in theoretical mediators (e.g., condom use negotiation beliefs, pro-Black ethnic identity) was sustained at 12 months. HIV condition participants also reported lower depressive symptom severity, with statistical significance noted at immediate post and at 3 months. The findings highlight the importance and challenges of engaging Black youth in culturally and contextually relevant, developmentally and psychologically appropriate HIV/STI prevention interventions. Future work is needed to avoid unnecessary health complications in this demographic.

Keywords

Black; emotion regulation; HIV/STI; intervention; mental health

The HIV/sexually transmitted infection (STI) epidemic in the United States disproportionately affects Black youth. Compared to their White heterosexual counterparts, Black high school students are significantly more likely to initiate sexual activity before age 13 (7.5% vs. 2.1%, $p<0.01$) and have sex with four or more persons during their lives (14.8% vs. 8.6%, $p<0.01$) (Centers for Disease Control and Prevention [CDC], 2018c); this heightens their risk for HIV/STIs. While Syphilis and HIV are less prevalent than Chlamydia and Gonorrhea among heterosexual youth (CDC, 2018a; CDC, 2018b), they become more prominent in adulthood and have dire health consequences (e.g., congenital Syphilis, late AIDS diagnosis) (Tsevat et al., 2017). Moreover, antimicrobial resistance, a global concern, is making STIs more difficult to treat (Wi et al., 2017).

Areas such as Philadelphia, PA are hit particularly hard, with stark HIV disparities noted among heterosexual cases (Brawner et al, 2017; Philadelphia Department of Publich Health [PDPH], 2017a). In Philadelphia's predominantly Black public high schools, 6.1% of females and 2.4% of males tested positive for Chlamydia and/or Gonorrhea (PDPH, 2017b). One in five of the City's *total* Chlamydia cases were among females aged 15 to 19, with prevalence rates approaching 8,000 per 100,000 (PDPH, 2017b). Gonorrhea prevalence rates among males and females aged 15 to 19 exceed 1,000 per 100,000 (PDPH, 2017b). Compared to a national sample, Black youth in Philadelphia are significantly more likely to have ever drank alcohol, used drugs (e.g., synthetic marijuana), and not used condoms (CDC, 2016). Moreover, research documents alarming reports of sexual partner concurrency

(i.e., more than two in five participants reported having sex with more than one person in the same day) (Brawner et al., 2017). These are known contributors to rapid HIV/STI spread.

To contextualize these statistics—and avoid further marginalization/vilification of this key population—interactive effects across individual, social and structural domains must be acknowledged (Brawner, 2014). This includes recognizing that factors such as racism, discrimination and neighborhood disadvantage influence HIV/STI disease burden (Banks et al., 2020); multi-level interventions are needed to rectify these injustices (Auerbach, 2009; Hosek & Pettifor, 2019). While engaging in this macro-level work, racial/ethnic identity, gender role norms, mental illness and emotion regulation are readily modifiable mediators of HIV/STI risk-related sexual behaviors among Black youth. These factors influence HIV/STI risk as some youth engage in risk behaviors (e.g., condomless sex) to cope with feelings such as sadness and/or inferiority (Brawner et al., 2017; Donenberg et al., 2012; Foley et al., 2019; Lanier et al., 2017; Tull et al., 2012; Weiss et al., 2019). Targeting these mediators (e.g., bolstering pro-Black identity, regulating emotions) can reduce HIV/STI risk, yet limited interventions exist to address affective components of the sexual decision-making process.

Multisession (Salam et al., 2016; Scott-Sheldon et al., 2011) and single session (Crosby et al., 2019; Dolcini et al., 2010) interventions have effectively increased condom use, decreased the number of sexual partners and reduced incident STIs among Black youth (Goesling et al., 2014). In fact, 29 evidence-based HIV prevention interventions have been packaged for national dissemination. However, barriers to implementation (e.g., cost, time) have hindered some of these programs from achieving maximal impact, and HIV/STI incidence and prevalence rates among Black youth remain high. Further, an international systematic review highlights the paucity of HIV/STI prevention interventions that address the role of mental illness and emotion regulation in sexual risk behaviors (Salam et al., 2016). Some of the interventions that incorporate affect management have decreased sexual activity and HIV transmission myths, and increased consistent condom use and self-efficacy (Brown et al., 2014; Brown et al., 2017; Houck et al., 2018). These interventions are delivered either as family-based (Brown et al., 2014; Esposito-Smythers et al., 2017) or youth-only models (Brown et al., 2017; Houck et al., 2018). Most of these existing studies, however, include predominantly non-Black samples, have small sample sizes, or are not tailored to address key socio-structural factors that contribute to psychological distress and risk behaviors among Black youth.

To fill this gap, “Project GOLD: We are Kings and Queens” was a pilot randomized controlled trial of a psychoeducational HIV/STI prevention intervention designed to address the role of mental illness and emotion regulation in HIV/STI risk among heterosexually-active Black youth aged 14 to 17 (N=108). This paper reports results from the 12-month trial alongside research challenges to facilitate engagement of this demographic in HIV/STI prevention work. The long-term goal is to enhance culturally and contextually relevant, developmentally and psychologically appropriate sexual health promotion programs for Black youth.

Materials and Methods

Institutional Review Boards at the first author's home institution, health department and school district approved the study. Participants provided written informed consent, without the requirement of a parental permission waiver; non-affiliated youth legal experts deemed they met legal age of consent criteria for the research procedures (Brawner & Sutton, 2018). The trial ran from August 2014 to December 2016; see (Brawner et al., 2019a and Brawner et al., 2019b) for the intervention development process and study protocol. All research activities took place at the first author's institution. Due to delays and accrual difficulties, the protocol was expanded to include youth in the general community (n=58, 54%), in addition to those who were currently receiving outpatient mental health treatment (n=50, 46%).

All participants were recruited from outpatient mental health treatment programs or general community settings via community partner referrals, face-to-face encounters, flyers and social media. Those who were recruited from public areas (e.g., parks, community events) and self-reported that they were not currently receiving mental health treatment at the time of screening were labeled as general community participants in the dataset. Those who were recruited from outpatient mental health treatment programs or self-reported currently receiving mental health treatment were labeled as in treatment participants. After initial screening for preliminary eligibility, participants underwent an interviewer-administered structured clinical interview using the MINI International Neuropsychiatric Inventory (van Vliet & de Beurs, 2007) to determine mental health diagnoses and rule out exclusionary conditions (e.g., active psychosis, schizophrenia). The most frequent diagnoses were substance use disorders (15%), obsessive compulsive disorder (7%) and post-traumatic stress disorder (6%) (Opara et al., 2021).

The permuted-block randomization technique was used with a block size of 4 and a 1:1 allocation ratio. ALH (biostatistician) generated the randomization list using a pseudo-randomizer computer program. The Research Coordinator implemented the treatment allocation protocol; the investigators were blinded. To reduce the risk of encountering a floor or ceiling effect with intervention responsiveness, participants were stratified based on their Patient Health Questionnaire (PHQ-9) total scores (none/moderate depression versus moderately severe/severe depression) and gender.

Participants were randomized to either the HIV/STI prevention intervention or the general health control condition (i.e., diet, exercise). The 2-day (3 hours/day) intervention drew from psychology (Beck, 2011; Gross, 2015), developmental and behavior change theories (Azjen, 1991), and was embedded in a social determinants of health framework (Dean & Fenton, 2010). Content on emotion regulation (e.g., meditation skills) was included in both intervention conditions as it related to general life (e.g., identifying triggers) and sexual decision-making (HIV only; e.g., alternatives to using sex as a coping strategy). As a result, the intervention addresses the way one's emotions (e.g., anger, sadness) affect decisions about sex. Activities were also threaded throughout the curriculum to highlight social determinants of sexual behaviors such as financial independence and stability, navigating parental conflict and residential instability, and dealing with daily stressors such as racism. Booster sessions were not included to promote feasibility if integrated into programs with

limited resources. Facilitators underwent 16 hours of training for their respective study arms and rated activity adherence after each session; reported fidelity was 98%.

The design included pretest, immediate posttest, and 3-, 6-, and 12-month follow-up assessments. With the study's fixed end date of December 2016, many participants were only scheduled to complete the 3-month follow-up. At the baseline and follow-up assessments, participants completed a computer-assisted personal interview (CAPI) with questions on sociodemographics, sexual behaviors, and theoretical mediators of HIV/STI risk. They were also tested for HIV (oral swab), and Chlamydia and Gonorrhea (urine sample).

Past 30-day alcohol and marijuana use were measured in response to the question, "In the past 30 days, on average how many days did you use [alcohol/marijuana]"? Response options ranged from 1 (never) to 10 (5 or more times per day). Attitudes toward condom use (e.g., condom use hedonistic beliefs) were measured using validated scales from our previous research and included 5-point Likert response options ranging from 1 (strongly disagree) to 5 (strongly agree) (Ordinal Cronbach's $\alpha = 0.54$ to 0.90); all reported Cronbach's α are from this study's sample. The Children's Emotion Management Scale (CEMS)(Zeman et al., 2001) was used to assess self-reported sadness and anger management on a 3-point Likert scale of 1 (hardly ever) to 3 (often). The instrument includes subscales of inhibition, dysregulation and coping, with higher values indicating more of each construct (ordinal Cronbach's $\alpha = 0.63$-0.87). Ethnic identity was assessed using the revised Adolescent Survey of Black Life (ASBL)(Resnicow et al., 1999) which measures: 1) attitudes about being Black, 2) attitudes toward Whites, and 3) perceptions of racism. Items were scored on a 4-point Likert scale ranging from 1 (agree a lot) to 4 (disagree a lot). Higher values indicate higher levels of the construct (ordinal Cronbach's $\alpha = 0.68$-0.91). Gender role norms were measured using The Attitudes Toward Women Scale for Adolescents (ATWSA) (Galambos et al., 1985). Responses are rated on a 4-point Likert scale, 1 (strongly disagree) to 4 (strongly agree), to assess participants' attitudes of adolescents toward gender roles (e.g. women's rights and roles compared to men's; ordinal Cronbach's $\alpha = 0.81$). HIV/STI knowledge was measured using true/false items with myths and facts about HIV/STI transmission (e.g., "using Vaseline as a lubricant when having sex lowers the chance of getting STIs and HIV/AIDS"); higher scores indicate more HIV/STI knowledge (Cronbach's $\alpha = 0.82$) (Koniak-Griffin & Brecht, 1995). The PHQ-9, a depression screening tool (Kroenke et al., 2001), was used to assess depressive symptom severity. Items were rated from 0 (not at all) to 3 (nearly every day), with higher scores reflecting greater symptom severity (ordinal Cronbach's $\alpha = 0.82$).

