

School-Based Randomized Controlled Trial of an HIV/STD Risk-Reduction Intervention for South African Adolescents

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Objective: To test the efficacy of a school-based human immunodeficiency virus/sexually transmitted disease (HIV/STD) risk-reduction intervention for South African adolescents.

Design: A cluster-randomized, controlled design with assessments of self-reported sexual behavior collected before intervention and 3, 6, and 12 months after intervention.

Setting: Primary schools in a large, black township and a neighboring rural settlement in Eastern Cape Province, South Africa.

Participants: Nine of 17 matched pairs of schools were randomly selected. Sixth-grade students with parent or guardian consent were eligible.

Interventions: Two 6-session interventions based on behavior-change theories and qualitative research. The HIV/STD risk-reduction intervention targeted sexual risk behaviors; the attention-matched health promotion control intervention targeted health issues unrelated to sexual behavior.

Outcome Measures: The primary outcome was self-report of unprotected vaginal intercourse in the previous 3 months averaged over the 3 follow-ups. Secondary outcomes were other sexual behaviors.

Results: A total of 1057 (94.5%) of 1118 eligible students (mean age, 12.4 years) participated, with 96.7% retained at the 12-month follow-up. Generalized estimating equation analyses adjusted for clustering from 18 schools revealed that, averaged over the 3 follow-ups, a significantly smaller percentage of HIV/STD risk-reduction intervention participants reported having unprotected vaginal intercourse (odds ratio [OR], 0.51; 95% confidence interval [CI], 0.30-0.85), vaginal intercourse (OR, 0.62; 95% CI, 0.42-0.94), and multiple sexual partners (OR, 0.50; 95% CI, 0.28-0.89), when adjusted for baseline prevalences, compared with health-promotion control participants.

Conclusion: This is the first large-scale, community-level, randomized intervention trial to show significant effects on the HIV/STD sexual risk behavior of South African adolescents in the earliest stages of entry into sexual activity.

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SOUTH AFRICA HAS THE LARGEST number of persons living with human immunodeficiency virus/sexually transmitted disease (HIV/STD) in the world, an estimated 5 500 000.^{1,2} About 18.8% of South African individuals aged 15 to 49 years have HIV,³ and new HIV infections are being driven by the high incidence in those aged 15 to 24 years. It is estimated that more than one-half of all South African individuals aged 15 years in 2006 will not survive to 60 years of age.⁴ Young adolescents, before or just after the initiation of sexual activity, are singularly important to intervention efforts because they are highly vulnerable and have not established habitual patterns of sexual behavior.

Studies in the United States have identified efficacious sexual risk-reduction in-

terventions for adolescents.⁵⁻⁷ However, few randomized controlled trials of interventions in sub-Saharan Africa have had follow-up periods as long as 12 months after intervention.⁸⁻¹² Other studies conducted with adolescents in sub-Saharan Africa used quasiexperimental designs, had brief follow-up periods, experienced significant loss at follow-up, or obtained nonsignificant intervention effects on behavior.¹³⁻¹⁶

Here we describe a cluster-randomized controlled trial that tested the efficacy of an HIV/STD risk-reduction intervention compared with a health-promotion control intervention among sixth-grade students in schools in Mdantsane, a large black township, and Berlin, a neighboring rural settlement, in Eastern Cape Province, South Africa. Eighteen schools, matched in pairs, were randomly selected and then randomized to 1 of the 2 interventions. We hy-

pothesized that fewer participants in the HIV/STD risk-reduction intervention compared with the health-promotion control intervention would report unprotected vaginal intercourse during a 12-month follow-up period.

METHODS

Institutional review board No. 8 at the University of Pennsylvania, which was the designated institutional review board under the federal-wide assurances of the University of Pennsylvania and the University of Fort Hare, reviewed and approved the study. The institutional review board at the Centers for Disease Control and Prevention deferred approval to the institutional review board at University of Pennsylvania. The study was conducted in Mdantsane, an urban township (population, 177 816 persons), and Berlin (population, 2271 persons), a neighboring rural settlement near East London in Eastern Cape Province, South Africa, where Xhosa is the first language for 95.1% of the population.¹⁷ The apartheid regime created Mdantsane, the second largest South African township after Soweto, as living space for cheap African labor. Schools that taught sixth-grade students and served the general population were eligible to participate. There were 36 primary schools in Mdantsane and Berlin. One school for children with learning disabilities was ineligible, leaving 35 eligible schools, 26 in Mdantsane and 9 in Berlin. All 35 eligible schools agreed to participate in the trial. We created 17 matched pairs of schools that had similar numbers of sixth-grade students, classrooms, and classrooms with electricity—a proxy for poverty. We matched urban and rural schools separately. From the 17 matched pairs, we randomly selected 9 pairs; 7 pairs were composed of urban schools and 2 were composed of rural schools.

