

Efficacy of a Theory-Based Abstinence-Only Intervention Over 24 Months

A Randomized Controlled Trial With Young Adolescents

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Objective: To evaluate the efficacy of an abstinence-only intervention in preventing sexual involvement in young adolescents.

Design: Randomized controlled trial.

Setting: Urban public schools.

Participants: A total of 662 African American students in grades 6 and 7.

Interventions: An 8-hour abstinence-only intervention targeted reduced sexual intercourse; an 8-hour safer sex-only intervention targeted increased condom use; 8-hour and 12-hour comprehensive interventions targeted sexual intercourse and condom use; and an 8-hour health-promotion control intervention targeted health issues unrelated to sexual behavior. Participants also were randomized to receive or not receive an intervention maintenance program to extend intervention efficacy.

Outcome Measures: The primary outcome was self-report of ever having sexual intercourse by the 24-month follow-up. Secondary outcomes were other sexual behaviors.

Results: The participants' mean age was 12.2 years; 53.5% were girls; and 84.4% were still enrolled at 24 months. Abstinence-only intervention reduced sexual initiation (risk ratio [RR], 0.67; 95% confidence interval [CI], 0.48-0.96). The model-estimated probability of ever having sexual intercourse by the 24-month follow-up was 33.5% in the abstinence-only intervention and 48.5% in the control group. Fewer abstinence-only intervention participants (20.6%) than control participants (29.0%) reported having coitus in the previous 3 months during the follow-up period (RR, 0.94; 95% CI, 0.90-0.99). Abstinence-only intervention did not affect condom use. The 8-hour (RR, 0.96; 95% CI, 0.92-1.00) and 12-hour comprehensive (RR, 0.95; 95% CI, 0.91-0.99) interventions reduced reports of having multiple partners compared with the control group. No other differences between interventions and controls were significant.

Conclusion: Theory-based abstinence-only interventions may have an important role in preventing adolescent sexual involvement.

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ADOLESCENTS RISK THE DELTERIOUS consequences of early sexual involvement including human immunodeficiency virus (HIV),¹ other sexually transmitted infections (STIs),² and unintended pregnancies.^{3,4} In the United States, these risks are especially great among African American adolescents.^{2,5,6} In 2005, 17% of adolescents in the United States were African American but 69% of adolescents with HIV/AIDS were African American.⁵ Rates of STI are the highest among African American individuals and adolescents, particularly adolescent girls.² Pregnancy rates have been higher among African American adolescents than among their Hispanic and white counterparts.⁷ Adolescents who initiate sexual intercourse at younger ages have

a greater risk of STI⁸ and pregnancy⁹ and report more sexual risk behaviors including multiple sexual partners.^{10,11}

*For editorial comment
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Although considerable research suggests that behavioral interventions can reduce sexual behaviors related to risk of STI among adolescents,¹²⁻¹⁴ including younger adolescents aged 11 to 15 years,¹⁵⁻¹⁸ a public policy debate has revolved around the appropriateness and efficacy of different sexual risk-reduction interventions. Some have advocated abstinence interventions; others have advocated comprehensive interventions—abstinence and, for sexually active adolescents, condom use. Absti-

nence interventions have been criticized for containing inaccurate information, portraying sex in a negative light, using a moralistic tone,^{19,20} and risking unintended adverse consequences.²⁰⁻²² This debate notwithstanding, the United States has primarily funded and promoted abstinence education both in the United States and abroad,²⁰ and many states have mandated that HIV/STI education for children stress abstinence.^{23,24}

Despite the widespread implementation of abstinence interventions and the controversy regarding their appropriateness, few randomized controlled trials have tested their efficacy.^{12-14,22} This has led to calls for more rigorous abstinence intervention research.^{12,20,22,25} The ideal abstinence intervention would incorporate principles of efficacious HIV/STI risk reduction behavioral interventions. It would draw on formative research on the population and behavior change theory to address motivation and build skills to practice abstinence; it would not be moralistic, and it would not stress the “inadequacies” of condoms.

Here we report the results of a trial regarding the efficacy of such a theory-based abstinence-only intervention. African American students in grades 6 and 7 were randomly assigned to an 8-hour abstinence-only intervention, an 8-hour safer sex-only intervention, an 8- or 12-hour combined abstinence and safer-sex intervention, or an 8-hour health-promotion control group. We hypothesized that fewer participants in the abstinence-only intervention than in the control group would report ever having sexual intercourse by the 24-month follow-up.