The primary outcome was proportion of condom use for vaginal sex; the secondary outcome was number of sexual partners. Both the primary and secondary outcomes were measured as past 3 months self-reported behavior. Given high reports of sexual partner concurrency, we estimated the effect of the intervention on whether participants had sex with more than one person in the same day, month or while already in a sexual relationship. Effects on theoretical mediators (e.g., condom use beliefs) were also estimated. The number of positive HIV/STI cases was too small to include in effect estimations.

For the analyses, descriptive statistics were used to characterize the study variables at each time point, and their changes from baseline by intervention condition. Since all continuous variables were not normally distributed, non-parametric exact Wilcoxon rank-sum tests were used to examine differences in rank sum scores across the two conditions. Comparisons of categorical variables relied on Fisher's exact tests. We hypothesized that compared to the general health group, participants in the HIV intervention group would have an increased proportion of condom use for vaginal sex, fewer sexual partners and an increase in mediators purported to reduce sexual risk behaviors (e.g., condom use negotiation beliefs). As this was a small pilot study, the focus was on estimation of effect and not formal hypothesis testing. Effect sizes were based on $\eta 2$ (eta-squared) for continuous variables (small [0.01], medium [0.06], and large [>0.14]) and Cramer's V for categorical variables (small [0.10-0.29], medium [0.30-0.50], and large [>0.50]). Statistical significance was taken at the 0.05 level, and did not adjust for multiplicity given the pilot nature of this study. Reporting effect sizes to supplement p-values is recommended in intervention research due to potential differences between statistical and practical significance (Sun et al., 2010). All analyses were performed using SAS, version 9.4 (SAS Institute Inc., Cary, NC). Pairwise deletion (available-case analysis) was used to handle missing data.

The original intent was to examine change in the study outcomes from baseline to 12 months. However, with the study delays and fixed end date, the majority of participants could only be scheduled for the 3-month follow-up. For post-hoc power analysis, the primary research comparison was change from baseline to 3 months in proportion of condom use for vaginal sex (primary outcome) across the HIV intervention and general health groups. Observed mean changes in proportion of condom use for vaginal sex for the two groups were 0.21 (HIV intervention) versus −0.02 (general health). For group sample sizes of 16 and 13 with complete data for the primary outcome at both timepoints, respectively, this study had 9% power to detect a mean difference of 0.23 in changes in proportion of condom use at 3 months using a two-sided, Wilcoxon rank-sum test and a type 1 error rate (alpha) of 0.05. Of note, the actual comparison did not demonstrate a statistically significant difference, with p=0.20.

Results

See Figure 1 for the Consolidated Standards of Reporting Trials (CONSORT) diagram. Most (89%) of those eligible to participate enrolled in the study; 45 participants were lost to follow-up after screening. After randomization, one participant did not receive the intervention and was connected to care in accordance with the study's suicide risk assessment protocol for suicidality at the baseline visit. Completion (attendance both intervention days) was approximately 90% in both conditions, with no statistically significant differences between conditions. Attrition across the follow-up periods ranged from 17%-42%. Tables 1, 2 and 3 detail the reasons for missing data at each time point and sample characteristics according to dropout status. Those who dropped out were slightly younger (M=15.5 vs. 16, p=0.0052; see Table 3). The predominant causes were lost to follow-up, placement in residential treatment, incarceration and withdrawal. Of the three withdrawn participants, two were at the request of participants, and one was a parent request. Sadly, one participant died from unrelated gun violence.

At baseline, participants were 15.78 years old (SD=0.97), mostly male (62%), used condoms 66% of the time for vaginal sex (SD=0.40) and had 3 sexual partners in the past 3 months (SD=3.79). Compared to HIV participants (see Table 4), general health participants had statistically significantly more: sexual partners in the past 3 months (Median=2 vs. 1, p=0.04, η^2=0.04), same month sexual partner concurrency (57% vs. 35%, p=0.02, Cramer's V=0.23) and past 30-day alcohol use (Median=2 [1 to 3 times last month] vs. 1 [never], p=0.01, η^2=0.13). These participants also reported a practically significant difference in past 30-day marijuana use (Median=3 [1 to 2 times per week] vs. Median=2 [1 to 3 times last month], p=0.15, η^2=0.04).

Means are reported below for readability; however, the non-parametric analyses were based on comparisons of the medians. There were no statistically significant differences observed in behavior change from baseline. However, there were multiple variables with practically significant effect sizes (see Table 5). At 3 months, compared to general health participants, HIV participants had an increased proportion of condom use for vaginal sex (77% vs. 64%, Mean change [M_Δ]=0.21 vs. −0.02, p=0.20, η^2=0.06). At 6 months, HIV participants had fewer sexual partners (M=1 vs. 1.67, M_Δ= −0.54 vs. −0.57, p=0.24, η^2=0.05), less same day sexual partner concurrency (6% vs. 33%, p=0.08, V=0.41) and increased anger coping (M=2.47 vs. 2.24, M_Δ= 0.28 vs. 0.06, p=0.15, η^2=0.06). An increase in several mediators was sustained at 12 months among HIV participants including condom use prevention beliefs (M=4.55 vs. 4.28, M_Δ=0.61 vs. 0, p=0.36, η^2=0.04), condom use negotiation beliefs (M=4.55 vs. 4.22, M_Δ= 0 vs. −0.04, p=0.32, η^2=0.05), condom use self-efficacy (M=4.40 vs. 4.15, M_Δ= 0.11 vs. 0.02, p=0.22, η^2=0.07), pro-Black ethnic identity (M=3.55 vs. 3.46, M_Δ= 0.14 vs. 0.23, p=0.69, η^2=0.01) and HIV/STI knowledge (M=0.77 vs. 0.70, M_Δ= 0.06 vs. 0.09, p=0.35, η^2=0.04). HIV participants also reported lower depressive symptom severity, with statistical significance noted from baseline at immediate post (M=2.19 vs. 2.80, M_Δ= −1.06 vs. 0.10, p=0.01, η^2=0.07) and 3 months (M=2.82 vs. 4.24, M_Δ= −0.37 vs. 1.42, p=0.048, η^2=0.06). Participants in both conditions also experienced a practically significant decrease in past 30-day alcohol and marijuana use.

Discussion

Despite the well-documented role of mental illness and emotion regulation in youth risk behaviors, a paucity of HIV/STI prevention interventions incorporate these factors. Project GOLD was designed to address this gap, merging advances in HIV/STI prevention science with evidence-based psychological practices (e.g., emotional expression). Reporting of clinical trial results—including null effects—is key to research rigor, and these findings advance the science. While the small pilot was not powered to demonstrate a *statistically* significant effect on condom use or number of sexual partners, there were *practically* significant changes worth noting. Compared to general health participants, HIV participants reported 13% more condom use for vaginal sex at 3 months, fewer sexual partners and 27% less same day sexual partner concurrency at 6 months, and an increase in key mediators of sexual behaviors (e.g., condom use negotiation beliefs, pro-Black ethnic identity) that was sustained at 12 months. These clinically meaningful signals of the intervention's utility are comparable to findings from previous HIV prevention interventions that showed similar changes (Dolcini et al., 2010; Houck et al., 2018; Scott-Sheldon et al., 2011). Further, the

findings give insight into attitudes, psychological symptoms and behaviors over time, which can be used to promote sexual health among Black youth.

It is critical that behavioral HIV/STI prevention interventions are prioritized for heterosexually-active Black youth, delivered in a culturally and contextually congruent manner and include modules on the role of mood and emotion regulation in safer sexual behaviors. A group behavioral intervention targeted emotion regulation and demonstrated delayed vaginal intercourse and increased condom use, with a sustained effect 2.5 years post-intervention (Houck et al., 2018). This emphasizes the importance and potential impact of such work. Technological advances can also be leveraged to meet youth where they are, factoring in novel experiences through simulation and social media. As an example, researchers have demonstrated preliminary feasibility, acceptability and impact on enhancing emotion regulation in risky situations by pairing immersive virtual reality environments with an emotion regulation and risk reduction intervention (Hadley et al., 2018). Others have also noted the relevance of social media in delivering sexual health messages, promoting the use of online platforms to mitigate risk behaviors (Stevens et al., 2017; Stevens et al., 2020).

Regarding challenges, although the research team gathered extensive contact information from participants, the majority of those lost to follow up had unstable contact information and could not be located. This alongside the case of suicidality, number of participants incarcerated and placed in residential treatment, and the victim of gun violence speak to the high psychiatric acuity and adversities faced by the study population. Moreover, those who completed the intervention faced difficulties with work schedules, childcare (for their own children and/or those of relatives) and transportation. The partnering mental health treatment programs also struggled to engage Black youth in care. Altogether, this hindered potential enrollment, further reducing the already small sample size, but more importantly, amplifies systemic issues faced by Black youth. As others work with this demographic, it will be important to consider these factors and strategize ways to better meet their needs. Such research should be a public health priority for Black youth given that: 1) Black females aged 15 to 19 have the highest risk of repeat Chlamydial infections (44%) compared to women of other ages and racial/ethnic groups (Cha et al., 2019), and 2) factors such as depressive symptoms have been documented to affect condom use self-efficacy, condomless sex and number of sexual partners over time (Foley et al., 2019).