We used a cluster-randomized controlled trial design. Within each pair, using computer-generated random number sequences, we randomized 1 school to the HIV/STD risk-reduction intervention and the other to the health-promotion control intervention using concealment of allocation techniques designed to minimize bias in assignment of randomized clinical trials. The biostatistician (S.J.B.) in Philadelphia, Pennsylvania, conducted the computer-generated random assignments, and the project director (S.F.J.) in East London, South Africa, implemented the assignments. We enrolled the schools in the trial during a 13-month period beginning in October 2004, with all data collection completed by December 2006.

To recruit participants, Xhosa-speaking community members made announcements at the selected schools and distributed letters and consent forms for parents or guardians to all sixth-grade students. At the time of recruitment, school administrators, potential participants, and recruiters were blind to the specific intervention to which the school had been randomized, and recruiters followed a common standardized scripted recruitment procedure at all schools. At 12 schools, sixth-grade students who had written parent or guardian consent were eligible to participate. At 6 schools, where there were too few classrooms to accommodate all students who had consent, we randomly selected students as eligible from among those with consent.

We held the intervention and data collection sessions at the students' schools during the extracurricular period at the end of the school day. Participants completed confidential questionnaires before and 3, 6, and 12 months after the intervention. Students who completed the preintervention questionnaire and attended session 1 of the intervention were enrolled in the trial. Participants were compensated with a notebook, pen, and pencil for the 3-month follow-up; a T-shirt for the 6-month follow-up; and a backpack for the 12-month follow-up.

INTERVENTIONS

The interventions were developed based on social cognitive theory,¹⁸ the theory of planned behavior,¹⁹ and extensive formative research, or "targeted ethnography."²⁰ We conducted 9 focus groups with 89 Xhosa-speaking sixth-grade students, 4 focus groups with 34 parents of sixth-grade Xhosa-speaking students, and 1 focus group with 12 teachers of such students in Mdantsane and Berlin.

Both interventions consisted of 12 one-hour modules, with 2 modules delivered during each of 6 sessions on 6 consecutive school days. Both interventions were highly structured and implemented in small, mixed-sex groups by male and female adult, Xhosa-speaking, cofacilitator pairs using standardized intervention manuals. We conducted 3 pilot tests of the interventions with 116 sixth-grade students. The interventions were pilot tested in English in Mdantsane, translated into Xhosa, back-translated from Xhosa to English, pilot tested in Xhosa in Mdantsane and Berlin, and delivered in Xhosa in the main trial. Both interventions included interactive exercises, games, brainstorming, role-playing, and group discussions. The mixed-sex groups allowed inclusion of single-sex activities led by the same-sex facilitators. Electricity was not available in many of the classrooms; consequently, we could not use video, an often-used strategy in efficacious interventions. We therefore used comic workbooks—6 issues, 1 for each session—with a series of characters and storylines to address issues that we had learned during the formative research phase were important aspects of participants' lives, relevant to the targeted behaviors.

We designed the HIV/STD risk-reduction intervention to (1) increase HIV/STD risk-reduction knowledge, (2) enhance behavioral beliefs¹⁹ that support abstinence and condom use, and (3) increase skills and self-efficacy^{18,19} to negotiate abstinence and condom use and to use condoms. To facilitate cross-generational discussions of sexual matters, which formative research had revealed were very difficult for parents and children, we gave the students homework assignments to complete with a parent or caregiver. In addition, because girls in South Africa are vulnerable to rape and other aspects of male domination,^{21,22} sex-specific modules addressed sexuality, sexual maturation, appropriate sex roles, and rape myth beliefs.

The health-promotion intervention was designed to control for nonspecific features including group interaction and special attention.²³ It contained activities similar to the HIV/STD risk-reduction intervention but focused on behaviors linked to risk of heart disease, hypertension, stroke, diabetes, and certain cancers—leading causes of morbidity and mortality among South Africans.²⁴⁻²⁶ It was designed to increase fruit and vegetable consumption and physical activity and decrease cigarette smoking and alcohol use.