A common shortcoming of behavior-change interventions is that efficacy is demonstrated in the short term but disappears at longer-term follow-up. This may particularly be a problem for abstinence interventions.¹⁵ Unlike many risk behaviors (eg, cigarette smoking, drug use), sexual intercourse is an age-graded behavior; the expectation is that people will eventually have sexual intercourse. We designed a multifaceted intervention-maintenance program tailored to each intervention to extend the efficacy of the interventions. A secondary hypothesis, then, was that the intervention-maintenance program would enhance intervention efficacy.

METHODS

PARTICIPANTS

The participants were 662 African American students in grades 6 and 7 who were recruited from 4 public middle schools that serve low-income African American communities in a city in the northeastern United States; they were recruited between September 2001 and March 2002 via announcements by project staff in assemblies, classrooms, and lunchrooms, and letters to parents or guardians for the Promoting Health Among Teens (PHAT) Project, which was designed to reduce the chances of adolescents developing devastating health problems including cardiovascular diseases, cancers, and STIs, including HIV.

PROCEDURES

The Institutional Review Board of the University of Pennsylvania (approval No. 387200) and the Research Ethics Board of the University of Waterloo approved the study. African

American students in grades 6 and 7 at the 4 participating schools who had written parent or guardian consent were eligible to participate. In this randomized controlled trial, students were stratified by age and sex and, using a computer-generated random number sequence, randomly allocated to an 8-hour abstinence-only intervention, an 8-hour safer sex-only intervention, an 8-hour comprehensive intervention, a 12-hour comprehensive intervention, or an 8-hour health-promotion control intervention. They were also randomly assigned to intervention maintenance or no intervention maintenance and to a group of 6 to 8 participants. One researcher conducted the computer-generated random assignments and distributed the information to other researchers who executed the assignments.

Adolescents were enrolled in the study in 4 cycles or replications, 1 at each of 4 schools. The **Figure** shows the number of adolescents randomized to each condition. The intervention and data collection sessions were implemented on Saturdays in classrooms at the participating schools.

EXPERIMENTAL CONDITIONS

The interventions were based on social cognitive theory,^{26,27} the theory of reasoned action,^{28,29} and its extension, the theory of planned behavior.³⁰ They were highly structured, and facilitators implemented them following intervention manuals. Each intervention involved a series of brief group discussions, videos, games, brainstorming, experiential exercises, and skill-building activities. Four of the interventions consisted of 8 1-hour modules implemented during 2 sessions, and 1 consisted of 12 1-hour modules implemented over 3 sessions. All 5 were pilot tested.

Abstinence-Only Intervention

The 8-hour abstinence-only intervention encouraged abstinence to eliminate the risk of pregnancy and STIs including HIV. It was designed to (1) increase HIV/STI knowledge, (2) strengthen behavioral beliefs supporting abstinence including the belief that abstinence can prevent pregnancy, STIs, and HIV, and that abstinence can foster attainment of future goals, and (3) increase skills to negotiate abstinence and resist pressure to have sex. It was not designed to meet federal criteria for abstinence-only programs. For instance, the target behavior was abstaining from vaginal, anal, and oral intercourse until a time later in life when the adolescent is more prepared to handle the consequences of sex. The intervention did not contain inaccurate information, portray sex in a negative light, or use a moralistic tone. The training and curriculum manual explicitly instructed the facilitators not to disparage the efficacy of condoms or allow the view that condoms are ineffective to go uncorrected.

Safer Sex-Only Intervention

The 8-hour safer sex-only intervention encouraged condom use to reduce the risk of pregnancy and STIs, including HIV, if adolescents had sex. It was designed to (1) increase HIV/STI knowledge, (2) enhance behavioral beliefs that support condom use, and (3) increase skills to use condoms and negotiate condom use. It was not designed to influence abstinence.

Comprehensive Interventions

Two comprehensive interventions combined the abstinence and safer-sex, HIV risk-reduction interventions. One was 12 hours, and the other was 8 hours and contained similar content. Both

