Efficacy of an HIV Prevention Intervention for African American Adolescent Girls
A Randomized Controlled Trial

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ADOLESCENTS ARE ACKNOWLedged as a population at increased risk of human immunodeficiency virus (HIV) infection.[1-5] Among adolescents, African American girls are a subgroup at particularly high risk of HIV infection. A seroepidemiologic study of Job Corps applicants reported that HIV prevalence among African American adolescent girls was significantly higher than among their white or Hispanic female peers (4.9 vs 0.7 and 0.6 per 1000, respectively) and exceeds that of white, Hispanic, and African American male adolescents (0.8, 1.5, and 3.2 per 1000, respectively). African American adolescent girls in the South had the highest prevalence (6.4 per 1000) relative to adolescents from other geographic regions.[6]

Recent meta-analyses and reviews indicate that theoretically derived and empirically based HIV interventions can

Context African American adolescent girls are at high risk for human immunodeficiency virus (HIV) infection, but interventions specifically designed for this population have not reduced HIV risk behaviors.

Objective To evaluate the efficacy of an intervention to reduce sexual risk behaviors, sexually transmitted diseases (STDs), and pregnancy and enhance mediators of HIV-preventive behaviors.

Design, Setting, and Participants Randomized controlled trial of 522 sexually experienced African American girls aged 14 to 18 years screened from December 1996 through April 1999 at 4 community health agencies. Participants completed a self-administered questionnaire and an interview, demonstrated condom application skills, and provided specimens for STD testing. Outcome assessments were made at 6- and 12-month follow-up.

Intervention All participants received four 4-hour group sessions. The intervention emphasized ethnic and gender pride, HIV knowledge, communication, condom use skills, and healthy relationships. The comparison condition emphasized exercise and nutrition.

Main Outcome Measures The primary outcome measure was consistent condom use, defined as condom use during every episode of vaginal intercourse; other outcome measures were sexual behaviors, observed condom application skills, incident STD infection, self-reported pregnancy, and mediators of HIV-preventive behaviors.

Results Relative to the comparison condition, participants in the intervention reported using condoms more consistently in the 30 days preceding the 6-month assessment (unadjusted analysis, intervention, 75.3% vs comparison, 58.2%) and the 12-month assessment (unadjusted analysis, intervention, 73.3% vs comparison, 56.5%) and over the entire 12-month period (adjusted odds ratio, 2.01; 95% confidence interval [CI], 1.28-3.17; P=.003). Participants in the intervention reported using condoms more consistently in the 6 months preceding the 6-month assessment (unadjusted analysis, intervention, 61.3% vs comparison, 42.6%), at the 12-month assessment (unadjusted analysis, intervention, 58.1% vs comparison, 45.3%), and over the entire 12-month period (adjusted odds ratio, 2.30; 95% CI, 1.51-3.50; P<.001). Using generalized estimating equation analyses over the 12-month follow-up, adolescents in the intervention were more likely to use a condom at last intercourse, less likely to have a new vaginal sex partner in the past 30 days, and more likely to apply condoms to sex partners and had better condom application skills, a higher percentage of condom-protected sex acts, fewer unprotected vaginal sex acts, and higher scores on measures of mediators. Promising effects were also observed for chlamydia infections and self-reported pregnancy.
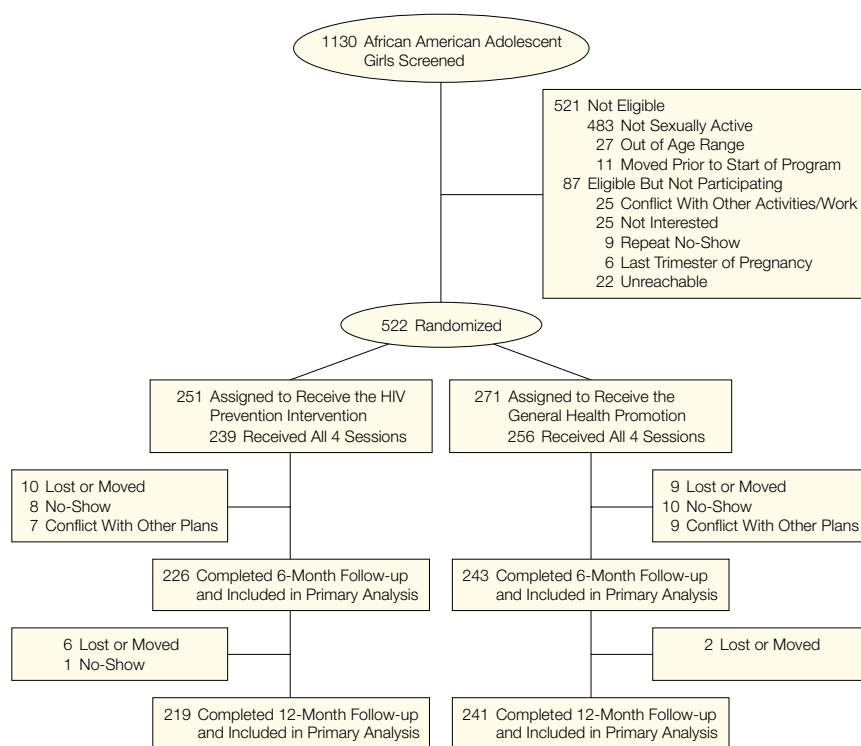
Conclusion Interventions for African American adolescent girls that are gender-tailored and culturally congruent can enhance HIV-preventive behaviors, skills, and mediators and may reduce pregnancy and chlamydia infection.