The cofacilitators were 43 adults (21 women and 22 men) aged 27 to 56 years (mean, 42 years) from the community who were bilingual in English and Xhosa. Their median education was a bachelor's degree; 65% had worked as teachers and 63% had previously taught HIV education. The process of selecting them involved oral and performance-based interviewing. We randomly assigned them to 8 days of training to implement 1 of the 2 interventions. In this way, we randomized facilitators' characteristics across interventions.⁵ During the training, the trainers modeled the intervention activities and the facilitators learned their assigned intervention, practiced implementing it, received feedback, and created common responses to potential issues that might arise during implementation. The importance of fidelity to the intervention was emphasized.

ASSESSMENTS

Assessments were conducted before, immediately after, and 3, 6, and 12 months after intervention via confidential question-

naires that were written in Xhosa following translation and back-translation from English. We pilot tested the questionnaire with 64 sixth-grade students from Mdantsane and Berlin. Adults from the community who were bilingual in Xhosa and English and blind to the participants' intervention assignment implemented a read-aloud procedure; students completed questionnaires at their desks while data collectors read the questions aloud. Data collectors received 2-day training that included modeling of data collection procedures and practice with performance feedback.

The primary outcome was report of unprotected vaginal intercourse measured using the question, "In the past three months, on how many days did you have vaginal intercourse without using a condom?" Vaginal intercourse was defined as "your penis in a female's vagina" (male version) or "a boy's penis in your vagina" (female version). Participants' responses were coded 1 if they did not have vaginal intercourse without using a condom and 2 if they did have vaginal intercourse without using a condom. Secondary outcomes included sexual experience and recent vaginal intercourse, heterosexual anal intercourse, and multiple partners. Sexual experience was assessed using the question, "Have you ever had vaginal intercourse?" Questions regarding recent sexual activity used a 3-month reporting period. Recent vaginal intercourse was assessed using the appropriate sex-specific item, "In the past three months, did you have vaginal intercourse with a female (male)?" Similarly, recent heterosexual anal intercourse was assessed using the item, "In the past three months, have you had anal intercourse with a female?" (male version). Anal intercourse was defined using the term "anus/behind." Having multiple partners was measured using the question, "In the past three months, how many females (male version) have you had vaginal intercourse with?" Participants' responses were coded 1 if they had fewer than 2 partners and 2 if they had 2 or more partners.

We took several steps to increase the validity of self-reported sexual behavior. To facilitate the students' ability to recall, we asked them to report their behaviors during a brief period (ie, past 3 months),²⁷ wrote the dates comprising the period on a chalkboard, and gave them calendars clearly highlighting the period. We stressed the importance of responding honestly, informing them that their responses would be used to create programs for other Xhosa-speaking 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 regarding sensitive issues.²⁸

SAMPLE SIZE AND STATISTICAL ANALYSIS

The a priori unit of inference in this trial was the individual. A sample size calculation was performed to detect an a priori effect size of Cohen $d=0.25$ on unprotected intercourse, adjusting for expected variance inflation due to clustering.²⁹ We chose $d=0.25$ based on a meta-analysis of HIV risk-reduction intervention studies³⁰ because, at the study's onset, no data were available on which to base an effect-size estimate specific to the study population. Based on pilot data, we estimated an intraclass correlation coefficient of 0.00864. Assuming $\alpha=.05$, a 2-tailed test, intraclass correlation coefficient=0.00864, $d=0.25$, 20% attrition at 12-month follow-up, and $n=1100$ sixth-grade students enrolled in the trial from 16 schools with an average of 67 students in each school, the trial was estimated to have 80% power to detect $d=0.25$ effect of the intervention.

