

# Efficacy of Sexually Transmitted Disease/Human Immunodeficiency Virus Sexual Risk–Reduction Intervention for African American Adolescent Females Seeking Sexual Health Services

## *A Randomized Controlled Trial*

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**Objectives:** To evaluate the efficacy of an intervention to reduce incident sexually transmitted disease (STD) and enhance STD/human immunodeficiency virus (HIV)–preventive behaviors and psychosocial mediators.

**Design:** A randomized controlled trial of an HIV prevention program.

**Setting:** Clinic-based sample in Atlanta, Georgia.

**Participants:** African American adolescent females (N=715), aged 15 to 21 years, seeking sexual health services. Participants completed an audio computer-assisted self-interview and provided self-collected vaginal specimens for STD testing.

**Intervention:** Intervention participants received two 4-hour group sessions and 4 telephone contacts over a 12-month period, targeting personal, relational, socio-cultural, and structural factors associated with adolescents' STD/HIV risk, and were given vouchers facilitating male partners' STD testing/treatment.

**Main Outcome Measure:** Incident chlamydial infections.

**Results:** Over the 12-month follow-up, fewer adolescents in the intervention had a chlamydial infection (42 vs 67; risk ratio [RR], 0.65; 95% confidence interval [CI], 0.42 to 0.98;  $P=.04$ ) or recurrent chlamydial infection (4 vs 14; RR, 0.25; 95% CI, 0.08 to 0.83;  $P=.02$ ). Adolescents in the intervention also reported a higher proportion of condom-protected sex acts in the 60 days preceding follow-up assessments (mean difference, 10.84; 95% CI, 5.27 to 16.42;  $P<.001$ ) and less frequent douching (mean difference,  $-0.76$ ; 95% CI,  $-1.15$  to  $-0.37$ ;  $P=.001$ ). Adolescents in the intervention were also more likely to report consistent condom use in the 60 days preceding follow-up assessments (RR, 1.41; 95% CI, 1.09 to 1.80;  $P=.01$ ) and condom use at last intercourse (RR, 1.30; 95% CI, 1.09 to 1.54;  $P=.005$ ). Intervention effects were observed for psychosocial mediators of STD/HIV–preventive behaviors.

**Conclusion:** Interventions for African American adolescent females can reduce chlamydial infections and enhance STD/HIV–preventive behaviors and psychosocial mediators of STD/HIV–preventive behaviors.

**Trial Registration:** clinicaltrials.gov Identifier: NCT00633906

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**A**MONG ADOLESCENTS, A PERSISTENT health disparity has been the disproportionate impact of sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV) infection, on African American adolescent females.<sup>1-4</sup> A subpopulation at higher risk for STD/HIV infection may be African American adolescent females seeking sexual health services, given their high STD rates, recurrent infections,<sup>5-8</sup> and lack of adop-

tion of STD/HIV–preventive strategies.<sup>9</sup> This subpopulation may be particularly vulnerable to HIV infection attributable

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to increased biological susceptibility associated with STDs.<sup>10-13</sup> Given the marked racial disparity in STDs and HIV, there is a clear and compelling urgency to develop risk-reduction interventions for this population.

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Factors affecting STD and HIV infection rates among African American adolescent females are complex, multifactorial, and not fully understood. Individual-level risk behaviors do not fully account for observed differences in STD/HIV. Social factors, such as sexual networks and partner concurrency, may facilitate the spread of STD/HIV in this population, and sociocultural factors, such as poverty; lack of access to STD treatment<sup>14</sup>; residing in the southern United States, a region with a high prevalence of STDs and HIV<sup>15-20</sup>; and some hygienic practices (eg, douching),<sup>21</sup> may be important determinants of STD/HIV infection. To address these factors, interventions targeting broader social factors have been advocated.<sup>14,22</sup>

Several STD/HIV interventions are available for adolescents, including minority adolescents<sup>23-37</sup> and lower-risk African American adolescent females.<sup>38</sup> However, caution is warranted in generalizing intervention effects from studies with lower-risk and racially diverse samples to a sample of high-risk African American adolescent females seeking sexual health services, a population for which few interventions have demonstrated effectiveness in reducing STDs and STD/HIV-associated sexual behaviors.<sup>34,35</sup> Moreover, most interventions focus on modifying individual-level risk factors such as STD/HIV knowledge, perceived risk and severity of STD/HIV, and condom skills.<sup>36</sup> However, for high-risk African American adolescent females, interventions that target a broader range of risk factors, such as personal, relational, sociocultural, and structural factors, may be more effective.<sup>14,39-43</sup>

The objective of the present study was to evaluate the efficacy of a gender- and culturally tailored STD/HIV intervention for African American adolescent females seeking sexual health services in the southern United States.