The study limitations must be acknowledged. The sample was small, the fixed end date meant fewer participants completed the 6- and 12-month follow-ups, and there was considerable attrition. This reduced power for the behavioral outcomes, limited detection of effects and increases uncertainty in the findings. The outcomes were self-reported and thus susceptible to bias; participants did undergo HIV/STI testing but there were too few cases to include in the analyses. The intent was to test an intervention for youth experiencing mental illness and emotion regulation, yet depressive symptoms were low in the sample—PHQ-9 scores less than four indicate minimal depression. However, depressive symptoms were only one of many symptoms participants experienced (e.g., anxiety) and they reported difficulties regulating anger and sadness, thus the overall objective was still achieved. Given that the intervention demonstrated practically significant findings that are comparable to previous

results of successful HIV prevention interventions, it should be tested in a fully powered trial for final determinations. The results contribute to the literature, highlighting a novel intervention that was successfully implemented with a group at increased risk for HIV/STIs.

Comprehensive behavioral interventions that include nontraditional targets (e.g., emotion regulation) may decrease HIV/STI risk and help Black youth address mediating factors (e.g., psychological distress) that affect their health. Project GOLD was developed to advance the science in this area, and requires subsequent evaluation in a larger sample. Given the severity of HIV/STIs, strategies are needed now more than ever to engage Black youth in sexual health promotion to prevent future complications.

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Data Availability Statement:

The data that support the findings of this study are available on request from the corresponding author, BMB. The data are not publicly available due to information that could compromise the privacy of research participants.

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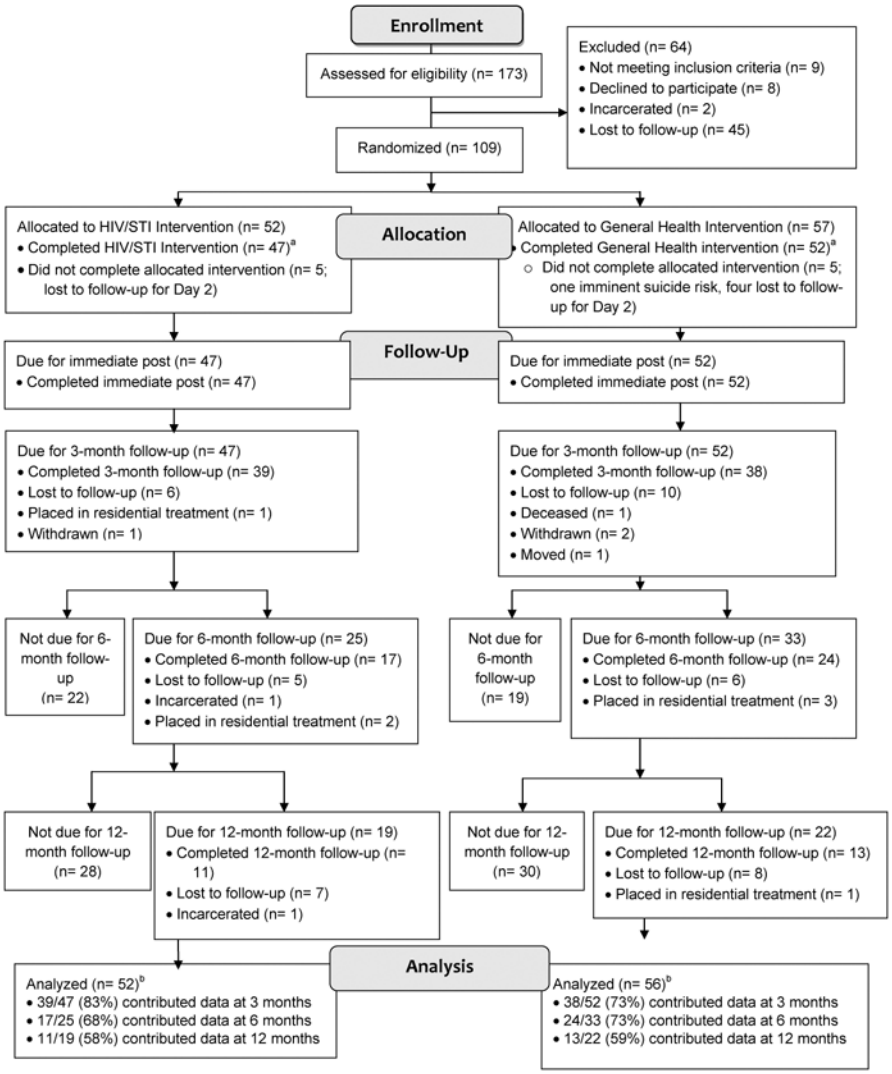

Figure 1.

Consolidated Standards of Reporting Trials (CONSORT) diagram. [a]Completion was defined as attending intervention Day 1 and Day 2. [b]The study's fixed end date was December 2016 thus all participants who completed the intervention were due to complete the immediate post and 3-month follow-ups; however, not all participants were due for the 6- and 12-month follow-ups. Numbers reflect those who were due to (denominator) and actually (numerator) completed their assigned follow-ups.

Table 1.

Descriptive Statistics on Reasons for Missing Data at Each Time Point for Proportion of Condom Use for Vaginal Sex and Number of Sexual Partners (HIV condition).

Reason	**Time Point**				
	Baseline	***3-Month FU***	***6-Month FU***	***12-Month FU***	***Total***
Proportion of Condom use for Vaginal Sex					
n					
%					
Row %					
Column %					
Had complete information	30	21	9	5	65
	25.42	17.80	7.63	4.24	55.08
	46.15	32.31	13.85	7.69	
	57.69	55.26	52.94	45.45	
Incomplete data for # times had vaginal sex and used condoms	14	7	3	2	26
	11.86	5.93	2.54	1.69	22.03
	53.85	26.92	11.54	7.69	
	26.92	18.42	17.65	18.18	
Not sexually active	4	3	2	1	10
	3.39	2.54	1.69	0.85	8.47
	40.00	30.00	20.00	10.00	
	7.69	7.89	11.76	9.09	
Reported more # times used condoms than # times had vaginal sex	3	3	0	1	7
	2.54	2.54	0.00	0.85	5.93
	42.86	42.86	0.00	14.29	
	5.77	7.89	0.00	9.09	
Sexually active but provided zeroes for # times had sex and # times used condoms	0	4	3	2	9
	0.00	3.39	2.54	1.69	7.63
	0.00	44.44	33.33	22.22	
	0.00	10.53	17.65	18.18	

Reason	Time Point				
	Baseline	***3-Month FU***	***6-Month FU***	***12-Month FU***	***Total***
Unable to calculate: Zero in denominator	1	0	0	0	1
	0.85	0.00	0.00	0.00	0.85
	100.00	0.00	0.00	0.00	
	1.92	0.00	0.00	0.00	
Total	52	38	17	11	118
	44.07	32.20	14.41	9.32	100.00
Number of Sexual Partners					
Did not provide information for # of partners	5	3	2	0	10
	4.24	2.54	1.69	0.00	8.47
	50.00	30.00	20.00	0.00	
	9.62	7.89	11.76	0.00	
Had complete information	46	34	13	11	104
	38.98	28.81	11.02	9.32	88.14
	44.23	32.69	12.50	10.58	
	88.46	89.47	76.47	100.00	
Not sexually active	1	1	2	0	4
	0.85	0.85	1.69	0.00	3.39
	25.00	25.00	50.00	0.00	
	1.92	2.63	11.76	0.00	
Total	52	38	17	11	118
	44.07	32.20	14.41	9.32	100.00

Table 2.

Descriptive Statistics on Reasons for Missing Data at Each Time Point for Proportion of Condom Use for Vaginal Sex and Number of Sexual Partners (General Health condition).

Reason	**Time Point**				
	Baseline	***3-Month FU***	***6-Month FU***	***12-Month FU***	***Total***
Proportion of Condom use for Vaginal Sex					
n					
%					
Row %					
Column %					
Had complete information	36	20	12	9	77
	29.03	16.13	9.68	7.26	62.10
	46.75	25.97	15.58	11.69	
	64.29	60.61	54.55	69.23	
Incomplete data for # times had vaginal sex and used condoms	10	10	7	3	30
	8.06	8.06	5.65	2.42	24.19
	33.33	33.33	23.33	10.00	
	17.86	30.30	31.82	23.08	
Not sexually active	1	1	1	0	3
	0.81	0.81	0.81	0.00	2.42
	33.33	33.33	33.33	0.00	
	1.79	3.03	4.55	0.00	
Reported more # times used condoms than # times had vaginal sex	5	1	0	1	7
	4.03	0.81	0.00	0.81	5.65
	71.43	14.29	0.00	14.29	
	8.93	3.03	0.00	7.69	
Sexually active but provided zeroes for # times had sex and # times used condoms	3	1	2	0	6
	2.42	0.81	1.61	0.00	4.84
	50.00	16.67	33.33	0.00	
	5.36	3.03	9.09	0.00	

Reason	Time Point				
	Baseline	***3-Month FU***	***6-Month FU***	***12-Month FU***	***Total***
Unable to calculate: Zero in denominator	1	0	0	0	1
	0.81	0.00	0.00	0.00	0.81
	100.00	0.00	0.00	0.00	
	1.79	0.00	0.00	0.00	
Total	56	33	22	13	124
	45.16	26.61	17.74	10.48	100.00
Number of Sexual Partners					
n					
%					
Row %					
Column %					
Did not provide information for # of partners	4	7	6	2	19
	3.23	5.65	4.84	1.61	15.32
	21.05	36.84	31.58	10.53	
	7.14	21.21	27.27	15.38	
Had complete information	51	24	15	11	101
	41.13	19.35	12.10	8.87	81.45
	50.50	23.76	14.85	10.89	
	91.07	72.73	68.18	84.62	
Not sexually active	1	2	1	0	4
	0.81	1.61	0.81	0.00	3.23
	25.00	50.00	25.00	0.00	
	1.79	6.06	4.55	0.00	
Total	56	33	22	13	124
	45.16	26.61	17.74	10.48	100.00

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Table 3.