Later we decided to match schools in pairs and randomize them to interventions, although we ignored the pairing in the analyses because of the small number of pairs.^{31,32} Before analyzing inter-

vention efficacy, we used χ^2 and t tests to analyze attrition. In the primary analyses, the efficacy of the HIV/STD intervention compared with the health-promotion control intervention over the 3-, 6-, and 12-month follow-ups was tested using generalized estimating equation models, properly adjusting for longitudinal repeated measurements on students clustered within schools.^{33,34} The models were fit, and contrast statements were specified to obtain estimated odds ratios and corresponding 95% confidence intervals. Robust standard errors were used, and an exchangeable working correlation matrix was specified. The models included time-independent covariates, baseline measure of the criterion, intervention condition, and time (3 categories representing 3-, 6-, and 12-month follow-ups). However, analyses of sexual debut did not control for baseline because it was restricted to those who were sexually inexperienced at baseline. We report estimated average intervention effects over the 3 follow-ups constructed from appropriate estimate statements from fitted generalized estimating equation models and d values, calculated by transforming the odds ratios using Cox transformation.³⁵ Models assessing whether the efficacy of the intervention differed among the 3 follow-ups included the baseline measure of the criterion, intervention condition, time, and the intervention condition \times time interaction.

We had intended to examine self-reported consistent condom use as a secondary outcome measure but too few participants reported sexual intercourse at baseline to allow for meaningful analyses of changes over time in condom use. Also, because of the low percentage of participants who reported sexual intercourse, we examined binary measures rather than counts of sexual behaviors in the previous 3 months. Analyses were performed using an intent-to-treat mode, with participants analyzed based on their intervention assignment, regardless of the number of intervention or data-collection sessions attended. These analyses were completed using SAS version 9 (SAS Inc, Carey, North Carolina).

We conducted analyses of school-level intervention effects to confirm the robustness of our findings from individual-level analyses. We used meta-analyses³⁶ that allowed us to take into account the number of students in each pair of schools, giving more weight to larger pairs, similar to weighing larger studies more than smaller studies in a meta-analysis. This analytic approach also allowed us to examine whether the intervention effect size varied among the pairs of schools, just as a meta-analyst might test whether effect sizes were heterogeneous among trials. After fitting generalized estimating equation models as previously described, we constructed mean estimated proportions for each outcome for each school ($n=18$). We treated the estimated intervention difference for each pair as a study and constructed corresponding pooled estimates of intervention differences and 95% confidence intervals based on the 9 pairs using the "metan" command in Stata version 10 (Stata Corp, College Station, Texas), assigning weights to each pair proportional to the size of schools within pairs. Finally, we constructed an 8-degree-of-freedom test of whether intervention effects were heterogeneous across pairs.

RESULTS

Of the 1898 sixth-grade students enrolled at the schools, 1396 (73.6%) returned signed consent forms, 1118 were eligible to participate, and 1057 (94.5%) participated. **Table 1** shows that 558 girls and 499 boys participated. Their ages ranged from 9 to 18 years (mean [SD], 12.4 [1.2] years); 7.6% resided in Berlin; and the others resided in Mdantsane. Only 38.8% lived in a household with their father.

Table 1. Sociodemographic Characteristics of Participating Schools and Sixth-Grade Students by Intervention Condition at Baseline

Characteristic at Baseline	Participants in Intervention, No./Total (%)		Participants, No./Total (%)
	HIV/STD	Health Control	
School			
Sample	9	9	18
Rural	2	2	4
Urban	7	7	14
Classrooms, mean (SD)	9.7 (3.2)	8.9 (2.7)	9.3 (2.9)
Classrooms with electricity, mean (SD)	5.6 (5.8)	3.3 (3.8)	4.4 (4.9)
Sixth-grade students enrolled	940	958	1898
Returned signed consent	702 (74.7)	694 (72.4)	1396 (73.6)
Participant			
Sample	562	495	1057
Female	306/562 (54.5)	252/495 (50.9)	558/1057 (52.8)
Father present in household	203/544 (37.3)	194/479 (40.5)	397/1023 (38.8)
Rural resident	41/562 (7.3)	39/495 (7.9)	80/1057 (7.6)
Age group, y			
9-11	144/562 (25.6)	104/495 (21.0)	248/1057 (23.5)
12-13	330/562 (58.7)	304/495 (61.4)	634/1057 (60.0)
14-18	88/562 (15.7)	87/495 (17.6)	175/1057 (16.6)

Abbreviation: HIV/STD, human immunodeficiency virus/sexually transmitted disease.