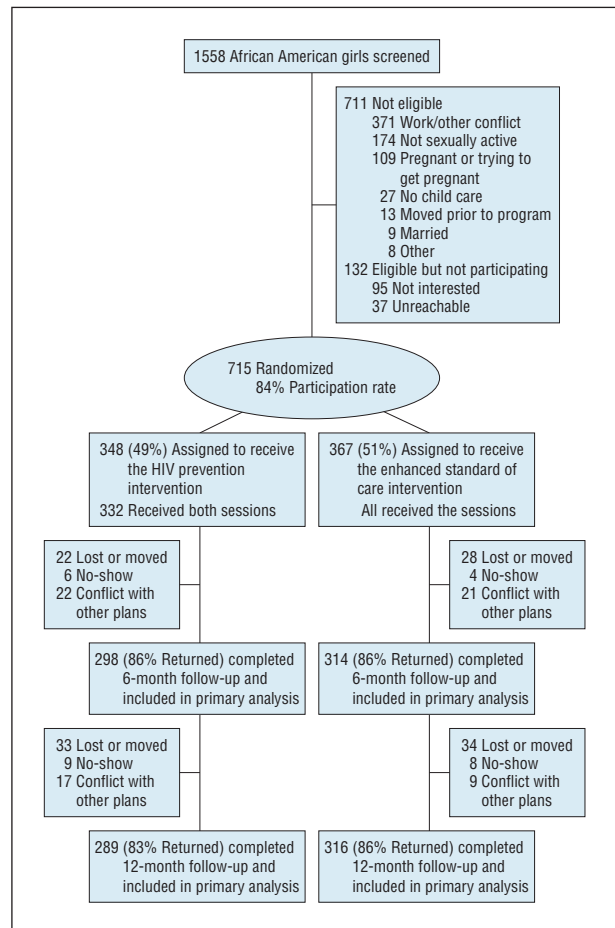
## METHODS

### PARTICIPANTS

From March 2002 to August 2004, African American adolescent females, 15 to 21 years of age (mean [SD], 17.8 [1.72] years), were recruited from 3 clinics in downtown Atlanta, Georgia, providing sexual health services to predominantly inner-city adolescents. A young African American woman recruiter approached adolescents in the clinic waiting area, described the study, solicited participation, and assessed eligibility. Eligibility criteria included self-identifying as African American, age 15 to 21 years, and reporting vaginal intercourse in the past 60 days. Adolescents who were married, currently pregnant, or attempting to become pregnant were excluded from the study. Adolescents returned to the clinic to complete informed consent procedures and baseline assessments and be randomized to trial conditions. Written informed consent was obtained from all adolescents, with parental consent waived for those younger than 18 years because of the confidential nature of clinic services. Of the eligible adolescents, 84.4% (N=715) enrolled in the study, completed baseline assessments, and were randomized to study conditions (**Figure**). Participants were compensated \$50 for travel and child care to attend intervention sessions and complete assessments. The Emory University institutional review board approved all study protocols.

### STUDY PROCEDURES

The study used a 2-arm randomized controlled trial design. Assignment to study conditions was implemented subsequent to



**Figure.** Participant allocation to trial study conditions. HIV indicates human immunodeficiency virus.

baseline assessment using concealment of allocation procedures, defined by protocol and compliant with published recommendations.<sup>44-46</sup> Prior to enrollment, investigators used a computer algorithm to generate a random allocation sequence and opaque envelopes to execute the assignments.

### INTERVENTION METHODS

Prior to developing the study conditions, extensive qualitative research was conducted with adolescents from the study clinics. Prior to implementing the main trial, both conditions were field tested with adolescents recruited from study clinics to assess the gender and cultural appropriateness of the intervention, the comparison condition, and assessment procedures.

The intervention (HORIZONS) consisted of 3 components: (1) administering two 4-hour group STD/HIV prevention sessions, (2) providing vouchers to participants to give to their male sexual partners to facilitate access to STD screening/treatment, and (3) administering 4 brief telephone contacts to reinforce prevention information presented in group sessions.

Two 4-hour group sessions were each facilitated by trained African American women health educators, implemented on 2 consecutive Saturdays with, on average, 8 participants attending each session. The intervention was based on Social Cognitive Theory,<sup>47</sup> the Theory of Gender and Power,<sup>48,49</sup> and previously published interventions for adolescent females seeking clinical services.<sup>38</sup> Intervention sessions were interactive, fostered a sense of cultural and gender pride, and emphasized diverse factors contributing to adolescents' STD/HIV risk, in-

cluding individual factors (STD/HIV risk–reduction knowledge, perceived peer norms supportive of condom use, condom use skills), relational factors (persuasive communication techniques to enhance male partner responsibility for condom use<sup>50</sup>), sociocultural factors (encouraged participants to reduce douching), and structural factors (to facilitate male partners accessing STD services, participants received \$20 vouchers redeemable by their male partner[s] toward the cost of STD services). Participants also role-played informing male sex partners about their STD status and encouraging partners to seek STD screening/treatment. To reinforce prevention concepts discussed in group sessions, health educators administered 4 brief (15-minute) telephone contacts to adolescents: 1 contact 3 to 4 weeks following completion of the baseline assessment, a second contact 10 to 12 weeks following baseline assessment, a third contact 3 to 4 weeks following the 6-month follow-up assessment, and a final contact 10 to 12 weeks following the 6-month follow-up assessment.