Baseline sample characteristics according to dropout status (N = 108)

Characteristic	Overall Sample (N = 108)	Dropout Status		P-value[1]	Effect Size[2]
		Dropped (N = 46)	Retained (N = 62)		
Intervention Condition [n (%)]				0.6548	0.04
HIV	52 (48.2%)	21 (45.7%)	31 (50.0%)		
GH	56 (51.8%)	25 (54.3%)	31 (50.0%)		
Age [Mean (SD)]	15.78 (0.97)	15.48 (0.96)	16.00 (0.92)	0.0052	0.56
Gender [n (%)]				0.3233	0.10
Male	67 (62.0%)	31 (67.4%)	36 (58.1%)		
Female	41 (38.0%)	15 (32.6%)	26 (41.9%)		
Living Status [n (%)]				0.3578	0.21
In a house that my parent/guardian owns	50 (46.3%)	21 (45.6%)	29 (46.8%)		
In a house that my parent/guardian rents	44 (40.7%)	17 (36.0%)	27 (43.6%)		
In an apartment that my parent/guardian rents	8 (7.4%)	5 (10.9%)	3 (4.8%)		
In a shelter	2 (1.9%)	0 (0.0%)	2 (3.2%)		
Other	4 (3.7%)	3 (6.5%)	1 (1.6%)		
Proportion of Condom Use for Vaginal Sex [Median (Q1, Q3)] *(n=66)*	1.0 (0.3, 1)	0.92 (0.5, 1)	1.0 (0.28, 1)	0.8538	0.001
Number of Sexual Partners in the Past 3 Months [Median (Q1, Q3)] *(n=97)*	1.0 (1, 3)	2.0 (1, 3)	1.0 (1, 2)	0.4677	0.01

Note: SD=standard deviation; Q1=lower quartile; Q3=upper quartile.

[1]P-values based on two-sample t-tests or Wilcoxon rank-sum tests for continuous variables, as appropriate; Fisher's exact tests was used for categorical variables with cells containing less than 5 participants, and chi-square tests for all other categorical variables.

[2]Effect sizes based on Cohen's d for age (small: 0.20, medium: 0.50, large: 0.80) or η^2 (eta-squared) for proportion of condom use and number of sexual partners (small: 0.01, medium: 0.06, large: >0.14); Cramer's V (weak: 0.10-0.30, medium: 0.40-0.50, large: >0.50) was used for all categorical variables (intervention condition, gender, living status).

Table 4.

Descriptive Statistics for Primary and Secondary Outcomes at Each Time Point by Intervention Condition.

	HIV Intervention (N=52)		General Health (N=56)			
	n	Mean (SD) or % Median (IQR)	n	Mean (SD) or % Median (IQR)	P-value[1]	Effect Size[2]
Proportion of Condom Use for Vaginal Sex in the Past 3 Months						
Baseline	30	0.64 (0.42) 0.92 (0.20, 1)	36	0.67 (0.39) 1 (0.42, 1)	0.7689	0.001
3 Months	21	0.77 (0.37) 1 (0.50, 1)	20	0.64 (0.38) 0.67 (0.33, 1)	0.2138	0.04
6 Months	9	0.58 (0.43) 0.60 (0.26, 1)	12	0.72 (0.35) 0.90 (0.45, 1)	0.4926	0.02
12 Months	5	0.73 (0.44) 1 (0.66, 1)	9	0.91 (0.19) 1 (1, 1)	0.3407	0.04
Number of Sexual Partners in the Past 3 Months						
Baseline	46	2.00 (2.49) 1 (1, 2)	51	2.88 (3.27) 2 (1, 3)	0.0381	0.04
3 Months	34	1.79 (3.00) 1 (1, 1)	24	4.17 (10.39) 1 (1, 3)	0.0561	0.06
6 Months	13	1.00 (0.71) 1 (1, 1)	15	1.67 (1.40) 1 (1, 2)	0.2392	0.05
12 Months	11	1.36 (0.92) 1 (1, 2)	11	1.91 (1.22) 2 (1, 2)	0.3912	0.04
Sex with More than One Person in the Same Day						
Baseline	52	Yes 25% No 75%	54	Yes 29.6% No 70.4%	0.6657	0.05
3 Months	38	Yes 16% No 84%	31	Yes 26% No 74%	0.3733	0.12
6 Months	17	Yes 6% No 94%%	18	Yes 33.3% No 66.7%	0.0877	0.34
12 Months	11	Yes 27.3% No 72.7%%	12	Yes 33.3% No 66.7%	>0.999	0.07
Sex with More than One Person in the Same Month						
Baseline	52	Yes 34.6% No 65.4%	54	Yes 57.4% No 42.6%	0.0209	0.23
3 Months	38	Yes 39.5% No 60.5%	31	Yes 54.5% No 45.2%	0.2324	0.15

	HIV Intervention (N=52)		General Health (N=56)			
	n	Mean (SD) or % Median (IQR)	n	Mean (SD) or % Median (IQR)	P-value[1]	Effect Size[2]
6 Months	17	Yes 47.1% No 52.9%	18	Yes 50% No 50%	>0.9999	0.03
12 Months	11	Yes 36.4% No 63.6%	12	Yes 66.7% No 33.3%	0.2203	0.30
Sex While Already in a Sexual Relationship with Someone Else						
Baseline	51	Yes 27.5% No 72.5%	54	Yes 42.6% No 57.4%	0.1521	0.16
3 Months	38	Yes 18.4% No 81.6%	31	Yes 38.7% No 61.3%	0.1028	0.23
6 Months	17	Yes 29.4% No 70.6%	18	Yes 38.9% No 61.1%	0.7247	0.10
12 Months	11	Yes 27.3% No 72.7%	12	Yes 41.7% No 58.3%	0.6668	0.15
Alcohol Use in the Past 30 Days						
Baseline	27	1.26 (0.45) 1.00 (1, 2)	26	2.19 (1.81) 2.0 (1, 2)	0.0104	0.13
3 Months	13	1.15 (0.38) 1.0 (1, 1)	12	1.50 (0.90) 1.0 (1, 2)	0.3056	0.05
6 Months	6	1.50 (0.55) 1.5 (1, 2)	9	1.44 (0.53) 1.0 (1, 2)	>.9999	0.001
12 Months	5	1.40 (0.55) 1.0 (1, 2)	7	1.57 (0.53) 2.0 (1, 2)	>.9999	0.02
Marijuana Use in the Past 30 Days						
Baseline	29	3.31 (2.73) 2 (1, 6)	29	4.31 (3.11) 3 (2, 6)	0.1545	0.04
3 Months	14	4.29 (3.07) 3 (2, 7)	17	3.65 (3.08) 3 (1, 5)	0.5966	0.01
6 Months	8	2.38 (2.0) 2 (1, 2.5)	11	4.45 (2.91) 4 (2, 7)	0.0824	0.16
12 Months	7	3 (2.65) 2 (1, 5)	6	6.17 (3.37) 5.5 (4, 10)	0.0822	0.23
Condom Use Prevention Beliefs						
Baseline	51	4.08 (1.12) 4.33 (3.67, 5)	56	4.30 (0.79) 4.33 (4, 5)	0.4540	0.01
Immediate Post	47	4.26 (0.86) 4.33 (4, 5)	48	4.17 (0.93) 4.5 (3.67, 5)	0.7109	0.001

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	HIV Intervention (N=52)		General Health (N=56)			
	n	Mean (SD) or % Median (IQR)	n	Mean (SD) or % Median (IQR)	P-value[1]	Effect Size[2]
3 Months	38	4.30 (0.74) 4.33 (4, 5)	33	4.26 (0.74) 4.33 (3.67, 5)	0.7911	0.001
6 Months	17	4.45 (0.56) 4.67 (4, 5)	19	4.23 (0.59) 4 (4, 5)	0.2940	0.03
12 Months	11	4.55 (0.58) 5 (4, 5)	12	4.28 (0.75) 4.50 (3.5, 5)	0.3081	0.04
Condom Use Attitude						
Baseline	50	4.24 (0.72) 4.50 (3.67, 4.67)	56	4.11 (0.65) 4.33 (3.67, 4.67)	0.1939	0.02
Immediate Post	44	4.22 (0.81) 4.33 (4.0, 4.67)	46	3.91 (0.83) 4.0 (3, 4.67)	0.0459	0.04
3 Months	38	4.25 (0.73) 4.33 (3.67, 5)	32	3.95 (0.78) 4 (3.33, 4.5)	0.0846	0.04
6 Months	17	4.08 (0.99) 4.33 (3.67, 5)	19	3.95 (0.87) 4 (3, 5)	0.5434	0.01
12 Months	11	4.03 (0.99) 4.33 (3, 5)	10	4.20 (0.80) 4.33 (3.3, 5)	0.7544	0.005
Condom Use Availability						
Baseline	51	4.17 (0.61) 4.0 (3.75, 4.75)	55	4.14 (0.54) 4 (3.75, 4.5)	0.6917	0.001
Immediate Post	46	4.20 (0.71) 4.25 (4.0, 4.75)	46	3.90 (0.60) 4.0 (3.5, 4)	0.0096	0.07
3 Months	37	4.19 (0.52) 4.0 (4, 4.5)	31	3.98 (0.65) 4 (3.5, 4.5)	0.0857	0.04
6 Months	17	4.35 (0.55) 4.25 (4, 5)	18	4.21 (0.47) 4 (4, 4.5)	0.3050	0.03
12 Months	11	4.41 (0.59) 4.75 (4, 4.75)	10	4.08 (0.50) 4 (4, 4.25)	0.0903	0.13
Condom Use Hedonistic Beliefs						
Baseline	49	2.59 (0.31) 2.67 (2.33, 2.83)	53	2.61 (0.35) 2.67 (2.5, 2.83)	0.6089	0.003
Immediate Post	44	2.74 (0.31) 2.83 (2.5, 3)	45	2.72 (0.34) 2.67 (2.5, 3)	0.9817	0.0
3 Months	35	2.68 (0.36) 2.67 (2.5, 3)	31	2.68 (0.32) 2.67 (2.5, 3)	0.8882	0.0
6 Months	17	2.65 (0.37) 2.83 (2.33, 2.83)	19	2.69 (0.34) 2.83 (2.33, 3)	0.7046	0.004