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Figure. Flow of Study Participants

HIV indicates human immunodeficiency virus. Lost participants were those who were unable to be contacted. No-show participants were contacted and scheduled for a visit but did not come in.

successfully promote the adoption of protective sexual behaviors among adolescents.[7-14] While encouraging, many studies are limited by the range of outcomes assessed and the magnitude and consistency of intervention effects observed.[15] Moreover, caution is warranted in generalizing intervention effects from HIV prevention studies with lower-risk and mixed racial/ethnic groups to sexually experienced African American adolescents, particularly African American girls. Overall, while African American adolescent girls are disproportionately affected by the HIV epidemic, no intervention designed specifically for this population has demonstrated efficacy in reducing HIV-associated risk behaviors.[12,16]

To address this health disparity, we evaluated the efficacy of an HIV prevention intervention in reducing risky sexual behaviors and sexually transmitted diseases and enhancing skills and mediators of HIV-preventive behaviors among sexually experienced African American adolescent girls residing in the southern United States.

METHODS
Participants

The study was conducted from September 1995 to August 2002. The University of Alabama at Birmingham Institutional Review Board (IRB) approved the study protocol prior to implementation. From December 1996 through April 1999, recruiters screened 1130 self-identified African American adolescent girls seeking services at 4 community health agencies. Of these, 609 (53.9%) met eligibility criteria. Eligibility criteria included being African American, female, and 14 to 18 years of age; reporting vaginal intercourse in the preceding 6 months; and providing written informed consent. Parental consent was waived by the IRB. Of those not eligible, nearly 93% were not sexually experienced. Thus, 522 adolescents agreed

to participate in the study, completed baseline assessments, and were randomized to study conditions (**FIGURE**). Participants were compensated $25 for travel and child care to attend intervention sessions and complete assessments.

Study Design

The study was a randomized controlled trial. Assignment to study conditions was conducted subsequent to baseline assessment using concealment of allocation procedures, defined by protocol and compliant with published recommendations.[17-19] Prior to enrollment, an investigator used a random-numbers table to generate the allocation sequence. As participants completed baseline assessments, sealed opaque envelopes were used to execute the assignments. Participants were randomly assigned to either the HIV intervention or a general health promotion condition.

Intervention Methods

The research team collaborated with African American adolescent girls in the community to develop the study conditions. The HIV intervention consisted of four 4-hour interactive group sessions implemented on consecutive Saturdays at a family medicine clinic. Each session had an average of 10 to 12 participants and was implemented by a trained African American female health educator and 2 African American female peer educators. Peer educators were instrumental in modeling skills and creating group norms supportive of HIV prevention. To reduce the likelihood that the effects of the HIV prevention intervention could be attributed to group interaction or Hawthorne effects, participants randomized to the general health promotion condition also received four 4-hour interactive group sessions, 2 sessions emphasizing nutrition and 2 sessions emphasizing exercise, administered on consecutive Saturdays. Prior to implementing the main trial, both conditions were field tested with adolescents from the study population.

Social cognitive theory[20] and the theory of gender and power[21,22] were comple-

mentary theoretical frameworks guiding the design and implementation of the HIV intervention. Session 1 emphasized ethnic and gender pride by discussing the joys and challenges of being an African American adolescent female, acknowledging the accomplishments of African American women, reading poetry written by African American women, and framing artwork created by African American women artists. Session 2 enhanced awareness of HIV risk-reduction strategies such as abstaining from sex, using condoms consistently, and having fewer sex partners. Session 3, through role-play and cognitive rehearsal, enhanced adolescents' confidence in initiating safer-sex conversations, negotiating safer sex, and refusing unsafe sexual encounters. Additionally, peer educators discussed the importance of abstinence and proper and consistent condom use and modeled condom skills. Session 4 emphasized the importance of healthy relationships. Health educators described how unhealthy relationships could make it difficult to practice safer sex.

Data Collection

Data collection occurred at baseline and at 6- and 12-month follow-up. At each assessment, data were obtained from 4 sources. First, participants completed a self-administered questionnaire assessing sociodemographics and psychosocial mediators of HIV-preventive behaviors. Subsequently, a trained African American female interviewer administered an interview assessing sexual behaviors. Next, the interviewer assessed participants' ability to correctly apply condoms using a direct observation of skills assessment protocol. Finally, participants provided 2 self-collected vaginal swab specimens that were analyzed for sexually transmitted diseases.