As shown in the **Figure**, all 18 schools remained in the trial to its completion. All participants attended intervention session 1; attendance at sessions 2 through 6 ranged from 97.0% to 98.6%. Follow-up return rates were excellent: 1029 (97.4%) completed the 3-month follow-up; 1030 (97.4%), the 6-month follow-up; 1022 (96.7%), the 12-month follow-up, and 1043 (98.7%), at least 1 follow-up. The percentage who attended at least 1 follow-up did not differ between the HIV/STD risk-reduction (98.8%) and control interventions (98.6%). Attending a follow-up session was unrelated to sex, father's presence in the household, residing in Berlin, or sexual behavior. However, participants aged 14 to 18 years (96.0%) were less likely to return for follow-up than those aged 12 to 13 (99.2%) or 9 to 11 years (99.2%) ($P = .003$).

EFFECTS OF HIV/STD RISK-REDUCTION INTERVENTION

Primary Outcome Measures

Table 2 presents descriptive statistics for sexual behaviors by intervention condition and assessment period. **Table 3** presents estimated intervention effects during the follow-up period, corresponding significance tests (both unadjusted and adjusted for baseline outcome), and intraclass correlation coefficients. A smaller percentage of participants in the HIV/STD risk-reduction intervention schools reported having unprotected vaginal intercourse in the past 3 months, averaged over follow-up (2.22%), compared with their counterparts in health-

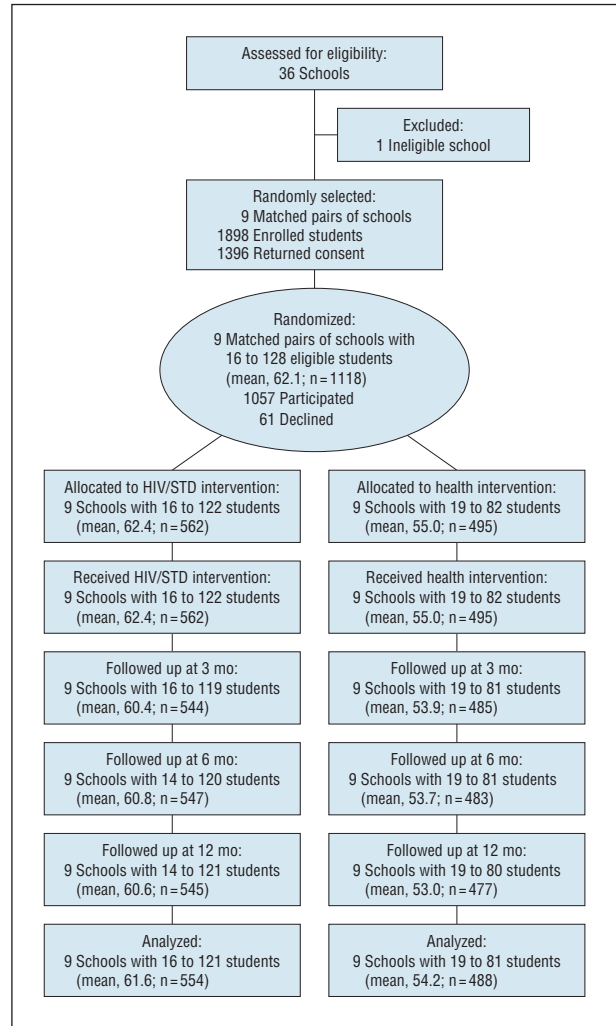


Figure. Flowchart of participating schools and sixth-grade students through the trial in Mdantsane and Berlin, South Africa, 2004 through 2006. Students who were not followed up failed to attend the scheduled follow-up sessions or make-up sessions for unknown reasons. Mean indicates the mean number of students in the 9 schools; n, the total number of students in the 9 schools.

promotion control schools (4.24%), controlling for baseline unprotected vaginal intercourse ($P = .01$; $d = 0.41$).

Secondary Outcome Measures

Averaged over follow-up, participants in the HIV/STD risk-reduction intervention were significantly less likely to report having vaginal intercourse (4.75% vs 7.20%; $P = .02$; $d = 0.29$) and multiple sexual partners (1.83% vs 3.19%; $P = .02$; $d = 0.42$) in the previous 3 months than participants in the health-promotion control intervention, controlling for baseline prevalences.