	HIV Intervention (N=52)		General Health (N=56)			
	n	Mean (SD) or % Median (IQR)	n	Mean (SD) or % Median (IQR)	P-value[1]	Effect Size[2]
12 Months	11	2.64 (0.43) 2.67 (2.33, 3)	9	2.85 (0.21) 2.83 (2.67, 3)	0.3134	0.05
Condom Use Impulsivity						
Baseline	50	2.15 (0.99) 2 (1.33, 2.67)	54	2.12 (0.98) 2.0 (1.33, 2.67)	0.8199	0.0
Immediate Post	45	1.93 (0.74) 2 (1.33, 2)	46	2.21 (0.90) 2.0 (1.67, 3)	0.1133	0.03
3 Months	38	1.86 (0.74) 2 (1, 2.33)	32	2.30 (0.99) 2.33 (1.67, 3)	0.0420	0.06
6 Months	17	1.88 (0.81) 2 (1, 2.67)	19	2.16 (1.01) 2.0 (1, 3)	0.5350	0.01
12 Months	11	1.85 (0.91) 1.67 (1, 3)	10	1.77 (0.74) 2.0 (1, 2)	0.8878	0.001
Condom Use Negotiation Beliefs						
Baseline	48	4.24 (0.70) 4.2 (4, 4.8)	55	4.28 (0.63) 4.40 (4, 5)	0.8192	0.001
Immediate Post	44	4.22 (0.66) 4.20 (4, 4.8)	45	4.12 (0.85) 4.20 (3.8, 5)	0.8370	0.0
3 Months	36	4.41 (0.69) 4.70 (4, 5)	32	4.04 (0.67) 4 (3.6, 4.8)	0.0124	0.09
6 Months	17	4.45 (0.58) 4.60 (4, 5)	18	4.18 (0.71) 4 (3.8, 5)	0.2911	0.03
12 Months	11	4.55 (0.54) 4.80 (4, 5)	10	4.22 (0.74) 4 (3.8, 5)	0.3714	0.04
Condom Use Self-efficacy						
Baseline	47	4.14 (0.61) 4 (3.83, 4.67)	51	4.15 (0.46) 4.17 (3.83, 4.5)	0.9347	0.0
Immediate Post	44	4.16 (0.59) 4.17 (3.92, 4.54)	43	4.0 (0.65) 4 (3.67, 4.58)	0.2302	0.02
3 Months	37	4.26 (0.56) 4.25 (4, 4.67)	31	3.95 (0.57) 3.83 (3.5, 4.5)	0.0106	0.10
6 Months	17	4.33 (0.51) 4.42 (4, 4.75)	18	4.12 (0.64) 4.04 (3.83, 4.67)	0.3536	0.03
12 Months	11	4.40 (0.55) 4.33 (3.83, 4.92)	10	4.15 (0.61) 4.0 (3.75, 4.67)	0.4354	0.03
Condom Use Subjective Norm						

	HIV Intervention (N=52)		General Health (N=56)			
	n	Mean (SD) or % Median (IQR)	n	Mean (SD) or % Median (IQR)	P-value[1]	Effect Size[2]
Baseline	51	4.24 (0.78) 4 (4, 5)	56	4.28 (0.69) 4.25 (4, 5)	0.9507	0.0
Immediate Post	44	4.25 (0.95) 4.5 (4, 5)	47	4.12 (0.92) 4.5 (3, 5)	0.4099	0.01
3 Months	38	4.5 (0.62) 4.75 (4, 5)	32	4.08 (0.77) 4 (3.5, 5)	0.0202	0.08
6 Months	17	4.41 (0.59) 4.5 (4, 5)	19	4.16 (0.82) 4 (3.5, 5)	0.3730	0.02
12 Months	11	4.32 (0.78) 4.5 (4, 5)	11	4.36 (0.90) 5 (3, 5)	0.7770	0.004
Condom Use Technical Skills						
Baseline	47	3.99 (0.80) 4 (3.5, 4.5)	53	4.08 (0.63) 4 (4, 4.5)	0.6003	0.003
Immediate Post	44	4.02 (0.67) 4.0 (3.75, 4.5)	45	3.88 (0.95) 4 (3.5, 4.5)	0.6037	0.003
3 Months	38	4.22 (0.80) 4 (4, 5)	32	3.92 (0.72) 4 (3.5, 4.5)	0.0612	0.05
6 Months	17	4.24 (0.71) 4 (4, 5)	18	4.14 (0.76) 4 (4, 5)	0.7801	0.002
12 Months	11	4.27 (0.75) 4 (3.5, 5)	10	4.10 (0.88) 4 (3, 5)	0.6818	0.01
Condom Knowledge						
Baseline	50	0.67 (0.28) 0.80 (0.6, 0.8)	55	0.69 (0.27) 0.8 (0.6, 1.0)	0.7513	0.001
Immediate Post	-	-	-	-	-	-
3 Months	-	-	-	-	-	-
6 Months	17	0.84 (0.20) 0.8 (0.8, 1.0)	18	0.79 (0.23) 0.8 (0.6, 1.0)	0.5715	0.01
12 Months	11	0.84 (0.25) 1 (0.6, 1.0)	12	0.75 (0.32) 0.8 (0.8, 1.0)	0.3368	0.04
Anger Inhibition Scale						
Baseline	51	2.03 (0.53) 2 (1.75, 2.5)	56	1.91 (0.51) 1.88 (1.50, 2.25)	0.1996	0.02
Immediate Post	45	2.09 (0.51) 2 (1.75, 2.5)	49	1.99 (0.52) 2 (1.75, 2.5)	0.3937	0.01

	HIV Intervention (N=52)		General Health (N=56)			
	n	Mean (SD) or % Median (IQR)	n	Mean (SD) or % Median (IQR)	P-value[1]	Effect Size[2]
3 Months	38	2.09 (0.55) 2 (1.75, 2.5)	33	1.92 (0.61) 2 (1.5, 2.5)	0.2727	0.02
6 Months	17	2.22 (0.5) 2.25 (2, 2.5)	20	1.95 (0.51) 2 (1.75, 2.13)	0.0917	0.08
12 Months	11	2.0 (0.69) 2 (1.5, 2.5)	12	2.0 (0.37) 2 (1.75, 2.25)	0.9750	0.0
Anger Dysregulation Scale						
Baseline	51	1.76 (0.62) 1.67 (1.33, 2.33)	56	1.70 (0.51) 1.67 (1.33, 2)	0.7037	0.001
Immediate Post	46	1.81 (0.49) 2.0 (1.33, 2)	49	1.79 (0.41) 1.67 (1.33, 2)	0.8541	0.0
3 Months	37	1.57 (0.47) 1.33 (1.33, 1.67)	33	1.74 (0.45) 1.67 (1.67, 2)	0.0675	0.05
6 Months	17	1.80 (0.60) 1.67 (1.33, 2.33)	20	1.83 (0.50) 2 (1.5, 2)	0.6637	0.01
12 Months	11	2.12 (0.78) 2.0 (1.67, 3.0)	12	1.75 (0.53) 1.67 (1.5, 2)	0.3129	0.04
Anger Coping Scale						
Baseline	51	2.24 (0.52) 2.25 (2, 2.75)	56	2.2 (0.45) 2 (2, 2.5)	0.6476	0.002
Immediate Post	46	2.24 (0.48) 2 (2, 2.5)	49	2.28 (0.47) 2.25 (2, 2.75)	0.6294	0.002
3 Months	38	2.41 (0.48) 2.5 (2, 3)	33	2.29 (0.49) 2.25 (2, 2.75)	0.3009	0.02
6 Months	17	2.47 (0.51) 2.5 (2, 3)	18	2.24 (0.53) 2 (2, 2.75)	0.2204	0.04
12 Months	11	1.89 (0.52) 2 (1.5, 2.25)	12	2.17 (0.43) 2 (1.88, 2.5)	0.2418	0.06
Sadness Inhibition Scale						
Baseline	52	2.09 (0.63) 2 (1.5, 2.63)	56	2.07 (0.59) 2.0 (1.75, 2.5)	0.8258	0.0
Immediate Post	44	2.1 (0.62) 2 (1.63, 2.75)	44	2.13 (0.55) 2 (1.75, 2.5)	0.8257	0.001
3 Months	38	2.15 (0.53) 2 (1.75, 2.5)	33	2.06 (0.53) 2 (1.75, 2.5)	0.5756	0.004
6 Months	17	2.13 (0.54) 2 (1.75, 2.5)	19	1.99 (0.54) 2 (1.75, 2.25)	0.9871	0.0