Primary Outcome Measure

Self-reported consistent condom use, the primary outcome, was defined as use of a condom during every episode of vaginal intercourse. Consistent condom use was assessed for the 30 days and the 6 months prior to baseline and at the 6- and 12-month assessments. This outcome was calculated by dividing the total number of episodes of vaginal intercourse by the total number of times a male condom was used, with a score of 1 representing consistent condom use. Consistent condom use was selected as a primary outcome based on demonstrated evidence of effectiveness in reducing sexually transmitted HIV infection.[23-25]

Other Outcome Measures

Self-reported Sexual Behaviors. Other self-reported behavioral outcomes included (1) condom use at last vaginal intercourse; (2) percentage of condom-protected vaginal intercourse acts in the 30 days preceding assessment; (3) percentage of condom-protected vaginal intercourse acts in the 6 months preceding assessment; (4) number of unprotected vaginal intercourse acts in the 30 days preceding assessment; (5) number of unprotected vaginal intercourse acts in the 6 months preceding assessment; (6) whether participants had a new vaginal sex partner in the 30 days preceding assessment; and (7) self-reported pregnancy. Additionally, a single item assessed the frequency with which participants applied condoms on their sex partners in the past 6 months. Responses ranged from 1 ("never") to 5 ("every time"). These measures of condom use were included to permit comparison with previous HIV interventions conducted among adolescents.[7,8,12,26,27] Preliminary research and our pilot study indicated that anal and oral sex are extremely low-prevalence behaviors in this population and therefore were not assessed as outcomes.

Several techniques were used to enhance the validity of participants' self-reported sexual behaviors. Participants were asked to report their behaviors over relatively brief time intervals to enhance accurate recall[28] and were provided calendars specifying the reporting intervals of interest. To enhance confidentiality, interviewers assured participants that codes rather than names would be used on records.[29] To minimize potential interviewer bias, interviewers were blinded to participants' condition assignments.

STD Status. Sexually transmitted disease (STD) incidence was defined as a positive laboratory test result for a new chlamydia, gonorrhea, or trichomonas infection at either the 6-month assessment or the 12-month assessment. Given the small sample size and limited power to detect differences in STD incidence for each assessment interval, incidence for each STD was determined only for the entire 12-month follow-up period. Given the expected low incidence of HIV during the 12-month follow-up, HIV testing was not conducted.

Specimens were collected after all other assessment procedures were completed. Participants provided 2 vaginal swabs at each of the 3 assessments.[30] One swab was evaluated for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* using the Abbott LCx Probe System (Abbott Labs, Abbott Park, Ill).[31] A second swab was tested for *Trichomonas vaginalis* using the InPouch TV test from BioMed Diagnostics Inc (San Jose, Calif).[32] All assays were conducted at the University of Alabama, Birmingham, Division of Infectious Diseases STD Research Laboratory. Adolescents testing positive for an STD were provided directly observable single-dose treatment, received appropriate risk-reduction counseling per Centers for Disease Control and Prevention recommendations, and were encouraged to refer sex partners for treatment. The county health department was notified of reportable STDs.

Psychosocial Mediators of Sexual Behavior. Psychosocial mediators were derived from the underlying theoretical frameworks and a review of the empirical literature. Constructs were assessed using scales with satisfactory psychometric properties previously used among African American adolescents.[27,33] HIV prevention knowledge was measured using a 16-item scale ($\alpha = .68$). Perceived partner-related barriers to condom use were measured using a 6-item scale that assessed attitudes that impede participants' ability to effectively use condoms ($\alpha = .82$). At-

titudes toward using condoms were measured using an 8-item scale (α = .68). Frequency of sexual communication was measured using a 5-item scale assessing the frequency with which participants discussed HIV-preventive practices with sex partners (α = .80). Condom use self-efficacy was measured using a 9-item scale that assessed participants' confidence in their ability to properly use condoms (α = .88). Participants' condom application skills were rated by interviewers using a structured scoring protocol that ranged from 0 to 6, with higher ratings reflecting greater proficiency at applying condoms.

Statistical Analyses

Sample size calculations for the primary behavioral outcome were conducted based on previous research in this population identifying approximately 25% consistent condom use. We projected a clinically meaningful effect size of a 50% increase in consistent condom use in the HIV intervention condition. Estimating 20% attrition over the 12-month follow-up period and setting the type I error rate at .05 for a 2-tailed test with power=0.80 required enrolling 250 participants in each study condition to detect the specified effect size.

Analyses were performed only on prespecified hypotheses using an intention-to-treat protocol in which participants were analyzed in their original assigned study conditions irrespective of the number of sessions attended.[34,35] At baseline, descriptive statistics were calculated to summarize sociodemographic variables, psychosocial mediators, sexual behaviors, and STD prevalence between study conditions. Differences between conditions were assessed using *t* tests for continuous variables and χ^2 analyses for categorical variables.[36] Variables in which differences between study conditions approached statistical significance or that were theoretically or empirically identified as potential confounders were included as covariates in the models.