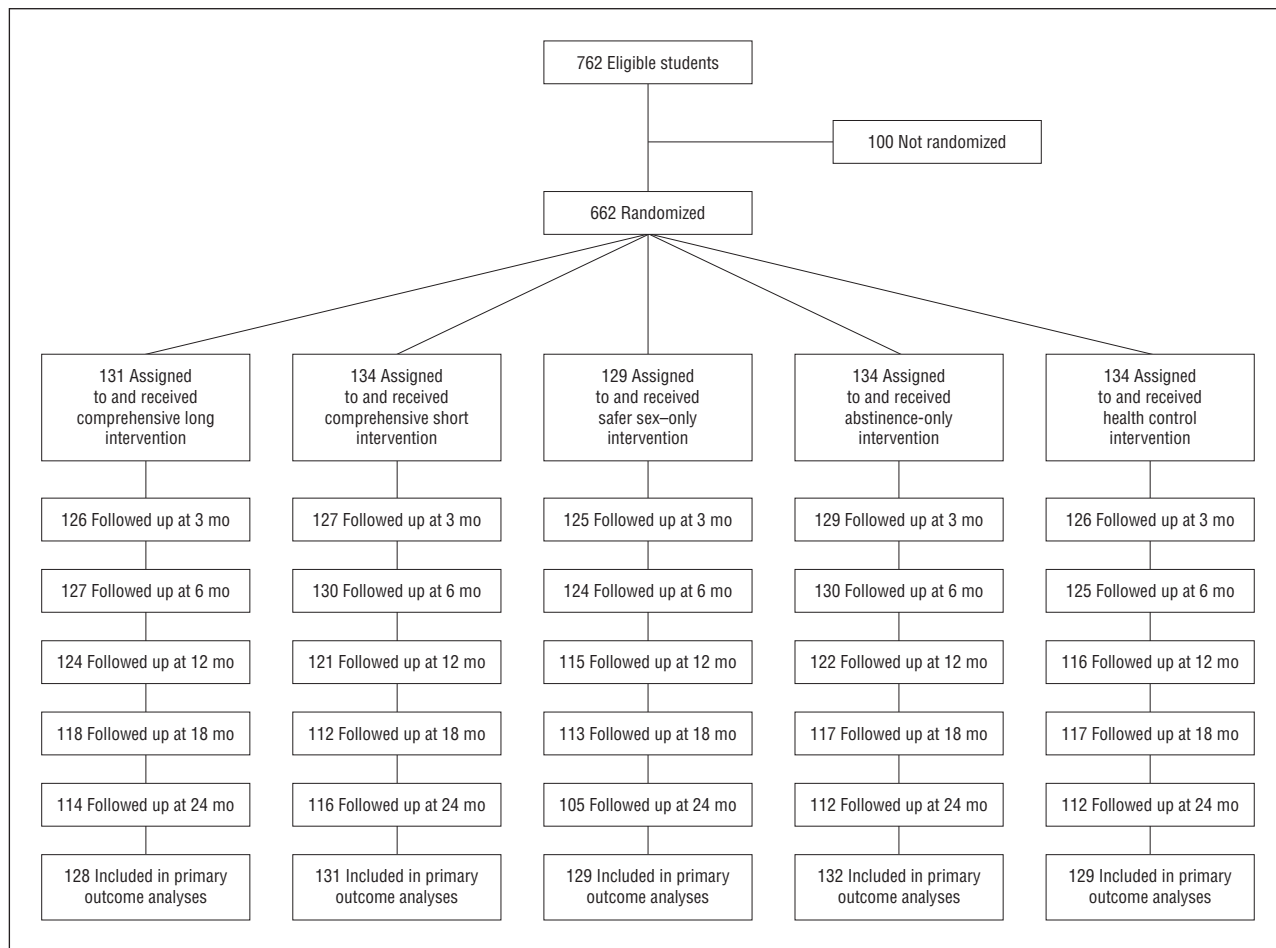


Figure. Progress of participating African American students in grades 6 and 7 through the trial. Students who were not followed up were absent at the time of the follow-up session and failed to attend the make-up sessions for unknown reasons.

targeted beliefs and skills to encourage abstinence and condom use. Both were designed to (1) increase HIV/STI knowledge, (2) strengthen behavioral beliefs supporting abstinence, (3) strengthen behavioral beliefs supporting condom use, (4) increase skills to negotiate abstinence, and (5) increase skills to use condoms and negotiate condom use.

The 12-hour version contained the safer-sex content (4 hours), the abstinence content (4 hours), and the general content common to both single-component interventions (4 hours). If the 12-hour version had a larger effect than the single-component interventions, it would not have been possible to distinguish the beneficial effects of greater intervention length from the benefits of combining the two components. To control for this, the 8-hour version was the same length as the single-component interventions.

Health-Promotion Control Intervention

The 8-hour health-promotion intervention, which served as the control, focused on behaviors associated with risk of heart disease, hypertension, stroke, diabetes, and certain cancers. It was designed to increase knowledge and motivation regarding healthful dietary practices, aerobic exercise, and breast and testicular self-examination, and to discourage cigarette smoking. It controls for Hawthorne effects to reduce the likelihood that effects of the HIV interventions could be attributed to nonspecific features including group interaction and special attention.³¹

Intervention-Maintenance Program

Participants were also randomly assigned to receive or not receive an intervention-maintenance program tailored to their intervention. It consisted of two 3-hour booster intervention sessions (6 weeks and 3 months after initial intervention sessions), 6 issues of a newsletter, and six 20-minute 1-on-1 counseling sessions during a 21-month period with their original facilitator.