	HIV Intervention (N=52)		General Health (N=56)			
	n	Mean (SD) or % Median (IQR)	n	Mean (SD) or % Median (IQR)	P-value[1]	Effect Size[2]
12 Months	11	2.05 (0.72) 2.25 (1.25, 2.5)	12	2.19 (0.30) 2 (2, 2.5)	0.8505	0.002
Sadness Dysregulation Scale						
Baseline	51	1.42 (0.47) 1.33 (1, 1.67)	55	1.44 (0.47) 1.33 (1, 1.67)	0.8051	0.001
Immediate Post	44	1.61 (0.56) 1.67 (1, 2)	45	1.71 (0.53) 1.67 (1.33, 2)	0.3416	0.01
3 Months	37	1.51 (0.48) 1.33 (1, 2)	33	1.58 (0.43) 1.67 (1.33, 2)	0.4357	0.01
6 Months	17	1.59 (0.56) 1.67 (1, 2)	19	1.60 (0.55) 1.33 (1, 2)	0.9094	0.0
12 Months	11	2.03 (0.69) 2 (1.33, 2.67)	12	1.58 (0.47) 1.5 (1.17, 2)	0.1184	0.11
Sadness Coping Scale						
Baseline	51	2.23 (0.50) 2.2 (1.8, 2.6)	53	2.31 (0.48) 2.2 (2, 2.6)	0.3795	0.01
Immediate Post	44	2.27 (0.46) 2.2 (2, 2.6)	45	2.28 (0.49) 2.2 (2, 2.8)	0.7447	0.001
3 Months	37	2.26 (0.46) 2.2 (2, 2.6)	33	2.37 (0.44) 2.4 (2, 2.8)	0.4358	0.01
6 Months	17	2.35 (0.46) 2.4 (2, 2.6)	19	2.17 (0.45) 2.2 (2, 2.6)	0.2478	0.04
12 Months	11	1.95 (0.54) 2 (1.4, 2.2)	12	2.32 (0.39) 2.2 (2, 2.6)	0.0918	0.12
Pro-Black Ethnic Identity Score						
Baseline	51	3.40 (0.39) 3.43 (3, 3.71)	54	3.37 (0.43) 3.43 (3, 3.71)	0.7174	0.001
Immediate Post	46	3.54 (0.35) 3.57 (3.29, 3.86)	48	3.50 (0.52) 3.57 (3.21, 3.86)	0.7198	0.001
3 Months	38	3.48 (0.42) 3.57 (3.29, 3.86)	32	3.44 (0.44) 3.43 (3, 3.93)	0.6816	0.002
6 Months	16	3.51 (0.52) 3.64 (3.07, 4)	20	3.49 (0.43) 3.57 (3.07, 3.86)	0.7223	0.004
12 Months	11	3.55 (0.42) 3.57 (3, 3.86)	12	3.46 (0.33) 3.50 (3.14, 3.71)	0.5758	0.01
Anti-White Ethnic Identity Score						

	HIV Intervention (N=52)		General Health (N=56)			
	n	Mean (SD) or % Median (IQR)	n	Mean (SD) or % Median (IQR)	P-value[1]	Effect Size[2]
Baseline	51	1.99 (0.49) 2 (1.5, 2.25)	52	1.99 (0.49) 2 (1.75, 2.25)	0.8357	0.0
Immediate Post	45	1.94 (0.55) 2 (1.5, 2.25)	46	1.96 (0.56) 2 (1.75, 2.25)	0.8427	0.0
3 Months	37	1.97 (0.56) 2 (1.5, 2.25)	28	2.04 (0.70) 2.0 (1.5, 2.5)	0.6544	0.003
6 Months	15	1.77 (0.67) 1.75 (1, 2.25)	18	2.14 (0.55) 2.13 (1.75, 2.5)	0.0733	0.10
12 Months	11	1.82 (0.40) 1.75 (1.5, 2)	11	1.98 (0.36) 2 (1.75, 2.25)	0.4186	0.03
Racism Awareness Ethnic Identity Score						
Baseline	49	2.82 (0.45) 2.80 (2.6, 3.2)	52	2.95 (0.50) 3 (2.6, 3.4)	0.2185	0.02
Immediate Post	44	2.87 (0.47) 2.8 (2.6, 3.2)	43	2.94 (0.55) 3 (2.6, 3.4)	0.6016	0.003
3 Months	37	2.97 (0.56) 3 (2.6, 3.2)	32	3.12 (0.59) 3 (2.8, 3.7)	0.3855	0.01
6 Months	16	2.72 (0.49) 2.7 (2.4, 3)	20	3.15 (0.55) 3.2 (2.7, 3.6)	0.0163	0.16
12 Months	11	2.76 (0.67) 2.8 (2.4, 3.4)	12	3.03 (0.67) 2.9 (2.7, 3.8)	0.2363	0.06
Attitudes Toward Women Score						
Baseline	48	1.97 (0.34) 2 (1.71, 2.17)	49	2.04 (0.43) 2.08 (1.83, 2.33)	0.2296	0.02
Immediate Post	41	2.93 (0.36) 2.92 (2.67, 3.17)	44	2.92 (0.44) 2.88 (2.54, 3.25)	0.6656	0.002
3 Months	36	1.96 (0.40) 2.08 (1.58, 2.25)	29	2.02 (0.41) 2.0 (1.83, 2.42)	0.6908	0.002
6 Months	15	2.01 (0.54) 2.08 (1.75, 2.58)	16	2.02 (0.45) 2.17 (1.79, 2.33)	0.9367	0.0
12 Months	10	2.03 (0.44) 2 (1.83, 2.25)	12	2.03 (0.44) 2.17 (1.71, 2.38)	0.8427	0.002
HIV/STD Knowledge Scale Score						
Baseline	50	0.64 (0.22) 0.71 (0.57, 0.79)	55	0.63 (0.21) 0.71 (0.57, 0.79)	0.7068	0.001
Immediate Post	45	0.64 (0.27) 0.67 (0.50, 0.83)	45	0.48 (0.25) 0.50 (0.33, 0.67)	0.0028	0.10

	HIV Intervention (N=52)		General Health (N=56)			
	n	Mean (SD) or % Median (IQR)	n	Mean (SD) or % Median (IQR)	P-value[1]	Effect Size[2]
3 Months	36	0.73 (0.21) 0.79 (0.64, 0.86)	30	0.57 (0.27) 0.57 (0.36, 0.79)	0.0107	0.10
6 Months	17	0.76 (0.21) 0.79 (0.71, 0.86)	18	0.72 (0.18) 0.71 (0.71, 0.86)	0.4011	0.02
12 Months	11	0.77 (0.19) 0.86 (0.64, 0.93)	12	0.70 (0.24) 0.75 (0.54, 0.86)	0.4736	0.02
Total PHQ-9 Score						
Baseline	52	3.17 (2.82) 2 (1, 5)	55	2.67 (3.07) 2 (0, 4)	0.1743	0.02
Immediate Post	47	2.19 (2.51) 2 (0, 3)	51	2.80 (3.79) 2 (0, 4)	0.7846	0.001
3 Months	38	2.82 (3.61) 1 (0, 5)	33	4.24 (5.35) 3 (0, 7)	0.3350	0.01
6 Months	17	2.94 (3.34) 2 (1, 3)	22	3.23 (4.06) 2 (0, 5)	0.7727	0.002
12 Months	11	3.18 (4.51) 1 (0, 6)	13	3.62 (3.8) 3 (1, 5)	0.4595	0.02

Note: SD=standard deviation; IQR=interquartile range

[1]P-values are based on non-parametric exact Wilcoxon rank-sum tests for continuous variables and Fisher's exact tests for categorical variables

[2]Effect sizes are based on η^2 (eta-squared) for continuous variables (small: 0.01, medium: 0.06, large: >0.14) and Cramer's *V* for categorical variables (small: 0.10-0.29, medium: 0.30-0.50, large: >0.50).

Table 5.

Descriptive Statistics of Change from Baseline for Primary and Secondary Outcomes by Intervention Condition.

	HIV Intervention (N=52)		General Health (N=56)			
	n	**Mean (SD) or % Median (IQR)**	**n**	**Mean (SD) or % Median (IQR)**	**P-value[1]**	**Effect Size[2]**
Change from Baseline in Proportion of Condom Use for Vaginal Sex in the Past 3 Months						
3 Months	16	0.21 (0.39) 0 (0, 0.50)	13	−0.02 (0.53) 0 (−0.33, 0.33)	0.1976	0.06
6 Months	8	0.01 (0.35) 0 (0, 0.20)	6	0.22 (0.53) 0.07 (0, 0.67)	0.4655	0.04
12 Months	5	0.04 (0.43) 0 (−0.20, 0)	7	0.52 (0.41) 0.50 (0, 1)	0.0833	0.23
Change from Baseline in Number of Sexual Partners in the Past 3 Months						
3 Months	32	0.22 (1.60) 0 (−1, 0.50)	23	2.35 (10.76) 0 (−1, 1)	0.6045	0.005
6 Months	13	−0.54 (0.97) −1 (−1, 0)	14	−0.57 (2.77) 0 (−1, 1)	0.2375	0.05
12 Months	11	−0.09 (0.94) 0 (−1, 0)	9	−0.56 (2.92) 0 (0, 0)	0.7307	0.005
Sex with More than One Person in the Same Day						
3 Months	38	Yes to Yes 10.5% Yes to No 7.9% No to Yes 5.3% No to No 76.3%	31	Yes to Yes 22.6% Yes to No 16.1% No to Yes 3.2% No to No 58.1%	0.3360	0.23
6 Months	17	Yes to Yes 5.9% Yes to No 11.8% No to Yes 0%	18	Yes to Yes 27.8% Yes to No 0% No to Yes 5.6%	0.0832	0.41
12 Months	11	No to No 82.4% Yes to Yes 18.2% Yes to No 0% No to Yes 9.1% No to No 72.7%	11	No to No 51.4% Yes to Yes 18.2% Yes to No 18.2% No to Yes 9% No to No 54.6%	0.7470	0.32
Sex with More than One Person in the Same Month						
3 Months	38	Yes to Yes 23.7% Yes to No 7.9% No to Yes 15.8% No to No 52.6%	31	Yes to Yes 45.2% Yes to No 12.9% No to Yes 9.7% No to No 32.3%	0.1851	0.27
6 Months	17	Yes to Yes 23.5% Yes to No 11.8%	18	Yes to Yes 44.4% Yes to No 5.6%	0.3784	0.32