The enhanced usual care comparison condition was a 1-hour group session, implemented by an African American woman health educator, consisting of a culturally and gender-appropriate STD/HIV prevention video, a question-and-answer session, and a group discussion. Participants also received telephone contacts on the same schedule as intervention participants but only to update locator information; no additional STD/HIV prevention education was provided.

Data collection occurred at baseline and 6 and 12 months following completion of the 2-session group-implemented STD/HIV intervention and consisted of an audio computer-assisted self-interview (ACASI) and self-collected vaginal swabs to assess STDs.

The ACASI technology enhances data accuracy, increases participants' comfort answering sexually explicit questions, and eliminates low literacy as a potential barrier.<sup>51,52</sup> The ACASI assessed sociodemographics, sexual history, attitudes, and psychosocial constructs associated with STD/HIV–preventive behaviors. Sexual behaviors were assessed for 2 periods, the 14 days and the 60 days preceding assessments. Several strategies were used to enhance accuracy and validity of self-reported sexual behaviors, included reporting behaviors over relatively brief intervals<sup>33</sup> and using the Timeline Followback method, an effective method to facilitate retrospective recall of STD/HIV sexual behaviors.<sup>54,55</sup> To enhance confidentiality, participants were informed that code numbers would be used on all records. To minimize potential assessment bias, ACASI monitors were blind to participants' condition assignment.

After completing the ACASI, participants provided 2 self-collected vaginal swab specimens.<sup>56</sup> Specimens were delivered to the Emory University Pathology Laboratory. One specimen was assayed for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. Initially, *C trachomatis* and *N gonorrhoeae* were assayed using the Abbott LCx Probe System (Abbott Laboratories, Abbot Park, Illinois).<sup>57-59</sup> In September 2002, this assay was discontinued and all subsequent testing used the BD ProbeTec ET *C trachomatis* and *N gonorrhoeae* Amplified DNA assay (Becton Dickinson and Company, Sparks, Maryland).<sup>60</sup> The second specimen was tested for *Trichomonas vaginalis* using a noncommercial real-time polymerase chain reaction assay.<sup>61</sup> Participants with a positive STD test result received directly observable single-dose antimicrobial treatment and 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.

## OUTCOME MEASURES

Intervention efficacy was assessed using both biological and behavioral outcomes.<sup>62,63</sup>

## Primary Biological Outcome

The primary biological outcome was number of incident chlamydial infections in adolescents at the 6- and 12-month assessment, defined as (1) a laboratory-confirmed test result for *Chlamydia* that was preceded by a negative test result or (2) a laboratory-confirmed test result for *Chlamydia* preceded by documented treatment with effective single-dose antibiotics. Chlamydia was selected as the primary outcome based on modeling studies suggesting that reductions in *Chlamydia* infections may be a promising surrogate marker for HIV incidence in prevention trials<sup>64</sup> and its higher prevalence and incidence compared with other treatable infections. Other STDs assessed included gonorrhea and trichomoniasis. These STDs were selected because they are reliably assessed and effectively treated with single-dose antimicrobial therapy.

## Behavioral Outcome Measures

The primary behavioral outcome was the proportion of condom-protected sex acts in the 60 days prior to the 6- and 12-month assessments, a measure frequently used to evaluate STD/HIV interventions.<sup>34,35</sup> This outcome was calculated as the number of times a condom was used during vaginal intercourse divided by the total number of vaginal intercourse occasions. Other behaviors assessed included number of lifetime sexual partners, condom use at last sex, consistent condom use, and frequency of douching. Consistent condom use (using a condom on every sexual episode) was selected based on its effectiveness in reducing STD/HIV.<sup>65-67</sup> Douching was selected based on evidence suggesting it may enhance STD vulnerability.<sup>21</sup>

## Psychosocial Constructs Associated With STD/HIV–Preventive Behaviors

Psychosocial constructs associated with STD/HIV–preventive behaviors were derived from the underlying theoretical frameworks, our qualitative research, and a review of the empirical literature. Constructs were assessed using scales with satisfactory psychometric properties previously used with African American adolescent females.<sup>68</sup> Knowledge of STD/HIV prevention was measured using an 11-item index. Condom use self-efficacy was measured using a 9-item scale ( $\alpha = .86$ ). Communication frequency with male partners about safer sex was assessed using a 6-item scale ( $\alpha = .83$ ).