Facilitators and Facilitator Training

The facilitators were 16 men and 51 women (mean age, 43.1 years); 61.2% had a master's degree; and 38.8% had a bachelor's degree. All were African American except for 1 Puerto Rican individual. We hired facilitators with the skills to implement any of the interventions, stratified them for sex and age, and randomly assigned them to receive 2.5 days of training to implement 1 of the 5 interventions. In this way, we randomized facilitators' characteristics across interventions, reducing the plausibility of attributing intervention effects to the facilitators' preexisting characteristics.

OUTCOMES

Participants completed preintervention, immediate postintervention, and 3-, 6-, 12-, 18-, and 24-month follow-up ques-

Table 1. Sociodemographic Characteristics and Self-reported Sexual Behaviors at Baseline of Participating African American Students in Grades 6 and 7 by Intervention Condition

Characteristic	Participants, No./Total (%)					
	Total	12-h Comprehensive	8-h Comprehensive	Safer Sex Only	Abstinence Only	Health Control
Sample size	662	131	134	129	134	134
Female	354/662 (53.5)	69/131 (52.7)	72/134 (53.7)	70/129 (54.3)	70/134 (52.2)	73/134 (54.5)
Grade 7	366/662 (55.3)	68/131 (51.9)	71/134 (53.0)	73/129 (56.6)	77/134 (57.5)	77/134 (57.5)
Live with both parents	221/655 (33.7)	46/130 (35.4)	46/133 (34.6)	40/126 (31.8)	43/133 (32.3)	46/133 (34.6)
Ever had sexual intercourse	153/655 (23.4)	31/128 (24.2)	28/133 (21.0)	32/127 (25.2)	27/133 (20.3)	35/134 (26.1)
Sexual intercourse in past 3 mo	79/657 (12.0)	14/130 (10.8)	14/132 (10.6)	15/128 (11.7)	16/133 (12.0)	20/134 (14.9)
Multiple sexual partners in past 3 mo	42/655 (6.4)	11/130 (8.5)	10/132 (7.6)	6/127 (4.7)	4/133 (3.0)	11/133 (8.3)
Unprotected intercourse in past 3 mo	19/655 (2.9)	3/130 (2.3)	2/131 (1.5)	7/127 (5.5)	1/133 (0.8)	6/134 (4.5)
Consistent condom use in past 3 mo	51/76 (67.1)	10/14 (71.4)	10/14 (71.4)	4/14 (28.6)	13/14 (92.9)	14/20 (70.0)
Randomized to intervention maintenance	315/662 (47.6)	69/131 (52.7)	70/134 (52.2)	68/129 (52.7)	70/134 (52.2)	70/134 (52.2)
Age, mean (SD), y	12.0 (0.8)	11.9 (0.8)	11.9 (0.8)	12.0 (0.8)	12.0 (0.8)	12.0 (0.8)

tionnaires. Follow-up data were collected between January 2002 and August 2004. All questions had been pilot tested to ensure that they were clear and that the phrasing was appropriate for the population. Preintervention and follow-up questionnaires assessed sexual behavior, demographic variables, and mediator variables. The postintervention questionnaire assessed mediator variables and evaluative ratings of the interventions.

The primary outcome for the abstinence-only intervention was report of ever having sexual intercourse by the 24-month follow-up. Secondary outcomes were other self-reported sexual behaviors in the previous 3 months such as sexual intercourse, multiple partners (having sexual intercourse with 2 or more partners), unprotected intercourse (1 or more sexual intercourse acts without using a condom), and consistent condom use (condom use during every sexual intercourse act).

Data collectors received 8 hours of training and were blind to the participants' intervention condition. We took several steps to increase the validity of self-reported sexual behavior. To facilitate participants' recall, we asked them to report their behaviors during a brief period (ie, past 3 months),³² wrote the dates comprising the period on a chalkboard, and gave them calendars highlighting the period. To reduce the likelihood that participants would minimize or exaggerate, we stressed the importance of responding honestly, informing them that their responses would be used to create programs for other African American adolescents like themselves and that we could do so only if they answered the questions honestly. We assured the participants that their responses would be kept confidential and that code numbers rather than names would be used on the questionnaires. Participants signed an agreement pledging to answer the questions honestly, a procedure that has been shown to yield more valid self-reports on sensitive issues.³³

SOCIAL DESIRABILITY RESPONSE MEASURE

The Marlowe-Crowne Social Desirability Scale³⁴ included in the preintervention questionnaire assessed the tendency of participants to describe themselves in favorable, socially desirable terms.