The effectiveness of the HIV intervention was analyzed over the entire 12-month period (from baseline to the 12-month assessment). Effectiveness was also investigated for the two 6-month periods from baseline to the 6-month assessment and from the 6-month to the 12-month assessment. The HIV intervention effects analysis for each of the two 6-month assessment periods used logistic regression to compute adjusted odd ratios (ORs) for dichotomous outcomes[37] and used linear regression[38] to compute adjusted means and mean differences for continuous outcomes. Each of these approaches included the corresponding baseline measure for the specific outcome as a covariate in the analysis.

To assess HIV intervention effects for the entire 12-month follow-up period, logistic and linear generalized estimating equation (GEE) regression models were designed specifically to control for repeated within-subject measurements. This technique allows for a differential number of observations on study participants over the longitudinal course of observation. These models included a time-independent variable (study condition) as well as time-dependent variables (covariates and outcomes). The models were adjusted for the corresponding baseline measure for each outcome and other covariates to obtain adjusted ORs to assess the effect of the intervention on dichotomous outcomes and adjusted mean differences to assess the effect of the intervention on continuous outcomes. Additionally, an indicator for the time period was included in the model to capture any unaccounted temporal effects.[39,40] An indicator for cohort was also included in the model to adjust for clustering. Fitted GEE parameters can be interpreted as the odds (in logistic models) or mean difference (in linear regression models) over the entire 12-month period for an "average" participant. The 95% confidence intervals (CIs) around the adjusted ORs and adjusted mean differences and the corresponding *P* values were also computed. To obtain adjusted means and mean differences, models were repeatedly estimated from the bootstrap samples where

samples were drawn with replacement at the level of the participant. For each model, adjusted means were calculated and standard errors were then calculated from the collection of bootstrap results.[41] Percentage of relative change for continuous variables was computed as the difference between the adjusted means for each condition divided by the adjusted mean for the comparison condition. Percentage of relative change provides a common measure of the magnitude of change across different scale measures relative to the baseline measure. Analyses were performed using STATA statistical software, version 8 (Stata Corp, College Station, Tex), and SAS, version 8 (SAS Institute Inc, Cary, NC).

RESULTS

Baseline

Of the 522 participants randomized, 251 were allocated to the HIV intervention and 271 to the general health promotion condition. At baseline, significant differences were observed for several variables associated with HIV sexual behaviors and were included as covariates in subsequent analyses.[7,42-46] No differences were observed for sociodemographic characteristics, the primary outcome measure, or other outcome measures (**TABLE 1**).

Quality Assurance

Trained monitors attended all study sessions and rated the fidelity of implementation to assess quality assurance.[47] Nearly 98% of the activities in each study condition were implemented with fidelity. Participants' attendance in each condition was high; 95.2% (n=239) completed all 4 intervention sessions and 94.5% (n=256) completed all 4 general health promotion sessions. Additionally, participants' confidential ratings of their satisfaction with the delivery and content of each session, assessed using a 5-point scale, indicated comparably high ratings between the HIV intervention (mean [SD], 4.82 [0.11]) and the general health promotion comparison (mean [SD], 4.76 [0.09]).

Attrition

Of the 251 participants allocated to the HIV intervention, 226 (90%) completed the 6-month assessment and 219 (87.3%) completed the 12-month assessment. Of the 271 participants allocated to the general health promotion condition, 243 (89.7%) completed the 6-month assessment and 241 (88.9%) completed the 12-month assessment (Figure). No differences in attrition were observed between study conditions at either the 6-month (*P*=.89) or 12-month (*P*=.56) assessment. Additionally, no differences between study conditions for sociodemographic characteristics were observed at either the 6- or 12-month assessment. Finally, no differences were observed in baseline variables for either study condition in participants retained in the trial compared with those unavailable for follow-up.

Effects of the HIV Intervention

Effects of the intervention on the primary outcome, consistent condom use, and other dichotomous outcomes are presented in TABLE 2. These analyses were performed separately at the 6-month assessment (baseline to 6-month assessment), at the 12-month assessment (6- to 12-month assessment), and over the entire 12-month period (baseline to 12-month assessment). Relative to participants in the general health promotion condition, participants in the HIV intervention were more likely to report using condoms consistently in the 30 days preceding the 6-month assessment (unadjusted analysis, intervention, 75.3% vs comparison, 58.2%; adjusted OR, 1.77; 95% CI, 0.97-3.20; *P*=.06) and the 12-month assessment (unadjusted analysis, intervention, 73.3% vs comparison, 56.5%; adjusted OR, 2.23; 95% CI, 1.17-4.27; *P*=.02) and over the entire 12-month period (adjusted OR, 2.01; 95% CI, 1.28-3.17; *P*=.003). Likewise, participants in the HIV intervention were more likely to report using condoms consistently during the 6 months prior to the 6-month assessment (unadjusted analysis, intervention, 61.3% vs comparison, 42.6%; adjusted OR, 2.48; 95% CI, 1.44-4.26; *P*=.001) and the 12-

month assessment (unadjusted analysis, intervention, 58.1% vs comparison, 45.3%; adjusted OR, 2.14; 95% CI, 1.20-3.84; *P*=.01) and over the entire 12-month period (adjusted OR, 2.30; 95% CI, 1.51-3.50; *P*<.001). Additionally, participants in the HIV intervention were more likely to report using a condom at

last vaginal sexual intercourse, less likely to self-report a pregnancy, and less likely to report having a new vaginal sex partner in the 30 days prior to assessments.