## STATISTICAL METHODS

We projected an intervention effect of 20% reduction in incident chlamydial infections over the 12-month follow-up period. Using methods outlined in Rochon<sup>69</sup> for repeated measurements, and estimating a 20% correlation between measurements and 80% retention at the 6- and 12-month assessments and setting the type I error rate at 0.05 for a 2-tailed test, with power=0.80, required enrolling 700 participants to detect this effect size.

Analyses were performed only on prespecified hypotheses using an intention-to-treat protocol with participants analyzed in their original assigned study conditions irrespective of the number of sessions attended.<sup>70,71</sup> At baseline, descriptive statistics summarized sociodemographic variables, psychosocial constructs associated with STD/HIV–preventive behaviors, sexual behaviors, and STD prevalence between study conditions. Differences were assessed using *t* tests for continuous variables and  $\chi^2$  analyses for categorical variables.<sup>72</sup> Variables in which differences approached statistical significance or that were theoretically or empirically identified as

potential confounders were included as covariates in the models.

The intervention effects investigation for each of the two 6-month assessment periods (baseline to 6 months and 6 to 12 months) used logistic regression to compute adjusted odds ratios (ORs) for dichotomous outcomes<sup>73</sup> and linear regression<sup>74</sup> 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 intervention effects for the entire 12-month follow-up period, logistic and linear generalized estimating equations regression models controlled for repeated within-subject measurements.<sup>75,76</sup> These models allow for a differential number of repeated observations of study participants over the longitudinal course of a study. Fitted models were adjusted for the corresponding baseline measure 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 time was included in the model to capture any unaccounted temporal effects, and an indicator for site and cohort were included to adjust for clustering; no time-dependent variables affected by treatment were included. Estimated generalized estimating equations regression coefficients were 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 interval (CI) around the adjusted ORs and adjusted mean differences, and corresponding *P* value, were also computed. Odds ratios were converted to risk ratios (RRs) for interpretation and discussion.

To obtain standard errors for adjusted (least squares) means and mean differences, models were repeatedly estimated from bootstrap samples drawn with replacement at the level of the participant. For each bootstrap sample, adjusted (least squares) means were calculated and then standard errors were calculated from the collection of bootstrap results.<sup>77</sup> Percentage of relative change for continuous variables was computed as the difference between the adjusted means for each condition (mean difference) divided by the adjusted mean for the comparison condition. Percentage of relative change provides a common metric for measuring the magnitude of change across different measures relative to the baseline measure. Analyses were performed using Stata statistical software (version 10; StataCorp, College Station, Texas).

## RESULTS

### BASELINE

Baseline assessments indicated a high prevalence of STD/HIV-associated sexual behaviors and STDs. On average, adolescents reported 9 lifetime sex partners and 13 episodes of vaginal sex in the previous 60 days, with only 21.7% reporting consistent condom use and 43% using a condom at last sex. Approximately 46% had an STD, with *Chlamydia* (30.3%) having a higher prevalence relative to trichomoniasis (19.3%; *P* < .001) and gonorrhea (13.8%; *P* < .001).

Of the 715 adolescents randomized, 348 were allocated to the intervention and 367, to the comparison condition (*P* = .48). To control for differences on key variables between study conditions at baseline, these variables were included as covariates in subsequent analyses (**Table 1**).

## QUALITY ASSURANCE

All participants assigned to the comparison condition received the STD/HIV prevention education session; 95% of participants assigned to the STD/HIV intervention condition received both group sessions of the intervention. Participants provided anonymous ratings of the study conditions for satisfaction with session delivery and value of session content using a 5-point Likert scale. Both conditions received comparably high ratings. Trained monitors attended all intervention and comparison condition sessions and, based on a standardized checklist, rated fidelity of implementation as high. Sixty-five percent of telephone contacts in the intervention were completed.

### RETENTION

Retention was comparable between study conditions (Figure). Overall, 91% of participants completed at least 1 follow-up assessment; rates for the intervention and comparison condition were, respectively, 91.4% and 91.3% (*P* = .96). No differences in retention were observed between study conditions at the 6-month (*P* = .98) or 12-month (*P* = .28) assessment. Additionally, no differences between study conditions were observed for sociodemographic characteristics at the 6- or 12-month assessment. Separate analyses for each study condition observed no differences on baseline variables for participants retained in the trial compared with those unavailable for follow-up.

### EFFECTS OF THE INTERVENTION

#### Intervention Effects on STD Incidence

Over the 12-month follow-up period, 42 adolescents in the intervention, compared with 67 adolescents in the comparison condition, had a chlamydial infection (RR, 0.65; 95% CI, 0.42 to 0.98; *P* = .04) (**Table 2**). Thus, adolescents in the intervention, relative to adolescents in the comparison condition, had, on average, a 35% lower risk of acquiring a chlamydial infection over the 12-month follow-up period.