	HIV Intervention (N=52)		General Health (N=56)			
	n	Mean (SD) or % Median (IQR)	n	Mean (SD) or % Median (IQR)	P-value[1]	Effect Size[2]
		No to Yes 23.5% No to No 41.2%		No to Yes 5.6% No to No 44.4%		
12 Months	11	Yes to Yes 18.2% Yes to No 18.2% No to Yes 18.2% No to No 45.4%	11	Yes to Yes 45.4% Yes to No 18.2% No to Yes 18.2% No to No 18.2%	0.3971	0.34
Sex While Already in a Sexual Relationship with Someone Else						
3 Months	37	Yes to Yes 8.1% Yes to No 13.5% No to Yes 10.8% No to No 67.6%	31	Yes to Yes 32.3% Yes to No 9.7% No to Yes 6.5% No to No 51.6%	0.0978	0.31
6 Months	17	Yes to Yes 17.7% Yes to No 11.8% No to Yes 11.8% No to No 58.8%	18	Yes to Yes 33.3% Yes to No 11.1% No to Yes 5.6% No to No 50%	0.8237	0.20
12 Months	11	Yes to Yes 9.1% Yes to No 18.2% No to Yes 18.2% No to No 54.6%	11	Yes to Yes 36.4% Yes to No 9% No to Yes 9% No to No 45.6%	0.5621	0.34
Change from Baseline in Alcohol Use Past 30 Days						
3 Months	10	0.0 (0.47) 0.0 (0, 0)	8	−0.38 (0.74) −0.50 (−1, 0)	0.1604	0.10
6 Months	2	0.50 (0.71) 0.5 (0, 1)	6	−1.50 (2.17) −1 (−3, 0)	0.2857	0.18
12 Months	4	−0.25 (0.50) 0.0 (−0.5, 0)	5	−1.60 (2.41) −1 (−3, 0)	0.5000	0.05
Change from Baseline in Marijuana Use in the Past 30 Days						
3 Months	12	0.67 (3.28) 1 (−0.5, 2)	15	−1.53 (4.0) 0 (−3,0)	0.1012	0.10
6 Months	7	−1.0 (2.94) −1 (−4, 0)	8	−0.88 (1.96) −0.5 (−1.5, 0.5)	0.8014	0.004
12 Months	5	−0.4 (4.72) 0.0 (−5, 2)	4	−0.75 (1.71) −0.5 (−2, 0.5)	0.9603	<0.001
Change from Baseline in Condom Use Prevention Beliefs						
Immediate Post	47	0.20 (1.15) 0.0 (−0.33, 0.67)	48	−0.11 (0.84) 0.0 (−0.33, 0.33)	0.3265	0.01
3 Months	38	0.27 (1.23) 0.0 (−0.33,0.33)	33	−0.09 (0.83) 0.0 (−0.67, 0.33)	0.6942	0.002

	HIV Intervention (N=52)		General Health (N=56)			
	n	Mean (SD) or % Median (IQR)	n	Mean (SD) or % Median (IQR)	P-value[1]	Effect Size[2]
6 Months	17	0.43 (1.30) 0.0 (−0.33, 1)	19	0.02 (0.93) 0.0 (−1, 0.67)	0.4731	0.01
12 Months	11	0.61 (1.39) 0 (0, 2)	12	0.0 (0.94) 0.0 (−0.67, 0.33)	0.3616	0.04
Change from Baseline in Condom Use Attitude						
Immediate Post	43	−0.09 (0.94) 0 (−0.33, 0.33)	46	−0.19 (0.74) 0 (−0.33, 0.33)	0.4786	0.01
3 Months	38	−0.05 (0.8) 0 (0, 0.33)	32	−0.04 (0.81) 0 (−0.5, 0.5)	0.9138	<0.001
6 Months	17	−0.29 (1.06) 0 (−0.67, 0.33)	19	−0.26 (0.56) 0 (−0.67, 0)	0.7820	0.002
12 Months	11	−0.39 (1.04) 0 (−1.33, 0.33)	10	−0.13 (0.82) 0 (−0.33, 0)	0.8858	0.001
Change from Baseline in Condom Use Availability						
Immediate Post	45	−0.02 (0.79) 0 (−0.25, 0.5)	46	−0.24 (0.69) 0 (−0.75, 0.25)	0.1581	0.02
3 Months	36	0.03 (0.66) 0 (−0.5, 0.25)	30	−0.04 (0.90) 0 (−0.5, 0.5)	0.7424	0.002
6 Months	17	0.09 (0.84) 0 (−0.25, 0.5)	17	0.06 (0.58) 0 (−0.25, 0.25)	0.7941	0.002
12 Months	11	0.09 (0.80) 0.5 (−0.75, 0.75)	10	0 (0.71) 0 (−0.5, 0.25)	0.6966	0.01
Change from Baseline in Condom Use Hedonistic Beliefs						
Immediate Post	43	0.17 (0.40) 0.17 (−0.17, 0.33)	44	0.10 (0.38) 0.17 (−0.08, 0.33)	0.8408	<0.001
3 Months	35	0.04 (0.30) 0 (−0.17, 0.33)	30	0.09 (0.40) 0.17 (−0.17, 0.33)	0.5161	0.01
6 Months	17	0.02 (0.34) 0 (−0.17, 0.33)	18	0.02 (0.41) 0 (−0.17, 0.33)	0.7395	0.003
12 Months	11	0.02 (0.46) 0 (−0.17, 0.33)	9	0.04 (0.48) 0 (−0.17, 0)	0.7850	0.004
Change from Baseline in Condom Use Impulsivity						
Immediate Post	44	−0.19 (1.0) 0 (−0.67, 0.33)	45	0.12 (0.92) 0 (−0.33, 0.33)	0.5863	0.003
3 Months	37	−0.23 (0.91) 0 (−0.67, 0.33)	31	0.08 (0.99) 0 (−0.67, 0.67)	0.2483	0.02

	HIV Intervention (N=52)		General Health (N=56)			
	n	Mean (SD) or % Median (IQR)	n	Mean (SD) or % Median (IQR)	P-value[1]	Effect Size[2]
6 Months	17	−0.29 (1.24) 0 (−1.0, 0.33)	18	0.07 (1.21) 0 (−0.67, 1.0)	0.5237	0.01
12 Months	11	−0.27 (1.08) −0.33 (−0.67, 0.67)	10	−0.27 (0.98) 0 (−0.67, 0)	>0.9999	<0.001
Change from Baseline in Con idom Use Negotiation Beliefs						
Immediate Post	42	−0.03 (0.83) 0 (−0.2, 0.2)	45	−0.13 (0.89) 0 (−0.4, 0.2)	0.6874	0.002
3 Months	34	0.16 (0.60) 0.20 (0, 0.4)	32	−0.11 (0.87) 0 (−0.7, 0.3)	0.0585	0.05
6 Months	17	0 (0.73) 0 (0, 0.4)	18	0.02 (0.86) 0 (−0.4, 0)	0.1832	0.05
12 Months	11	0 (0.46) 0 (−0.2, 0.4)	10	−0.04 (0.82) 0 (−0.6, 0)	0.3212	0.05
Change from Baseline in Condom Use Self-Efficacy						
Immediate Post	41	−0.01 (0.75) 0 (−0.33, 0.33)	41	−0.14 (0.66) −0.08 (−0.42, 0.17)	0.4806	0.01
3 Months	34	0.12 (0.55) 0.08 (−0.08, 0.42)	29	−0.11 (0.71) −0.08 (−0.5, 0.33)	0.1339	0.04
6 Months	17	0.13 (0.71) 0.33 (−0.25, 0.5)	16	−0.04 (0.62) −0.12 (−0.33, 0.21)	0.2135	0.05
12 Months	11	0.11 (0.43) 0.25 (−0.33, 0.5)	10	0.02 (0.70) −0.08 (−0.33, 0.08)	0.2171	0.07
Change from Baseline in Condom Use Subjective Norm						
Immediate Post	43	0.03 (0.90) 0 (0, 0.5)	47	−0.15 (0.95) 0 (−0.5, 0.5)	0.3225	0.01
3 Months	38	0.20 (0.92) 0 (0, 0)	32	−0.09 (0.89) 0 (−0.5, 0.5)	0.6821	0.002
6 Months	17	0.15 (0.90) 0 (0, 0)	19	−0.18 (0.97) 0 (−1, 0.5)	0.2548	0.04
12 Months	11	0.18 (1.06) 0 (−1, 1)	11	0.14 (1.38) 0.5 (−1, 1.5)	0.9472	<0.001
Change from Baseline in Condom Use Technical Skills						
Immediate Post	41	0.0 (1.03) 0 (−0.5, 0.5)	44	−0.14 (0.97) 0 (−0.5, 0.5)	0.5131	0.01
3 Months	35	0.2 (0.81) 0 (0, 1)	32	−0.09 (0.89) 0.0 (−0.5, 0.5)	0.2420	0.02