At baseline, 96.7% of participants reported never having vaginal intercourse. Boys were less likely than girls to report sexual inexperience (93.5% vs 99.5%; $P < .001$). Although the percentage who were sexually inexperienced decreased to 76.8% by the 12-month follow-up, the effect of the intervention on sexual inexperience was nonsignificant. In addition, although the participants in the HIV/STD risk-reduction intervention were less likely to report having heterosexual anal intercourse in the pre-

Table 2. Students Reporting Sexual Behaviors, HIV/STD Knowledge, and Self-efficacy Outcomes by Intervention Condition and Assessment Period

Outcomes	No./Total (%) by Intervention							
	Baseline		3		6		12	
	HIV/STD (n=562)	Health-Promotion (n=495)	HIV/STD (n=544)	Health-Promotion (n=485)	HIV/STD (n=547)	Health-Promotion (n=483)	HIV/STD (n=545)	Health-Promotion (n=477)
Unprotected vaginal intercourse in the past 3 mo	4/561 (0.71)	3/495 (0.61)	9/543 (1.66)	20/485 (4.12)	14/545 (2.57)	20/482 (4.15)	12/545 (2.20)	21/477 (4.40)
Vaginal intercourse in the past 3 mo	7/560 (1.25)	5/495 (1.01)	18/543 (3.31)	35/485 (7.22)	31/547 (5.67)	33/482 (6.85)	27/545 (4.95)	37/476 (7.77)
Multiple sexual partners in the past 3 mo	4/560 (0.71)	1/494 (0.20)	8/544 (1.47)	18/484 (3.72)	12/546 (2.20)	16/482 (3.32)	9/544 (1.65)	13/476 (2.73)
Sexually inexperienced	533/557 (95.7)	481/492 (97.8)	459/544 (84.4)	414/485 (85.4)	433/547 (79.2)	391/483 (81.0)	418/545 (76.7)	367/477 (76.4)
Anal intercourse in the past 3 mo	3/561 (0.53)	4/495 (0.81)	9/544 (1.65)	15/484 (3.10)	5/547 (0.91)	14/483 (2.90)	17/545 (3.12)	20/476 (4.20)

Abbreviation: HIV/STD, human immunodeficiency virus/sexually transmitted disease.

Table 3. GEE Empirical Significance Tests and Effect Size Estimates for the Overall Intervention Effect (3-, 6-, and 12-mo Follow-up Assessments) Unadjusted for Baseline Prevalence and Adjusted for Baseline Prevalence

Outcome	ICC ^a	Unadjusted for Baseline		Adjusted for Baseline	
		OR (95% CI)	P Value	OR (95% CI)	P Value
Unprotected vaginal intercourse in the past 3 mo	0.007	0.52 (0.31-0.87)	.01	0.51 (0.30-0.85)	.01
Vaginal intercourse in the past 3 mo	0.005	0.62 (0.42-0.94)	.02	0.62 (0.42-0.94)	.02
Multiple sexual partners in the past 3 mo	0.005	0.55 (0.31-0.98)	.04	0.50 (0.28-0.89)	.02
Sexually inexperienced	0.007	1.05 (0.76-1.45)	.78
Anal intercourse in the past 3 mo	0.003	0.58 (0.33-1.02)	.06	0.60 (0.34-1.05)	.07

Abbreviations: CI, confidence interval; ellipses, analysis not conducted; GEE, generalized estimating equation; ICC, intraclass correlation coefficient; OR, odds ratio.

^aThe ICCs were estimated by fitting a model using the GEE approach and assuming an exchangeable working correlation structure with a logit link, unadjusted for baseline, controlling for clustering of students within schools (n=18).

vious 3 months (1.98%) than were the participants in the health-promotion control intervention (3.34%), this difference was not statistically significant ($P = .07$; $d = 0.31$). Few participants (0.38%) reported engaging in same-sex sexual behavior at baseline, and only 3.97% ever reported such behavior by the 12-month follow-up. The intervention condition \times time interactions were not significant, indicating that the effects of the intervention did not significantly differ among the 3 follow-up assessments.

Table 4, which presents the results of the meta-analyses, reveals that results at the school level were nearly identical to those at the individual level, though slightly more significant statistically. The test of heterogeneity of treatment effects among school pairs was not significant on any outcomes. There were no adverse events.

COMMENT

Our results indicate that a theory-based, contextually appropriate HIV/STD risk-reduction intervention delivered in schools can be effective in shaping the sexual behavior of young adolescents before or at the beginning of their sexual lives. Averaged over the 3 follow-ups, the intervention reduced by approximately 50%

the percentage of adolescents who reported unprotected vaginal intercourse compared with a health-promotion attention intervention. Moreover, the intervention's efficacy did not differ significantly among the 3 follow-up assessment periods.