Subset analyses examined intervention effects for recurrent chlamydial infections (positive test result at the 6- and 12-month assessment). Over the 12-month follow-up period, 18 adolescents had recurrent infections, 14 in the comparison condition and 4 in the intervention condition (RR, 0.25; 95% CI, 0.08 to 0.83; *P* = .02).

Fewer adolescents in the intervention, relative to the comparison condition, were observed with laboratory-confirmed incident gonorrhea (23 vs 25) or trichomoniasis (52 vs 57), though differences were not significant (RR<sub>gonorrhea</sub>, 0.85; 95% CI, 0.44 to 1.63; *P* = .62) and (RR<sub>trichomoniasis</sub>, 0.96; 95% CI, 0.59 to 1.54; *P* = .87).

#### Intervention Effects on Behavioral and Psychosocial Outcomes

Adolescents in the intervention, relative to the comparison condition, reported a higher proportion of condom-

**Table 1. Comparability Between Study Conditions at Baseline**

Characteristic	Mean (SD)		P Value
	STD/HIV Intervention (n=348)	Enhanced Standard of Care (n=367)	
<b>Sociodemographics</b>			
Age, y	17.79 (1.71)	17.78 (1.73)	.94
Currently in school, No. (%)	230 (66.1)	237 (64.6)	.67
Family aid index	0.78 (0.95)	0.91 (1.07)	.09
Poor neighborhood quality	0.58 (0.93)	0.62 (0.95)	.56
Employed, No. (%)	106 (30.5)	104 (28.3)	.53
Age of boyfriend, y	20.89 (4.32)	20.61 (4.21)	.42
Length of relationship, mo	15.30 (14.19)	15.11 (16.00)	.87
<b>Psychosocial mediators</b>			
Condom use self-efficacy	15.25 (6.51)	15.65 (6.53)	.41
Partner communication frequency	11.58 (4.55)	11.37 (4.09)	.51
Refusal self-efficacy	24.49 (4.04)	24.50 (3.62)	.97
Fear of condom negotiation	10.21 (4.29)	10.15 (4.13)	.86
STD/HIV prevention knowledge	19.10 (2.16)	19.13 (2.10)	.82
<b>Sexual behaviors</b>			
Condom use in past 14 d	50.42 (44)	53.29 (45)	.44
Condom use in past 60 d	51.00 (41)	52.22 (41)	.71
Consistent condom use in past 14 d, No. (%)	97 (35.1)	128 (41.6)	.11
Consistent condom use in past 60 d, No. (%)	69 (23.1)	86 (27.2)	.24
Condom use during last sex, No. (%)	152 (43.9)	153 (41.7)	.55
Sex partners generally ≥2 y older, No. (%)	214 (61.9)	245 (66.8)	.27
Casual sex partner, No. (%)	105 (30.2)	120 (32.7)	.47
In past 60 d, No. of times having sex while high	2.21 (7.46)	1.97 (5.00)	.62
In past 60 d, No. of vaginal sex partners	1.54 (1.38)	1.60 (1.44)	.56
In past 60 d, No. of times having vaginal sex	13.08 (16.63)	11.90 (14.36)	.36
<b>STD</b>			
Chlamydia	110 (31.6)	107 (29.2)	.48
Gonorrhea	51 (14.7)	48 (13.1)	.54
Trichomoniasis	72 (20.7)	60 (18.0)	.36
<b>Potential covariates</b>			
Depression, No. (%)	16.60 (7.11)	17.12 (7.19)	.33
Sexual adventurousness, No. (%)	17.41 (3.79)	17.65 (4.10)	.40
Social support, No. (%)	34.97 (6.85)	35.03 (6.22)	.90
Peer norms supporting risk, No. (%)	20.25 (4.92)	20.44 (4.80)	.61
Self-esteem, No. (%)	33.50 (5.29)	32.98 (5.39)	.19
Lifetime experience of emotional abuse, No. (%)	204 (58.6)	233 (63.5)	.18
Lifetime experience of physical abuse, No. (%)	160 (46.0)	177 (48.2)	.55
Lifetime experience of forced vaginal sex, No. (%)	91 (26.1)	86 (23.4)	.40
Emotional abuse by boyfriend in past 60 d (only for those with boyfriends and >18 y), No. (%)	34 (18.6)	57 (28.2)	.03
Physical abuse by boyfriend in past 60 d (only for those with boyfriends and >18 y), No. (%)	22 (12.0)	31 (15.3)	.34
No. of days using marijuana in past 60 d	12.06 (20.05)	10.42 (19.21)	.32
No. of days using alcohol in past 60 d	4.40 (9.37)	4.49 (9.33)	.90

Abbreviations: HIV, human immunodeficiency virus; STD, sexually transmitted disease.