	HIV Intervention (N=52)		General Health (N=56)			
	n	Mean (SD) or % Median (IQR)	n	Mean (SD) or % Median (IQR)	P-value[1]	Effect Size[2]
6 Months	17	0.24 (0.79) 0.5 (0, 0.5)	18	−0.03 (0.88) 0 (−0.5, 0)	0.1529	0.06
12 Months	11	0.18 (0.51) 0 (0, 0.5)	10	−0.15 (0.97) 0 (−1, 0)	0.1492	0.10
Change from Baseline in Condom Knowledge						
6 Months	17	0.14 (0.32) 0.2 (0, 0.20)	18	0.13 (0.31) 0 (0, 0.20)	0.6864	0.01
12 Months	11	0.05 (0.27) 0 (−0.2, 0.20)	12	0.12 (0.45) 0.20 (0, 0.20)	0.1978	0.07
Change from Baseline in Anger Inhibition Scale						
Immediate Post	45	0.05 (0.60) 0 (−0.25, 0.5)	49	0.10 (0.49) 0.25 (−0.25, 0.5)	0.6647	0.002
3 Months	38	−0.01 (0.68) 0 (−0.5, 0.5)	33	0 (0.52) 0.0 (−0.25, 0.25)	0.9212	<0.001
6 Months	17	0.18 (0.56) 0.25 (−0.25, 0.5)	20	0.04 (0.47) 0.13 (−0.25, 0.25)	0.4959	0.01
12 Months	11	0.09 (0.82) −0.25 (−0.25, 0.5)	12	0.10 (0.60) 0.25 (−0.25, 0.5)	0.6834	0.01
Change from Baseline in Anger Dysregulation Scale						
Immediate Post	46	0.04 (0.61) 0 (−0.33, 0.33)	49	0.10 (0.48) 0 (0, 0.33)	0.7143	0.001
3 Months	37	−0.08 (0.58) 0 (−0.33, 0.33)	33	0.09 (0.43) 0 (0, 0.33)	0.1064	0.04
6 Months	17	0.02 (0.48) 0 (−0.33, 0.33)	20	0.02 (0.46) 0 (−0.33, 0.33)	0.9630	<0.001
12 Months	11	0.18 (0.92) 0 (−0.67, 0.67)	12	0 (0.53) 0 (−0.33, 0.33)	0.8771	0.001
Change from Baseline in Anger Coping Scale						
Immediate Post	46	0.01 (0.47) 0 (−0.25, 0.25)	49	0.07 (0.36) 0 (−0.25, 0.25)	0.4386	0.01
3 Months	38	0.07 (0.47) 0 (−0.25, 0.5)	33	0.02 (0.38) 0 (−0.25, 0.25)	0.7103	0.002
6 Months	17	0.28 (0.4) 0.5 (0, 0.5)	18	0.06 (0.48) 0.13 (−0.25, 0.25)	0.1458	0.06
12 Months	11	−0.16 (0.39) −0.25 (−0.5, 0.25)	12	0.06 (0.37) 0 (−0.25, 0.38)	0.1148	0.11

	HIV Intervention (N=52)		General Health (N=56)			
	n	Mean (SD) or % Median (IQR)	n	Mean (SD) or % Median (IQR)	P-value[1]	Effect Size[2]
Change from Baseline in Sadness Inhibition Scale						
Immediate Post	44	−0.02 (0.57) 0 (−0.25, 0.25)	44	0.08 (0.60) 0 (−0.25, 0.38)	0.3965	0.01
3 Months	38	0.11 (0.64) 0 (−0.25, 0.5)	33	−0.03 (0.48) 0 (−0.25, 0.25)	0.4629	0.01
6 Months	17	0.07 (0.65) 0 (−0.25, 0.25)	19	−0.01 (0.52) 0 (−0.5, 0.25)	0.7722	0.002
12 Months	11	0.09 (0.63) 0 (−0.5, 0.5)	12	0.17 (0.75) 0.13 (−0.5, 0.88)	0.8039	0.003
Change from Baseline in Sadness Dysregulation Scale						
Immediate Post	44	0.17 (0.54) 0 (−0.33, 0.33)	44	0.27 (0.65) 0.33 (0, 0.67)	0.1913	0.02
3 Months	37	0.17 (0.51) 0 (0, 0.33)	33	0.14 (0.53) 0 (0, 0.67)	0.9855	<0.001
6 Months	17	0.16 (0.5) 0 (−0.33, 0.67)	18	0.15 (0.51) 0 (0, 0.67)	0.8646	0.001
12 Months	11	0.55 (0.65) 0.67 (0, 1)	12	0.11 (0.64) 0 (0, 0.5)	0.2304	0.06
Change from Baseline in Sadness Coping Scale						
Immediate Post	44	0.06 (0.52) 0 (−0.2, 0.4)	42	0 (0.51) 0 (−0.2, 0.4)	0.6859	0.002
3 Months	37	0.08 (0.56) 0 (−0.2, 0.4)	32	0 (0.42) 0 (−0.2, 0.4)	0.6020	0.004
6 Months	17	0.32 (0.58) 0.20 (−0.2, 0.8)	17	0.02 (0.48) −0.2 (−0.4, 0.6)	0.2254	0.04
12 Months	11	−0.02 (0.68) −0.2 (−0.6, 0.4)	12	0.17 (0.67) 0 (−0.4, 0.7)	0.5578	0.02
Change from Baseline in Pro-Black Ethnic Identity Score						
Immediate Post	45	0.13 (0.39) 0 (0, 0.29)	47	0.11 (0.48) 0.14 (0, 0.43)	0.4412	0.01
3 Months	38	0.10 (0.36) 0 (−0.14, 0.29)	32	0.04 (0.37) 0 (−0.14, 0.14)	0.6182	0.004
6 Months	16	0.11 (0.43) 0.14 (−0.07, 0.36)	20	0.14 (0.38) 0 (0, 0.29)	0.9356	<0.001
12 Months	11	0.14 (0.34) 0.14 (−0.14, 0.29)	12	0.23 (0.32) 0.14 (0, 0.43)	0.6874	0.01

	HIV Intervention (N=52)		General Health (N=56)			
	n	Mean (SD) or % Median (IQR)	n	Mean (SD) or % Median (IQR)	P-value[1]	Effect Size[2]
Change from Baseline in Anti-White Ethnic Identity Score						
Immediate Post	44	−0.07 (0.56) 0 (−0.25, 0.25)	44	−0.06 (0.51) 0 (−0.38, 0.25)	0.8953	<0.001
3 Months	36	0 (0.48) 0 (−0.25, 0.25)	27	0.03 (0.49) 0 (−0.25, 0.25)	0.8935	<0.001
6 Months	15	−0.25 (0.64) 0 (−.05 0.25)	17	0.04 (0.48) −0.25 (−0.25, 0.25)	0.3480	0.03
12 Months	11	−0.05 (0.6) 0 (−0.5, 0.5)	11	0.02 (0.43) 0 (−0.25, 0.25)	0.8155	0.002
Change from Baseline in Racism Awareness Ethnic Identity Score						
Immediate Post	42	0.07 (0.45) 0 (−0.2, 0.4)	43	0.01 (0.55) 0 (−0.2, 0.4)	0.9612	<0.001
3 Months	35	0.17 (0.5) 0.2 (−0.2, 0.4)	31	0.19 (0.58) 0 (−0.2, 0.4)	0.6888	0.002
6 Months	16	−0.05 (0.51) 0 (−0.4, 0.2)	19	0.29 (0.6) 0.2 (0, 0.6)	0.1096	0.07
12 Months	11	0.02 (0.53) 0 (−0.4, 0.4)	12	0.07 (0.42) −0.1 (−0.2, 0.4)	0.9015	0.001
Change from Baseline in Attitudes Toward Women Score						
Immediate Post	40	1 (0.64) 1 (0.67, 1.46)	41	0.86 (0.83) 0.75 (0.25, 1.25)	0.1536	0.03
3 Months	34	0.01 (0.29) 0 (−0.17, 0.25)	27	0 (0.25) −0.08 (−0.17, 0.17)	0.6104	0.004
6 Months	15	0.07 (0.36) 0.17 (−0.17, 0.42)	14	−0.04 (0.27) −0.08 (−0.25, 0.17)	0.4187	0.02
12 Months	10	0.17 (0.42) 0.17 (0, 0.33)	11	−0.04 (0.32) 0 (−0.25, 0.17)	0.2730	0.06
Change from Baseline in HIV/STD Knowledge Scale Score						
Immediate Post	45	0 (0.3) 0.06 (−0.17, 0.19)	45	−0.14 (0.26) −0.13 (−0.3, −0.02)	0.0011	0.12
3 Months	35	0.06 (0.16) 0.07 (−0.07, 0.14)	30	−0.05 (0.31) 0 (−0.29, 0.21)	0.2478	0.02
6 Months	17	0.07 (0.24) 0.14 (0, 0.21)	18	0.06 (0.24) 0.04 (−0.07, 0.21)	0.4455	0.02

	HIV Intervention (N=52)		General Health (N=56)			
	n	Mean (SD) or % Median (IQR)	n	Mean (SD) or % Median (IQR)	P-value[1]	Effect Size[2]
12 Months	11	0.06 (0.16) 0.07 (0, 0.21)	12	0.09 (0.31) 0.14 (0.04, 0.21)	0.3534	0.04
Change from Baseline in PHQ-9 Score						
Immediate Post	47	−1.06 (2.03) −1 (−2, 0)	51	0.10 (2.45) 0 (−1, 2)	0.0070	0.07
3 Months	38	−0.37 (2.52) 0 (−2, 0)	33	1.42 (4.93) 0 (0, 2)	0.0480	0.06
6 Months	17	−1.06 (3.77) −2 (−3, 0)	22	0 (3.53) 0 (−2, 1)	0.1582	0.05
12 Months	11	−0.27 (4.45) −2 (−3, 1)	13	0.08 (3.20) 0 (−1, 1)	0.4305	0.03

Note: SD=standard deviation; IQR=interquartile range

[1]P-values are based on non-parametric exact Wilcoxon rank-sum tests for continuous variables and Fisher's exact tests for categorical variables

[2]Effect sizes are based on η^2 (eta-squared) for continuous variables (small: 0.01, medium: 0.06, large: >0.14) and Cramer's V for categorical variables (small: 0.10-0.29, medium: 0.30-0.50, large: >0.50).

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