SAMPLE SIZE AND STATISTICAL ANALYSIS

With $\alpha = .05$, 2-tailed, and 37.4% of the control group initiating sexual intercourse by 24-month follow-up, a total sample

size of 563 participants who completed the trial was projected to provide power of 80% to detect a difference of 16.8% in self-reported sexual intercourse between an HIV intervention condition and the control condition. We performed χ^2 and *t* tests to analyze attrition.

To test intervention effects, we used an intention-to-treat approach in which participants' data were analyzed regardless of the number of intervention or data collection sessions they attended. The efficacy of the HIV interventions on report of ever having sexual intercourse by the 24-month follow-up was tested using generalized linear regression with a log link, and the exponentiated coefficients, risk ratios (RR), and 95% confidence intervals (CI) are reported.³⁵ We used either of 2 error distributions (either Bernoulli or Poisson with robust variance estimator) depending on whether predicted probabilities violated the 0,1 range of probability. Effects of the HIV/STI interventions on recent sexual intercourse, multiple partners, unprotected intercourse, and consistent condom use during the 24-month follow-up period were tested using Poisson generalized estimating equations with a log link.³⁵ An unstructured working correlation matrix was specified in the generalized estimating equations analyses.

Analyses of recent sexual intercourse, multiple partners, and unprotected intercourse controlled for the baseline measures of the criterion, time, intervention-maintenance condition, sex, and age. Analyses of ever having sexual intercourse excluded participants who reported ever having sexual intercourse at baseline and controlled for intervention-maintenance condition, sex, and age. Analyses of consistent condom use excluded participants who did not report sexual intercourse in the past 3 months and controlled for time, intervention-maintenance condition, sex, and age. The latter did not control for baseline measures because the small number of participants reporting recent sexual intercourse at both baseline and follow-up would have severely limited the sample size. The significance criterion was set at $\alpha = .05$ except for post hoc analyses comparing the abstinence-only and 8-hour comprehensive interventions in which a type I error-adjusted α of $.05/2 = .025$ was used.

RESULTS

SAMPLE CHARACTERISTICS

Table 1 summarizes select participant characteristics at baseline. About 53.5% of participants were girls and 46.5%

Table 2. Self-reported Sexual Risk Behavior by Intervention Condition and Follow-up Visit