**Table 2. Effects of the Intervention on *Chlamydia* Incidence Over the 12-Month Follow-up**

Crude Cumulative Incidence of Chlamydial Infections: Baseline to 12 Months				GEE Model: Baseline to 12 Months	
No. of Participants		Crude RR (95% CI)	P Value	RR <sup>a</sup> (95% CI)	P Value
I	C				
42	67	0.71 (0.50 to 1.02)	.059	0.65 (0.42 to 0.98)	.04

Abbreviations: C, comparison condition; CI, confidence interval; GEE, generalized estimating equations; I, intervention condition; RR, risk ratio.  
<sup>a</sup>Comparison condition is the referent for calculation of the RR.

protected sex acts for the 14 days preceding follow-up assessments (mean difference, 8.17; 95% CI, 1.22 to 15.12;  $P=.004$ ) and the 60 days preceding follow-up assess-

ments (mean difference, 10.84; 95% CI, 5.27 to 16.42;  $P<.001$ ) and a reduction in douching (mean difference, -0.76; 95% CI, -1.15 to -0.37;  $P=.001$ ) (**Table 3**).

**Table 3. Effects of the Intervention on Continuous Measures of HIV/STD-Associated Sexual Behaviors**

	6-Month Assessment					12-Month Assessment					GEE Model: Baseline to 12-Month Assessment		
	Unadjusted Mean		Adjusted MD <sup>a</sup> (95% CI)	% Relative Change <sup>b</sup> (95% CI)	P Value	Unadjusted Mean		Adjusted MD <sup>a</sup> (95% CI)	% Relative Change <sup>b</sup> (95% CI)	P Value	Adjusted MD (95% CI)	% Relative Change (95% CI)	P Value
	I	C				I	C						
Condom use in last 14 d, %	0.60	0.48	5.49 (-1.87 to 12.86)	10.91 (-4.12 to 25.94)	.057	0.61	0.47	12.79 (3.06 to 22.52)	27.06 (3.26 to 50.85)	.001	8.17 (1.22 to 15.12)	16.60 (1.40 to 31.81)	.004
Condom use in last 60 d, %	0.63	0.47	12.09 (5.64 to 18.55)	24.63 (10.03 to 39.23)	<.001	0.61	0.48	10.78 (3.61 to 17.95)	21.43 (5.15 to 37.71)	.002	10.84 (5.27 to 16.42)	21.55 (9.15 to 33.96)	<.001
Douching frequency in past 30 d	0.71	1.36	-0.91 (-1.56 to -0.26)	57.16 (31.75 to 82.60)	.01	0.45	1.17	-0.60 (-0.95 to -0.25)	53.47 (30.69 to 76.25)	.003	-0.76 (-1.15 to -0.37)	55.65 (37.06 to 74.24)	.001

Abbreviations: C, comparison condition; CI, confidence interval; HIV, human immunodeficiency virus; I, intervention condition; MD, mean difference; STD, sexually transmitted disease.

<sup>a</sup>Adjusted MD between the I and C. Adjusted by the baseline value of the outcome variable, cohort, time, and other covariates (government financial aid, having a boyfriend, history of emotional abuse).

<sup>b</sup>Percentage of relative change = [MD/C<sub>adjusted</sub> × 100%].

**Table 4. Effects of the Intervention on Categorical Measures of HIV/STD-Associated Sexual Behaviors**

	6-Month Assessment					12-Month Assessment					GEE Model: Baseline to 12-Month Assessment	
	Adjusted Proportion, %		RR <sup>a</sup> (95% CI)	P Value	Adjusted Proportion, %		RR <sup>a</sup> (95% CI)	P Value	RR (95% CI)	P Value		
	I	C			I	C						
Consistent condom use in past 14 d	40.2	39.0	1.22 (0.84-1.57)	.33	49.7	39.0	1.70 (1.09-1.95)	.01	1.29 (1.01-1.59)	.04		
Consistent condom use in past 60 d	31.9	28.2	1.37 (0.91-1.81)	.14	40.5	30.1	1.75 (1.13-2.09)	.007	1.41 (1.09-1.80)	.01		
Condom use at last sexual intercourse	51.9	43.5	1.36 (0.98-1.58)	.06	53.3	42.7	1.51 (1.06-1.68)	.01	1.30 (1.09-1.54)	.005		

Abbreviations: C, comparison condition; CI, confidence interval; GEE, generalized estimating equations; HIV, human immunodeficiency virus; I, intervention condition; RR, risk ratio; STD, sexually transmitted disease.

<sup>a</sup>Adjusted by baseline value of the outcome variable, cohort, time, and covariates (government financial aid, having a boyfriend, history of emotional abuse). Comparison condition is the referent for computing the RR.