The effects of the HIV intervention on other measures of self-reported sexual behavior are presented in TABLE 3 and TABLE 4. Participants in the HIV inter-

Table 1. Comparability of the HIV Prevention and General Health Promotion Conditions*

Characteristics	HIV Prevention Intervention (n = 251)	General Health Promotion Condition (n = 271)
Sociodemographics		
Age, mean (SD), y	15.99 (1.25)	15.97 (1.21)
Did not complete 10th grade	115 (45.8)	132 (48.7)
Recipient of public assistance	45 (17.9)	50 (18.5)
Living in single-parent home	146 (74.1)	162 (72.3)
Living with someone other than a parent	54 (21.5)	47 (17.3)
Employed	40 (16.1)	53 (19.7)
Has children	60 (23.9)	63 (23.2)
Psychosocial mediators, mean (SD)†		
HIV knowledge	8.88 (3.25)	9.13 (3.03)
Condom attitudes	36.02 (4.22)	35.62 (4.42)
Condom barriers	42.23 (14.16)	43.13 (14.30)
Communication frequency	8.61 (4.10)	8.37 (4.50)
Condom use self-efficacy	30.74 (9.30)	30.52 (9.73)
Condom use skills	2.91 (1.30)	3.03 (1.18)
Sexual behaviors		
Percentage condom use in past 30 d, mean (SD)	79.23 (38)	77.47 (38)
Percentage condom use in past 6 mo, mean (SD)	72.44 (37)	70.38 (38)
Unprotected vaginal sex in past 30 d, mean (SD)	1.12 (2.84)	0.84 (2.01)
Unprotected vaginal sex in past 6 mo, mean (SD)	4.81 (16.01)	4.23 (10.25)
Put condom on partner in past 6 mo‡	1.49 (1.01)	1.46 (0.98)
Consistent condom use in past 30 d	60 (40.3)	75 (43.4)
Consistent condom use in past 6 mo	101 (43.5)	119 (48.6)
Condom use during last sex	74 (31.9)	79 (32.1)
Sexually transmitted diseases		
Positive for chlamydia	48 (19.2)	43 (15.9)
Positive for gonorrhea	14 (5.6)	13 (4.8)
Positive for trichomonas	33 (13.4)	33 (12.4)
Covariates		
Douching	73 (29.1)	98 (36.2)
Gang involvement	42 (16.8)	32 (12.0)
Depression§	126 (50.2)	119 (43.9)
Pregnancy desire	82 (32.7)	73 (26.9)
New partner in past 30 d	11 (4.4)	20 (7.4)
Consumed alcohol in past 30 d	65 (25.9)	58 (21.4)
Currently not attending school	25 (10.0)	24 (8.9)
Age of first nonconsensual sex, mean (SD), y‖	13.4 (2.5)	13.7 (2.8)

Abbreviation: HIV, human immunodeficiency virus.
*Data are expressed as No. (%) of participants unless otherwise noted.
†Psychosocial mediator data, except condom use skills, are based on scale scores. See "Psychosocial Mediators of Sexual Behavior" in the text for a description of the scales and their psychometrics.
‡Response categories ranged from 1 ("never") to 5 ("every time").
§Depression was assessed using the Center for Epidemiologic Studies–Depression inventory brief version (8 items). Scores ranged from 0 to 24 and the established scale cutoff was used to categorize participants as either depressed or not depressed (≥7 = depressed; <7 = not depressed).
‖Percentages reporting nonconsensual sex in the intervention and the comparison conditions were, respectively, 13.3% and 14.3%.

vention were more likely to report a significantly higher percentage of condom-protected sex acts in the 30 days and in the 6 months preceding the 6- and the 12-month assessments and over the entire 12-month period. Additionally, participants in the HIV intervention reported significantly fewer unprotected vaginal intercourse episodes in the 30 days and in the 6 months preceding the 6- and the 12-month assessments and over the entire 12-month period. Furthermore, participants in the HIV intervention reported a higher frequency of putting condoms on their partners at the 6- and 12-month assessments and over the entire 12-month period.