Intervention Condition	Participants, No./Total (%)					
	Baseline	3 mo	6 mo	12 mo	18 mo	24 mo
Ever had sexual intercourse ^a						
12-h Comprehensive	0/97 (0.0)	4/96 (4.2)	11/98 (11.2)	20/96 (20.8)	32/93 (34.4)	39/92 (42.4)
8-h Comprehensive	0/105 (0.0)	9/99 (9.1)	14/104 (13.5)	23/96 (24.0)	29/91 (31.9)	40/97 (41.2)
Safer sex only	0/95 (0.0)	15/93 (16.1)	22/92 (23.9)	32/88 (36.4)	39/87 (44.8)	44/85 (51.8)
Abstinence only	0/106 (0.0)	5/102 (4.9)	9/104 (8.7)	20/98 (20.4)	24/96 (25.0)	31/95 (32.6)
Health control	0/109 (0.0)	8/94 (8.5)	15/94 (16.0)	20/89 (22.5)	31/90 (34.4)	41/88 (46.6)
Had sexual intercourse in past 3 mo						
12-h Comprehensive	14/130 (10.8)	12/125 (9.6)	18/127 (14.2)	24/124 (19.4)	32/118 (27.1)	35/114 (30.7)
8-h Comprehensive	14/132 (10.6)	19/126 (15.1)	19/130 (14.6)	33/121 (27.3)	32/112 (28.6)	38/116 (32.8)
Safer sex only	15/128 (11.7)	22/124 (17.7)	21/122 (17.2)	34/115 (29.6)	40/113 (35.4)	42/105 (40.0)
Abstinence only	16/133 (12.0)	15/129 (11.6)	13/130 (10.0)	27/121 (22.3)	39/117 (33.3)	33/112 (29.5)
Health control	20/134 (14.9)	26/126 (20.6)	27/125 (21.6)	25/116 (21.6)	35/117 (29.9)	42/112 (37.5)
Had multiple sexual partners in past 3 mo						
12-h Comprehensive	11/130 (8.5)	7/126 (5.6)	7/127 (5.5)	13/124 (10.5)	10/118 (8.5)	16/114 (14.0)
8-h Comprehensive	10/132 (7.6)	6/126 (4.8)	6/129 (4.6)	9/121 (7.4)	16/112 (14.3)	13/116 (11.2)
Safer sex only	6/127 (4.7)	13/125 (10.4)	9/123 (7.3)	15/114 (13.2)	18/112 (16.1)	19/102 (18.6)
Abstinence only	4/133 (3.0)	5/129 (3.9)	5/130 (3.8)	12/122 (9.8)	21/115 (18.3)	15/112 (13.4)
Health control	11/133 (8.3)	14/126 (11.1)	19/125 (15.2)	11/115 (9.6)	18/117 (15.4)	18/112 (16.1)
Had unprotected sexual intercourse in past 3 mo						
12-h Comprehensive	3/130 (2.3)	5/126 (4.0)	2/126 (1.6)	7/124 (5.7)	6/118 (5.1)	8/113 (7.1)
8-h Comprehensive	2/131 (1.5)	2/126 (1.6)	1/130 (0.8)	6/121 (5.0)	10/111 (9.0)	8/115 (7.0)
Safer sex only	7/127 (5.5)	5/125 (4.0)	3/124 (2.4)	7/111 (6.3)	3/110 (2.7)	9/103 (8.7)
Abstinence only	1/133 (0.8)	1/128 (0.8)	1/129 (0.8)	7/122 (5.7)	8/117 (6.8)	8/112 (7.1)
Health control	6/134 (4.5)	4/126 (3.2)	11/125 (8.8)	7/116 (6.0)	7/117 (6.0)	8/110 (7.3)
Used condoms consistently during intercourse in past 3 mo ^b						
12-h Comprehensive	10/14 (71.4)	8/13 (61.5)	14/17 (82.4)	16/23 (69.6)	23/30 (76.7)	26/35 (74.3)
8-h Comprehensive	10/14 (71.4)	15/18 (83.3)	17/18 (94.4)	25/31 (80.6)	21/32 (65.6)	29/37 (78.4)
Safer sex only	4/14 (28.6)	16/21 (76.2)	17/20 (85.0)	24/34 (70.6)	34/40 (85.0)	31/42 (73.8)
Abstinence only	13/14 (92.9)	12/15 (80.0)	11/13 (84.6)	19/26 (73.1)	31/39 (79.5)	25/33 (75.8)
Health control	14/20 (70.0)	20/25 (80.0)	15/26 (57.7)	17/24 (70.8)	27/34 (79.4)	32/41 (78.0)

^aExcludes participants who reported sexual intercourse at baseline.

^bExcludes participants who did not have sexual intercourse in the past 3 months.

were boys. Age ranged from 10 to 15 years, with a mean (SD) of 12.2 (0.81); 44.7% were in grade 6 and 55.3% were in grade 7. About 33.7% lived with both of their parents. About 23.4% reported having experienced coitus at least once, 12.0% reported having coitus in the previous 3 months; 6.4%, multiple partners in the previous 3 months, and 2.9%, unprotected intercourse in the previous 3 months. Of those who reported intercourse in the previous 3 months, 67.1% reported consistent condom use. Only 2 respondents (0.3%) reported sexual relations with someone of their own sex.

INTERVENTION ATTENDANCE AND FOLLOW-UP RETENTION

The Figure shows the flow of participants through the trial. Of the 762 eligible students, 662 (86.9%) participated. We do not have information regarding the characteristics of the eligible students who did not participate. Attendance at intervention and data-collection sessions was excellent. All participants attended intervention session 1, and 642 or 97.0% attended session 2. Attendance at session 2 ranged from 95.5% to 98.5%, with no significant difference among interventions. Only the

12-hour comprehensive intervention had a session 3, and all participants attended it. Of the trial participants, 649 (98.0%) attended at least 1 of the follow-ups: 633 (95.6%) attended the 3-month, 636 (96.1%) attended the 6-month, 598 (90.3%) attended the 12-month, 577 (87.2%) attended the 18-month, and 559 (84.4%) attended the 24-month follow-up. The interventions did not differ significantly in retention at follow-up. Attending a follow-up session was unrelated to sex, age, living with both parents, or sexual behavior outcomes.