Furthermore, adolescents in the intervention were more likely to report consistent condom use for the 14 days preceding follow-up assessments (RR, 1.29; 95% CI, 1.01 to 1.59;  $P = .04$ ) and the 60 days preceding follow-up assessments (RR, 1.41; 95% CI, 1.09 to 1.80;  $P = .01$ ) and were more likely to report condom use at last sexual intercourse occasion (RR, 1.30; 95% CI, 1.09 to 1.54;  $P = .005$ ) (**Table 4**). Intervention effects were also observed for 3 psychosocial constructs associated with STD/HIV-preventive behaviors (**Table 5**).

#### Subgroup Analyses Among Adolescents Detected With STDs

Subgroup analyses indicate that STD-positive adolescents in the intervention condition, relative to the comparison condition, were more likely to self-report notifying male sex partner(s) of their STD status (OR, 2.1; 95% CI, 0.9 to 4.88;  $P = .09$ ) and have male partners receive STD treatment (OR, 2.15; 95% CI, 1.07 to 4.31;  $P = .03$ ).

Vouchers were one risk-reduction strategy distributed only to the intervention participants. Analyses indicate that 9.7% of participants had male partners redeem vouchers for STD services. Among those whose male part-

ners redeemed vouchers, approximately 50% tested positive for an STD as part of our project. The fact that only half of male partners who redeemed vouchers had partners with a positive STD diagnosis was not surprising, as the intervention encouraged all young women, regardless of STD status, to advocate for partner STD screening.

#### COMMENT

The HIV and STD epidemics among African American individuals in the United States are interrelated health crises that reflect long-standing racial disparities. Responding to a threat of this magnitude requires interventions that go beyond focusing on individual-level risk factors, particularly when addressing the needs of high-risk adolescents. The present study designed and evaluated a combination STD/HIV intervention, addressing a broad array of factors that influence African American adolescent females' sexual risk behaviors. Overall, the findings demonstrate evidence of efficacy in reducing chlamydial infections and enhancing STD/HIV-preventive sexual behaviors and psychosocial constructs associated with STD/HIV-preventive behaviors. The range, mag-

**Table 5. Effects of the Intervention on Hypothesized Psychosocial Mediators of HIV/STD-Preventive Behavior**

	6-Month Assessment					12-Month Assessment					GEE Model: Baseline to 12-Month Assessment		
	Unadjusted Mean		Adjusted MD <sup>a</sup> (95% CI)	% Relative Change <sup>b</sup> (95% CI)	P Value	Unadjusted Proportion, %		Adjusted MD <sup>a</sup> (95% CI)	% Relative Change <sup>b</sup> (95% CI)	P Value	Adjusted MD (95% CI)	% Relative Change (95% CI)	P Value
	I	C				I	C						
	I	C	(95% CI)	(95% CI)	Value	I	C	(95% CI)	(95% CI)	Value	(95% CI)	(95% CI)	Value
Partner communication frequency	11.66	10.96	0.63 (-0.15 to 1.41)	5.72 (-1.40 to 12.84)	.04	11.34	10.90	0.55 (-0.10 to 1.19)	5.05 (-0.69 to 10.78)	.15	0.60 (0.01 to 1.20)	5.45 (-0.13 to 11.04)	.04
Condom use self-efficacy	41.19	40.25	1.10 (0.29 to 1.91)	2.73 (0.73 to 4.73)	.008	41.80	40.27	1.78 (0.92 to 2.65)	4.44 (2.21 to 6.66)	<.001	1.46 (0.79 to 2.14)	3.64 (1.93 to 5.35)	<.001
STD/HIV prevention knowledge	18.24	17.92	0.33 (0.80 to 0.57)	1.82 (0.43 to 3.22)	.002	20.28	19.70	0.51 (0.25 to 0.77)	2.59 (1.23 to 3.95)	<.001	0.40 (0.18 to 0.62)	2.13 (0.96 to 3.30)	<.001

Abbreviations: C, comparison condition; CI, confidence interval; GEE, generalized estimating equations; HIV, human immunodeficiency virus; I, intervention condition; MD, mean difference; STD, sexually transmitted disease.

<sup>a</sup>Adjusted MD between the I and C. Adjusted by the baseline value of the outcome variable, cohort, time, and other covariates (government financial aid, having a boyfriend, history of emotional abuse).

<sup>b</sup>Percentage of relative change =  $[(MD/C_{adjusted}) \times 100\%]$ .

nitude, and consistency of effects strengthen confidence in the efficacy of the intervention and add to the collective empirical database indicating that STD/HIV interventions can be efficacious.<sup>36</sup>

Intervention efficacy may be partly attributable to contextualizing the intervention within a broader risk framework, designed not only to provide STD/HIV risk-reduction education and skills training, but to also intervene on relational, sociocultural, and structural factors that exacerbate African American adolescent females' risk for STDs and HIV. This is among the first STD/HIV interventions to include strategies to facilitate male sex partners' access to STD screening/treatment as well as reduce adolescents' frequency of douching. Combination STD/HIV interventions may be more efficacious in responding to the health crisis currently confronting African American adolescent females.