This study also revealed that, averaged over the 3 follow-ups, vaginal intercourse with multiple partners was reduced approximately 50% by the intervention compared with the control intervention. This is important because multiple partners, particularly concurrent partners, is believed to play a critical role in the spread of HIV.^{37,38} Interestingly, although the intervention produced a significant reduction in self-reported vaginal intercourse in the previous 3 months, it did not delay sexual debut. This contrasts with the results of a study with adolescents in Namibia⁹ in which the intervention delayed sexual debut but did not reduce recent vaginal intercourse.

The rates of sexual activity in this sample of young adolescents were relatively low, which presents challenges in achieving adequate statistical power. Despite this, we obtained significant effects on important sexual behavior outcomes. That school-level analyses confirmed the primary individual-level analyses strengthens confidence in the findings. Some might reason that,

Table 4. Meta-analysis Estimates of Pooled Intervention Effects and Corresponding 95% CIs of Predicted School Estimates From Fitted GEE Models

Outcome	Unadjusted for Baseline				Adjusted for Baseline			
	OR ^a (95% CI)	P Value	I ² , %	P Value	OR ^a (95% CI)	P Value	I ² , %	P Value
Unprotected vaginal intercourse in the past 3 mo	0.52 (0.346-0.770)	.001	0	>.99	0.54 (0.360-0.819)	.004	0	>.99
Vaginal intercourse in the past 3 mo	0.63 (0.468-0.839)	.002	0	>.99	0.65 (0.480-0.875)	.005	0	.99
Multiple sexual partners in the past 3 mo	0.55 (0.355-0.862)	.009	0	>.99	0.54 (0.339-0.860)	.01
Sexually inexperienced	1.06 (0.893-1.254)	.51	0	>.99
Anal intercourse in the past 3 mo	0.61 (0.397-0.933)	.02	0	>.99	0.55 (0.351-0.867)	.01	0	>.99

Abbreviations: CI, confidence interval; ellipses, analysis not conducted; GEE, generalized estimating equations; OR, odds ratio.

^aPredicted probabilities obtained from fitted GEE models, adjusted for clustering by school (Table 3, column 2). School summaries output to STATA Version 10 for computations of pooled intervention effects using the "metan" command.

because we applied Western theories to behavioral change in sub-Saharan Africa, intervention effects would be weak. However, the effects were at least as strong as those in meta-analyses of interventions for adolescents in the United States.³⁹⁻⁴² The approach of integrating behavior-change theories with qualitative information from the population, then, may yield an efficacious, contextually appropriate intervention.

Anal intercourse carries considerably higher risk of HIV transmission than vaginal intercourse.⁴³ Although the intervention effect on anal intercourse only approached statistical significance in the individual-level analysis, the school-level analysis revealed that the HIV/STD intervention produced a significant reduction in anal intercourse compared with the control intervention.

This study has several methodological strengths. It was conducted with young people in the context of a generalized HIV epidemic. The intervention was developed using both behavior-change theories and extensive formative research and delivered by well-trained cofacilitators who used manualized content. Participants were blind to intervention condition before enrollment, thus avoiding differential self-selection bias.⁴⁴ Matched pairs of schools were randomized to conditions, an attention-control intervention was used, no schools withdrew from the study, and enrollment rates, intervention attendance, and follow-up retention were excellent, strengthening internal validity. Schools were randomly selected, strengthening generalizability to other schools in the area. In addition, the analyses appropriately adjusted for clustering among participants in schools assessed longitudinally.

A limitation of the study is the reliance on self-reports of behavior. Using incidence of STDs or HIV as an outcome was not feasible in our population with a 96.7% rate of sexual inexperience. Another limitation is that the results may not generalize to all South African adolescents. Few studies have been conducted with South African individuals as young as our participants. Three studies that included adolescents comparable in age with our participants revealed rates of self-reported sexual inexperience greater than^{45,46} or similar to⁴⁷ those we observed.

In conclusion, sexual transmission of HIV is a major risk faced by adolescents in sub-Saharan Africa, and interven-

tions are needed urgently to reduce their risk. This study provides the first evidence that a theory-based, contextually appropriate intervention can reduce sexual risk behaviors, particularly unprotected vaginal intercourse, vaginal intercourse, and multiple partners, among young South African adolescents in the earliest stages of their sexual lives. Future research with more sexually experienced adolescents will have to explore whether such interventions can have an effect on condom use and STDs, including HIV.

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