EFFECTS ON PRIMARY OUTCOME

Table 2 presents sexual behavior outcomes by intervention condition and time. **Table 3** presents RRs and 95% CIs for intervention efficacy regarding sexual behavior outcomes. The abstinence-only intervention reduced sexual initiation ($P=.03$). The model-estimated probability of ever having sexual intercourse by the 24-month follow-up was 33.5% in the abstinence-only intervention and 48.5% in the health-promotion control group. The safer sex and comprehensive interventions did not differ from the control group in sexual initiation.

Table 3. Estimates of Intervention Effect Size for Self-reported Sexual Behavior Outcomes

Outcome ^b	Participants, No.	RR (95% CI) ^a			
		12-h Comprehensive	8-h Comprehensive	Safer Sex Only	Abstinence Only
Ever had sexual intercourse	457	0.87 (0.64-1.19)	0.86 (0.63-1.17)	0.95 (0.72-1.27)	0.67 (0.48-0.96)
Sexual intercourse in past 3 mo	657	0.95 (0.90-1.00)	0.98 (0.93-1.03)	1.00 (0.95-1.05)	0.94 (0.90-0.99)
Multiple sexual partners in past 3 mo	655	0.95 (0.91-0.99)	0.96 (0.92-1.00)	0.99 (0.95-1.04)	0.97 (0.93-1.01)
Unprotected sexual intercourse in past 3 mo	655	0.98 (0.95-1.02)	0.99 (0.95-1.02)	0.97 (0.94-1.01)	0.98 (0.95-1.01)
Consistent condom use in past 3 mo	292	0.98 (0.82-1.18)	1.08 (0.92-1.27)	1.09 (0.94-1.27)	1.03 (0.88-1.21)

Abbreviations: CI, confidence interval; RR, risk ratio.

^aThe effect size estimate is the RR (intervention coded as 1 vs health control coded as 0) for each human immunodeficiency virus/sexually transmitted infection intervention condition.

^bRisk ratios for ever having sexual intercourse were adjusted for intervention-maintenance condition, sex, and age at 24-month follow-up; for consistent condom use, time, intervention-maintenance condition, sex, and age over the entire follow-up period; all others, baseline measure of the criterion, time, intervention-maintenance condition, sex, and age over the entire follow-up period.

EFFECTS ON OTHER SEXUAL BEHAVIORS

The abstinence intervention also significantly reduced recent sexual intercourse. The model-estimated probability of reporting intercourse in the past 3 months averaged over the 3-, 6-, 12-, 18-, and 24-month follow-ups was 20.6% in the abstinence-only intervention compared with 29.0% in the control group ($P = .02$). The model-estimated probability was 20.6% in the 12-hour comprehensive intervention, a marginally significant difference ($P = .06$) from the control group. The safer sex and 8-hour comprehensive interventions did not have significant effects on recent intercourse compared with the control group.

Abstinence-only intervention participants did not differ from the control group in reports of multiple partners ($P = .13$). Participants in the 8-hour ($P = .03$; model-estimated probability, 8.8%) and 12-hour comprehensive intervention groups ($P = .02$; model-estimated probability, 8.7%) were significantly less likely to report having multiple partners than were those in the control group (model-estimated probability, 14.1%). No other differences were statistically significant. None of the interventions had significant effects on consistent condom use or unprotected intercourse. In the subgroup of participants who had their sexual debut during the trial, there was no difference between the abstinence-only intervention and the control group regarding consistent condom use.

Post hoc analyses revealed no significant differences between the abstinence intervention and the 8-hour comprehensive intervention on any sexual behavior outcome.

SOCIAL DESIRABILITY BIAS

Marlowe-Crowne Social Desirability Scale scores were unrelated to self-reported sexual behavior, including abstinence, at baseline and did not interact with the intervention condition to influence sexual behavior during the follow-up period.

INTERVENTION MAINTENANCE

Tests of intervention maintenance \times intervention condition interactions revealed no evidence that the intervention-maintenance program moderated the efficacy of

the interventions in reducing sexual initiation, recent sexual intercourse, or unprotected sexual intercourse. However, the intervention maintenance \times abstinence-only intervention ($P = .03$) and intervention maintenance \times 12-hour comprehensive intervention ($P = .04$) interactions on multiple partners were statistically significant. The abstinence-only intervention was more efficacious in reducing multiple partners than was the control group for those who received intervention maintenance (RR, 0.93; 95% CI, 0.88-0.98; $P = .006$) compared with those who did not (RR, 1.02; 95% CI, 0.96-1.08; $P = .57$). The 12-hour comprehensive intervention was more efficacious in reducing multiple partners than was the control group among those who received intervention maintenance (RR, 0.91; 95% CI, 0.86-0.96; $P = .004$) compared with those who did not (RR, 0.99; 95% CI, 0.93-1.06; $P = .83$).