The observed reduction in number of adolescents with chlamydial infections is of particular importance as *Chlamydia* is one of the most prevalent STDs among young African American adolescent females residing in the southern United States.<sup>18,78</sup> While *Chlamydia* is associated with serious health sequelae, including the potential risk of cervical squamous cell carcinoma,<sup>79</sup> it also increases susceptibility to HIV infection.<sup>10-13</sup> In the absence of a vaccine to prevent chlamydial infections of the female genital tract,<sup>80</sup> condoms used consistently and correctly remain the most effective strategy to reduce risk of infection.<sup>65-67,81-83</sup> Thus, interventions that can enhance condom use and produce even small reductions in *Chlamydia* incidence could result in sizeable reductions in disease-associated treatment costs<sup>84</sup> and reduce HIV morbidity and its associated treatment costs.<sup>85</sup>

Methodological strengths include using a randomized controlled trial design and a comparison condition that exceeds standards of care in STD/HIV prevention education available in most clinics. Providing additional STD/HIV prevention information may, in fact, attenuate differences between trial conditions, thus providing a more conservative test of the intervention.<sup>36</sup> Second is the use of laboratory-confirmed STDs to complement self-

reported behavior change and provide an objective measure of intervention efficacy. And, third, a number of strategies were used to enhance adolescents' self-report of sexual behaviors.<sup>62,63</sup>

The present study is not without limitations. The findings may not be applicable to African American adolescent females with different sociodemographic characteristics or risk profiles, as this was a high-risk population. Furthermore, the findings may not be applicable to adolescent females from other ethnic/racial groups or adolescent males. Additionally, while the findings are promising, it is unclear whether intervention effects are sustainable over protracted periods. Another concern is the reliability of self-reported outcomes, although previous research has established the validity and reliability of self-report sexual behavior,<sup>86-88</sup> specifically for young African American women.<sup>89,90</sup> Additionally, we cannot verify, other than through self-report, that participants in the intervention condition distributed vouchers to their male sex partners to facilitate accessing STD services.

## CONCLUSIONS

We have severely underestimated the intransigence and adverse impact of the STD/HIV "national health crisis" for African American individuals.<sup>1,2</sup> In the absence of vaccines for many STDs, including *Chlamydia*<sup>80</sup> and HIV,<sup>91</sup> there is a clear, cogent, and compelling urgency to implement the public health equivalent of a "full court press" to eliminate racial disparities in STDs and HIV. A comprehensive plan is needed that includes developing a national STD/HIV strategic plan and forging public and private coalitions, such as the National Chlamydia Coalition. While evidence-based risk-reduction interventions are a critical component of any comprehensive plan,<sup>92</sup> they may not be sufficient as stand-alone interventions to produce substantial and sustainable reductions in STD/HIV-associated behaviors and infection rates. Thus, research is needed to develop innovative prevention approaches that target a broader range of social determinants asso-

ciated with STD/HIV risk behaviors and disease<sup>14</sup> and combination behavioral, medical, and structural strategies to optimize the efficacy of STD/HIV prevention interventions.<sup>39,43,93</sup> Further, to maximize the full potential of STD/HIV prevention research to achieve population-level reductions in risk behaviors and disease requires development of a competent and fully operational infrastructure to promote the efficient dissemination and saturation of communities with evidence-based STD/HIV interventions. Programs such as the Centers for Disease Control and Prevention Diffusion of Effective Behavioral Interventions (DEBI) are essential to disseminate evidence-based interventions and provide training in program implementation to community-based agencies working in severely impacted African American communities.<sup>94,95</sup> Additionally, buttressing research efforts to develop effective risk-reduction interventions for males may be an important strategy that not only protects males, but concomitantly may also reduce the risk of STD/HIV infection among adolescent females.<sup>96</sup> Finally, we need to optimize the efficacy of existing STD/HIV prevention and control strategies, providing more accessible screening, treatment, and partner services tailored to African American communities.<sup>97</sup> Ultimately, however, political resolve and leadership are critical for supporting a continuum of prevention science research and the development of service delivery systems that can eliminate the racial disparity in STDs and HIV.

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### Announcement

**Submissions.** The Editors welcome contributions to Picture of the Month. Submissions should describe common problems presenting uncommonly, rather than total zebras. Cases should be of interest to practicing pediatricians, highlighting problems that they are likely to at least occasionally encounter in the office or hospital setting. High-quality clinical images (in either 35-mm slide or electronic format) along with parent or patient permission to use these images must accompany the submission. The entire discussion should comprise no more than 750 words. Articles and photographs accepted for publication will bear the contributor's name. There is no charge for reproduction and printing of color illustrations. For details regarding electronic submission, please see: <http://archpedi.ama-assn.org>.