Effects of the HIV intervention on incident STDs were also assessed. The crude STD incidence, by condition, was calculated for chlamydia (intervention, 2.1 vs comparison, 2.0 per 100 person-months), trichomonas (intervention, 0.9 vs comparison, 1.2 per 100 person-months), and gonorrhea (intervention, 0.9 vs comparison, 0.7 per 100 person-months). Results of GEE STD-specific analyses over the entire 12-month follow-up period, adjusting for the corresponding baseline variable and covariates, suggest a treatment advantage in reducing chlamydia infections (OR, 0.17; 95% CI, 0.03-0.92; P = .04). Intervention ef-

fects were not observed for trichomonas (OR, 0.37; 95% CI, 0.09-1.46; P = .16) or gonorrhea (OR, 0.14; 95% CI, 0.01-3.02; P = .21). The intervention effects reflect adjusted analyses. These findings may result from the relatively small number of incident STDs and missing data for some covariates, which affect the precision and stability of effect estimates.

The effects of the HIV intervention on empirically and theoretically derived psychosocial mediators of HIV-preventive behavior are presented in TABLE 5 and TABLE 6. In general, participants in the HIV intervention reported fewer perceived partner-

Table 2. Effects of the HIV Intervention on Self-reported Consistent Condom Use, Condom Use During Last Sex, Having a New Sex Partner, and Pregnancy

| | 6-Month Assessment | | | | 12-Month Assessment | | | | GEE Model, Baseline to 12-Month Assessment | |
| | Unadjusted, % | | | | Unadjusted, % | | | | | |
	Intervention	Comparison	OR (95% CI)*	P Value	Intervention	Comparison	OR (95% CI)*	P Value	OR (95% CI)	P Value
Consistent condom use in past 30 d	75.3	58.2	1.77 (0.97-3.20)	.06	73.3	56.5	2.23 (1.17-4.27)	.02	2.01 (1.28-3.17)	.003
Consistent condom use in past 6 mo	61.3	42.6	2.48 (1.44-4.26)	.001	58.1	45.3	2.14 (1.20-3.84)	.01	2.30 (1.51-3.50)	<.001
Condom use during last sex	80.7	54.1	5.08 (2.83-9.14)	<.001	72.3	53.9	3.32 (1.86-5.92)	<.001	3.94 (2.58-6.03)	<.001
New vaginal sex partner in past 30 d	2.7	7.4	0.29 (0.11-0.77)	.01	3.6	5.6	0.59 (0.19-1.84)	.36	0.40 (0.19-0.82)	.01
Self-reported pregnancy	3.6	7.0	0.38 (0.15-0.36)	.04	6.0	8.5	0.74 (0.30-1.82)	.52	0.53 (0.27-1.03)	.06

Abbreviations: CI, confidence interval; GEE, generalized estimating equation; HIV, human immunodeficiency virus; OR, odds ratio.
*Odds ratios were adjusted by the baseline value of the outcome variable and covariates (douching, gang involvement, depression, pregnancy desire, and having a new sex partner in the past 30 days).

Table 3. Effects of the HIV Intervention on Other Measures of Sexual Behavior, 6- and 12-Month Assessments

| | 6-Month Assessment | | | | | 12-Month Assessment | | | | |
| | Unadjusted Mean (SD) | | Adjusted Mean Difference (95% CI)* | Relative Change, % (95% CI)† | P Value | Unadjusted Mean (SD) | | Adjusted Mean Difference (95% CI)* | Relative Change, % (95% CI)† | P Value |
	I	C				I	C			
% Condom use in last 30 d	84.93 (30.80)	65.12 (44.30)	18.38 (10.47 to 25.45)	26.08 (13.82 to 39.39)	<.001	79.97 (36.64)	62.82 (45.28)	21.09 (10.73 to 32.20)	36.02 (16.58 to 61.03)	<.001
% Condom use in last 6 mo	82.29 (30.24)	61.65 (40.70)	17.33 (10.26 to 24.39)	23.11 (12.33 to 35.22)	<.001	73.49 (37.86)	57.58 (43.21)	18.33 (9.46 to 29.86)	26.65 (12.54 to 48.46)	.001
Episodes of unprotected vaginal sex in last 30 d	1.02 (3.37)	2.02 (4.26)	−1.06 (−1.82 to 0.27)	−50.69 (−72.75 to −15.83)	.046	1.15 (3.03)	2.04 (4.47)	−1.06 (−1.86 to 0.44)	−39.26 (−59.18 to 1.96)	.002
Episodes of unprotected vaginal sex in last 6 mo	3.77 (11.68)	9.24 (23.08)	−6.51 (−10.97 to −2.90)	−64.23 (−82.68 to −38.31)	.006	5.77 (16.41)	10.25 (24.66)	−5.51 (−11.18 to −0.34)	−39.31 (−65.72 to −10.18)	.02
Frequency of applying condoms on sex partners	2.18 (1.38)	1.51 (1.09)	0.69 (0.42 to 0.92)	45.99 (24.66 to 63.86)	<.001	1.97 (1.28)	1.59 (1.09)	0.44 (0.19 to 0.77)	28.39 (12.51 to 54.71)	.003

Abbreviations: C, comparison condition; CI, confidence interval; GEE, generalized estimating equation; HIV, human immunodeficiency virus; I, intervention condition.
*Mean difference between the intervention and comparison conditions, adjusted by the baseline value of the outcome variable and covariates (douching, gang involvement, depression, pregnancy desire, and having a new sex partner in past 30 days).
†Relative change = adjusted mean difference/adjusted comparison condition mean × 100%.

related barriers to condom use, more favorable attitudes toward using condoms, more frequent discussions with male sex partners about HIV prevention, higher condom use self-efficacy scores, and higher HIV prevention knowledge scores; in addition, they demonstrated greater proficiency in using condoms at the 6- and the 12-month assessments and over the entire 12-month period.

