ARTICLE

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 DELeterious 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 STI[8] and pregnancy[9] and report more sexual risk behaviors including multiple sexual partners.[10,11]

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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-

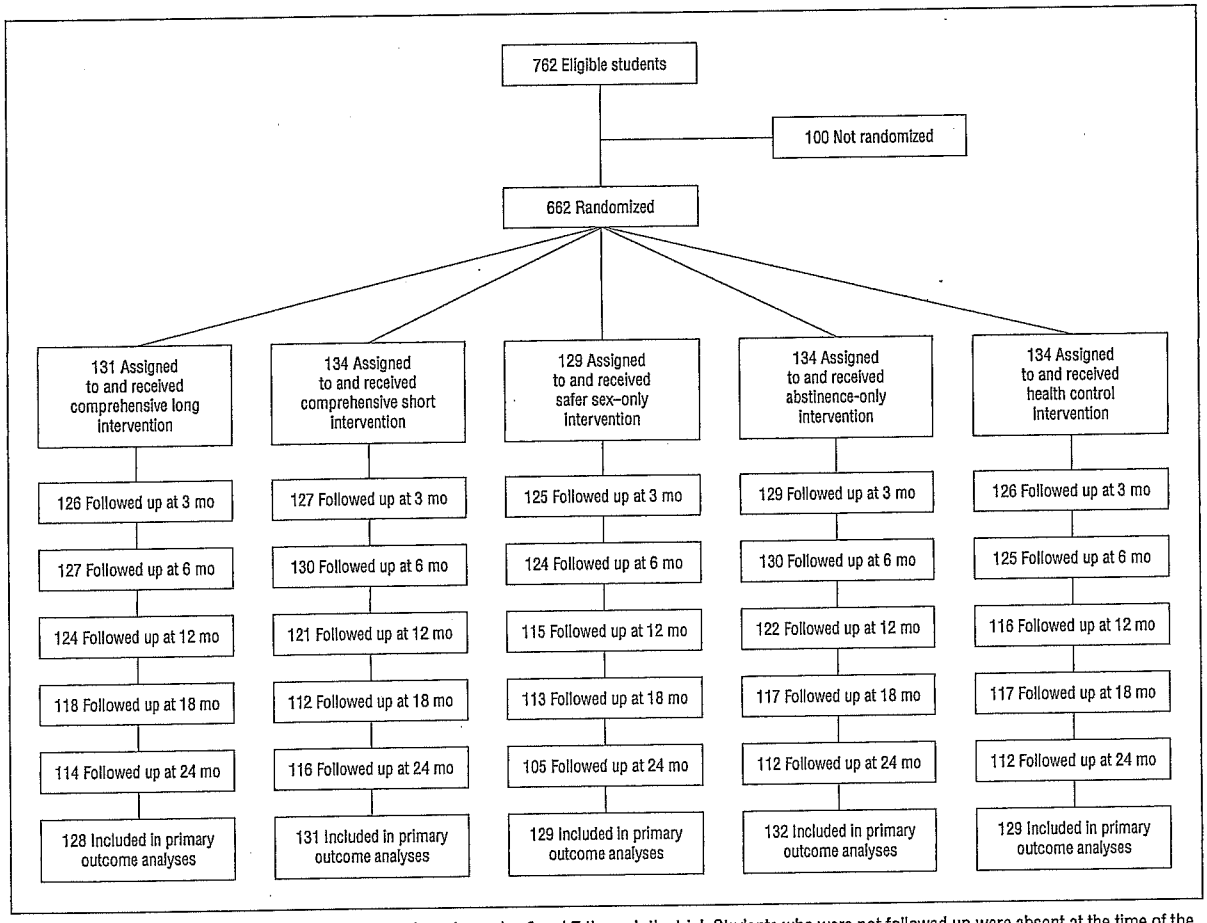

Figure. Progress of participating African American students in grades 6 and 7 through the trial. Students who were not followed up were absent at the time of the follow-up session and failed to attend the make-up sessions for unknown reasons.

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 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)

[a] Excludes participants who reported sexual intercourse at baseline.
[b] Excludes 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.

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 trial[37] and a literature review[38] 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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