No adverse events occurred during the study.

COMMENT

The results indicate that a theory-based abstinence-only intervention reduced self-reported sexual involvement among African American students in grades 6 and 7, a population at high risk of pregnancy and STIs, including HIV. The abstinence-only intervention compared with the health-promotion control intervention reduced by about 33% the percentage of students who ever reported having sexual intercourse by the time of the 24-month follow-up, controlling for grade, age, and intervention-maintenance condition. Although other studies have reported intervention-induced reductions in sexual intercourse among adolescents, this is the first randomized controlled trial to demonstrate that an abstinence-only intervention reduced the percentage of adolescents who reported any sexual intercourse for a long period following the intervention, in this case, 24 months after intervention.

We also found significant effects of the 8- and 12-hour comprehensive interventions on important HIV/STD risk-related behavior. Both comprehensive interventions significantly reduced the incidence of multiple sexual partners compared with the health control group. In addition, the 12-hour comprehensive intervention mar-

ginally significantly ($P = .06$) reduced the incidence of recent sexual intercourse compared with the health control group.

A common shortcoming of health-behavior interventions is that behavior change is often short-lived, disappearing on longer-term follow-up. We used a multifaceted, tailored intervention-maintenance program to address this shortcoming. Although many trials have used booster intervention sessions, this is one of few trials to test the efficacy of a randomly allocated strategy to extend interventions' efficacy. We found only modest effects of the intervention-maintenance program in enhancing efficacy. It enhanced the efficacy of the abstinence-only and comprehensive interventions in reducing multiple partners compared with the control group but did not enhance efficacy on sexual initiation, recent intercourse, or unprotected intercourse. Therefore, although the effects of our intervention maintenance component are promising, we encourage additional research to identify ways to extend the efficacy of HIV/STD risk reduction interventions.

A common concern about abstinence-only interventions is that they have the unintended effect of reducing condom use, ie, that children exposed to such interventions are subsequently less likely to use condoms if they have sexual intercourse.^{20,21,36} However, a randomized controlled trial³⁷ and a literature review³⁸ found no effects of abstinence interventions on condom use. Similarly, in this trial the abstinence-only intervention participants did not differ in self-reported consistent condom use compared with the control group.

The results of this trial should not be taken to mean that all abstinence-only interventions are efficacious. This trial tested a theory-based abstinence-only intervention that would not meet federal criteria for abstinence programs and that is not vulnerable to many criticisms that have been leveled against interventions that meet federal criteria.^{19,20,36} It was not moralistic and did not criticize the use of condoms. Moreover, it had several characteristics associated with effective sexual risk-reduction interventions. It was theory-based and tailored to the target population based on qualitative data and included skill-building activities. It addressed the context of sexual activity and beliefs about the consequences of sexual involvement derived from the target population.

The limitations of this trial should also be considered. The data were based on self reports, which can be inaccurate because of the failure of memory or socially desirable responding. As noted in the Methods, we used several procedures to increase the validity of self reports. In addition, analyses were inconsistent with the view that social desirability response bias accounted for the results. The relatively small number of sexually active adolescents limited the statistical power to test the effects of the safer sex and comprehensive interventions on condom use. Therefore, effects of these interventions on condom use were likely underestimated in this trial. The generalizability of the results may be limited to African American students in grades 6 and 7 who are willing to take part in a health promotion project on weekends. Whether the results would be similar with older

adolescents or those of other races or in other countries is unclear.

Despite these limitations, the results of this randomized controlled trial are promising. They suggest that theory-based abstinence-only interventions can have positive effects on adolescents' sexual involvement. This is important because abstinence is the only approach that is acceptable in some communities and settings in both the United States and other countries. This trial showed that having had a theory-based abstinence-only intervention would not necessarily reduce adolescents' condom use. Nevertheless, the results do not mean that abstinence-only intervention is the best approach or that other approaches should be abandoned. Theory-based abstinence-only interventions might be effective with young adolescents but ineffective with older youth or people in committed relationships. For the latter, other approaches that emphasize limiting the number of sexual partners and using condoms, including the comprehensive interventions used in this trial, might be more effective. Tackling the problem of STIs among young people requires an array of approaches implemented in a variety of venues. What the present results suggest is that theory-based abstinence-only interventions can be part of this mix. Using theory-based abstinence-only interventions selectively might contribute to the overall goal of curbing the spread of STIs in both the United States and other countries.

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