COMMENT

While other studies have shown that self-reported sexual risk behaviors can be reduced in adolescents, this is the first trial, to our knowledge, demonstrating that an HIV intervention can result in substantial reductions in sexual risk behaviors, including acquisition of a new male sex partner, and markedly enhance theoretically important mediators and skills associated with HIV-preventive behaviors among sexually experienced African American adolescent girls. Promising intervention effects were also observed for self-reported pregnancy and laboratory-confirmed chlamydia. Because STDs, particularly chlamydia, are prevalent among adolescents[48] and facilitate HIV transmission,[49,50] even small reductions in incidence could result in considerable reductions in treatment costs as well as sizable reductions in HIV

morbidity[51] and its associated treatment costs.[52] Furthermore, mathematical modeling studies suggest that reductions in incident chlamydia infections may be one of the most promising surrogate markers for HIV incidence in prevention trials.[53]

The efficacy of the HIV intervention may be attributable partly to the gender-tailored framework that highlighted the underlying social processes, such as the dyadic nature of sexual interactions, relationship power, and emotional commitment that may promote and reinforce risk behaviors. Conceptualizing HIV prevention within the broader context of a healthy relationship also marshaled new intervention strategies and offered new options for creating behavior change. Additionally, the thematic focus of the intervention, "Stay Safe for Yourself and Your Community," was designed to promote a sense of solidarity and ethnic pride among participants and may have inspired them to modify risk behaviors for altruistic motives: by enhancing their health, they were also enhancing the health of the African American community.

The present study has a number of methodological strengths. Foremost is the use of a randomized controlled trial design that includes a dose-equivalent comparison condition to minimize Hawthorne effects. Another methodological strength is the use of STDs and directly observed condom skills to complement self-reported behavior change.[47,54,55] However, STDs and self-reported behavior change are relatively independent measures for evaluating the efficacy of HIV interventions, and modifying sexual behavior may not necessarily result in reductions in STD

Table 4. Effects of the HIV Intervention on Other Measures of Sexual Behavior, GEE Model, Baseline to 12-Month Assessment

	Adjusted Mean Difference (95% CI)	Relative Change, % (95% CI)	P Value
% Condom use in last 30 d	21.09 (13.70 to 28.48)	36.07 (20.10 to 52.04)	<.001
% Condom use in last 6 mo	25.07 (19.89 to 30.25)	46.95 (33.96 to 59.94)	<.001
Unprotected vaginal sex in last 30 d	−1.17 (−1.88 to −0.45)	−45.43 (−65.85 to −25.02)	.001
Unprotected vaginal sex in last 6 mo	−7.15 (−11.38 to −2.93)	−56.24 (−77.15 to −35.32)	.001
Frequency of applying condoms on sex partners	0.58 (0.37 to 0.78)	37.76 (22.88 to 52.63)	<.001

Abbreviations: CI, confidence interval; GEE, generalized estimating equation; HIV, human immunodeficiency virus.

Table 5. Effects of the HIV Intervention on Psychosocial Mediators of Preventive Behavior, 6- and 12-Month Assessments*

	6-Month Assessment					12-Month Assessment				
	Unadjusted Mean (SD)		Adjusted Mean Difference (95% CI)†	Relative Change, % (95% CI)‡	P Value	Unadjusted Mean (SD)		Adjusted Mean Difference (95% CI)†	Relative Change, % (95% CI)‡	P Value
	I	C				I	C			
HIV knowledge	11.27 (2.72)	9.62 (3.29)	1.80 (1.34 to 2.42)	18.94 (13.70 to 27.46)	<.001	11.21 (2.89)	9.96 (3.20)	0.84 (0.28 to 1.50)	8.07 (2.35 to 14.79)	<.001
Condom attitudes	37.33 (3.28)	35.97 (4.37)	1.27 (0.52 to 1.84)	3.52 (1.42 to 5.09)	<.001	36.93 (3.91)	36.18 (4.00)	0.91 (0.08 to 1.67)	2.51 (0.21 to 4.64)	.008
Condom barriers	36.82 (13.07)	41.00 (15.19)	−4.81 (−7.03 to −2.22)	−11.64 (−16.61 to −5.74)	.003	37.21 (14.25)	40.08 (13.95)	−2.67 (−5.81 to −0.33)	−6.55 (−13.59 to −1.71)	.10
Communication frequency	9.44 (4.25)	8.30 (4.73)	1.27 (−0.29 to 2.28)	15.58 (3.13 to 29.32)	.007	8.95 (4.50)	7.97 (4.76)	1.15 (0.11 to 2.07)	14.87 (1.29 to 28.67)	.02
Condom use self-efficacy	36.51 (8.96)	32.58 (9.48)	4.25 (2.70 to 5.86)	13.15 (8.02 to 18.32)	<.001	37.35 (8.89)	34.26 (8.96)	3.65 (1.94 to 5.91)	10.38 (5.39 to 17.45)	<.001
Condom use skills§	4.40 (0.97)	3.32 (1.21)	1.13 (0.96 to 1.32)	34.17 (27.91 to 40.98)	<.001	4.34 (1.06)	3.50 (1.20)	0.97 (0.69 to 1.23)	27.78 (19.58 to 36.25)	<.001

Abbreviations: C, comparison condition; CI, confidence interval; GEE, generalized estimating equation; HIV, human immunodeficiency virus; I, intervention condition.
*Psychosocial mediators are based on scale scores. See "Psychosocial Mediators of Sexual Behavior" in the text for a description of the scales and their psychometrics.
†Mean difference between the intervention and comparison conditions, adjusted by the baseline value of the outcome variable and covariates (douching, gang involvement, depression, pregnancy desire, and having a new sex partner in past 30 days).
‡Relative change = adjusted mean difference/adjusted comparison condition mean × 100%.
§Participants completed a directly observed condom skills demonstration, rated using a structured scoring protocol, to assess ability to correctly apply condoms. Ratings ranged from 0 to 6, with higher ratings reflecting greater proficiency at applying condoms.

Table 6. Effects of the HIV Intervention on Psychosocial Mediators of Preventive Behavior, GEE Model, Baseline to 12-Month Assessment*

	Adjusted Mean Difference (95% CI)	Relative Change, % (95% CI)	P Value
HIV knowledge	1.45 (1.04 to 1.87)	14.79 (10.27 to 19.31)	<.001
Condom attitudes	1.18 (0.65 to 1.71)	3.28 (1.76 to 4.79)	<.001
Condom barriers	−4.57 (−6.66 to −2.48)	−10.85 (−15.50 to −6.20)	.002
Communication frequency	1.24 (0.70 to 1.77)	15.54 (8.31 to 22.77)	.001
Condom use self-efficacy	3.93 (2.60 to 5.25)	11.80 (7.61 to 15.99)	<.001
Condom use skills†	1.06 (.88 to 1.25)	31.72 (24.97 to 38.47)	<.001

Abbreviations: CI, confidence interval; GEE, generalized estimating equation; HIV, human immunodeficiency virus.
*Psychosocial mediators are based on scale scores. See "Psychosocial Mediators of Sexual Behavior" in the text for a description of the scales and their psychometrics.
†Participants completed a directly observed condom skills demonstration, rated using a structured scoring protocol, to assess ability to correctly apply condoms. Ratings ranged from 0 to 6, with higher ratings reflecting greater proficiency at applying condoms.

incidence.[56,57] Thus, rather than solely relying on any single measure, it is the weight of empirical evidence assessing the magnitude and consistency of intervention effects across the range of outcomes that is critical for adequately evaluating the efficacy of HIV interventions.

This study is not without limitations. First, the findings may not be applicable to African American adolescent girls with different sociodemographic characteristics or risk profiles. A second methodological concern is the reliability of self-reported outcome measures. Previous research has, however, established the validity and reliability of self-reported sexual behavior,[58-60] specifically for young African American women.[61,62] Third, incident STDs as outcomes represent a methodological improvement; however, the statistical power and precision of the effect estimates may be limited by small sample sizes, missing data, or number of incident infections. Future studies using STDs, particularly as the primary outcome, will require larger samples, longer follow-up, or samples that have a higher incidence of infection to yield more precise and stable effect estimates.[63,64]

CONCLUSION

Overall, the observed magnitude, consistency, and scope of effects strengthen confidence in the efficacy of the HIV intervention. Collectively, the research literature indicates that HIV prevention interventions for adolescents can be efficacious. However, it may be more difficult to change sexual risk behaviors among sexually experienced adolescents than among samples containing both sexually experienced and non–sexually experienced youth.[12] More intensive interventions may be necessary to motivate health-promoting behavior change among those who are sexually experienced. Thus, new and innovative intervention research is critical to optimizing HIV prevention effectiveness tailored for diverse adolescent populations, particularly high-risk youth.[16,65-69]

In response to the growing HIV epidemic among adolescents, there is a clear, cogent, and compelling urgency to develop and implement prevention interventions. Ultimately, to be optimally effective, the primary prevention of HIV among adolescents must emerge from the stigma of a hidden epidemic and become a public health priority. Only then will prevention research realize its potential and its promise of reducing the impact of the HIV epidemic among adolescents.

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