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HIV/STI Risk-Reduction Intervention Efficacy With South African Adolescents Over 54 Months

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Objective: Little research has tested HIV/sexually transmitted infection (STI) risk-reduction interventions' effects on early adolescents as they age into middle and late adolescence. This study tested whether intervention-induced reductions in unprotected intercourse during a 12-month period endured over a 54-month period and whether the intervention reduced the prevalence of STIs, which increase risk for HIV. ***Method:*** Grade 6 learners (mean age = 12.4 years) participated in a 12-month trial in Eastern Cape Province, South Africa, in which 9 matched pairs of schools were randomly selected and within pairs randomized to a theory-based HIV/STI risk-reduction intervention or an attention-control intervention. They completed 42- and 54-month postintervention measures of unprotected intercourse (the primary outcome), other sexual behaviors, theoretical constructs, and, at 42- and 54-month follow-up only, biologically confirmed curable STIs (chlamydial infection, gonorrhea, and trichomoniasis) and herpes simplex virus 2. ***Results:*** The HIV/STI risk-reduction intervention reduced unprotected intercourse averaged over the entire follow-up period (OR = 0.42, 95% CI [0.22, 0.84]), an effect not significantly reduced at 42- and 54-month follow-up compared with 3-, 6-, and 12-month follow-ups. The intervention caused positive changes on theoretical constructs averaged over the 5 follow-ups, although most effects weakened at long-term follow-up. Although the intervention's main effect on STIs was nonsignificant, an Intervention Condition × Time interaction revealed that it significantly reduced curable STIs at 42-month follow-up in adolescents who reported sexual experience. ***Conclusion:*** These results suggest that theory-based behavioral interventions with early adolescents can have long-lived effects in the context of a generalized severe HIV epidemic.

Keywords: South Africa, adolescents, HIV, intervention trial, sexually transmitted infections

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Accounting for an estimated 1.6 million deaths in 2012 (UNAIDS, 2013a), the HIV epidemic continues to have devastating effects on global health. Approximately 70% of new HIV infections occur in sub-Saharan Africa, where heterosexual exposure is the main mode of transmission (UNAIDS, 2013a). People ages 15–24 years account for 39% of new HIV infections (UNAIDS, 2013b), raising concern about HIV prevention for youth. In South Africa, the sub-Saharan African nation with the largest number of people living with HIV in the world that is experiencing a generalized (UNAIDS and World Health Organization, 2000) severe epidemic, HIV disproportionately affects young women: Approximately 3% of males and 7% of females ages 15–19 years are HIV positive, as are 5% of males and 21% of females ages 20–24 years (Shisana et al., 2009).

The median age of first sex in South Africa is about 16 years (Richter, 2005; Simbayi, Chauveau, & Shisana, 2004). Intervening in early adolescence, ages 10–14 years before or just after children become sexually active, is a way to educate them about safer sex practices before they establish habitual patterns of unsafe behavior (UNICEF, 2011). Although several randomized controlled trials (RCTs) have found that interventions reduced HIV sexual risk behaviors in early adolescents (Coyle, Kirby, Marin, Gomez, & Gregorich, 2004; J. B. Jemmott, Jemmott, & Fong, 1998, 2010; Stanton et al., 1996), only one such trial focused on sub-Saharan African early adolescents (J. B. Jemmott, Jemmott, O'Leary, et al., 2010).

Intervention trials with sub-Saharan African youth have had mixed results. One trial (Jewkes et al., 2008) found a reduced incidence of herpes simplex virus 2 (HSV-2), whereas two found interventions did not affect HSV-2 (Cowan et al., 2010; Ross et al., 2007). Two trials found intervention-induced reductions in sexual risk behaviors (Ross et al., 2007; Stanton et al., 1998), but two others (Cowan et al., 2010; Jewkes et al., 2008) did not. Moreover, no trials have tested the effects of HIV/sexually transmitted infection (STI) risk-reduction interventions in sub-Saharan African early adolescents as they age into middle and late adolescence when their sexual activity increases. Although some trials examined effects 2 or more years postintervention (Cowan et al., 2010; Doyle et al., 2010; Jewkes et al., 2008), the participants were older adolescents and the trials did not test statistically whether the interventions' effects were significantly reduced at longer term follow-up.

Here we report tests of (a) an intervention's effects on South African early adolescents during a 54-month postintervention period and (b) whether its effects were smaller 42 and 54 months postintervention compared with 3, 6, and 12 months postintervention. A cluster RCT of the HIV/STI risk-reduction intervention Let Us Protect Our Future with Grade 6 learners (mean age = 12.4 years) found that those in the intervention schools had lower odds of reporting vaginal intercourse, unprotected vaginal intercourse, and multiple partners during the 12-month postintervention period compared with an attention-matched control group (J. B. Jemmott, Jemmott, O'Leary, et al., 2010). The intervention also caused positive changes on potential mediators of sexual risk behaviors the intervention targeted (O'Leary et al., 2012). Besides examining these outcomes, we examined whether the intervention reduced the prevalence of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (GC), *Trichomonas vaginalis* (TV), and HSV-2 infections, based on assays of biological specimens 42 and 54 months postintervention.

Method

Institutional Review Board 8 at the University of Pennsylvania, the designated institutional review board under the federal-wide assurances of the University of Pennsylvania and the University of Fort Hare, South Africa, approved the study. The Human Research Ethics Committee of the University of the Witwatersrand approved the laboratory testing undertaken at the National Institute for Communicable Diseases. We conducted the study in an urban township and a neighboring semirural settlement in Eastern Cape Province, South Africa. Schools serving Grade 6 learners from the general population were eligible. Of 36 schools serving Grade 6 learners in the catchment area, one serving children with learning disabilities was ineligible, leaving 35 eligible schools; all agreed to participate. From 17 matched pairs of schools similar in numbers of Grade 6 learners, classrooms, and classrooms with electricity, including one "pair" consisting of three schools, we randomly selected nine.

We used a cluster RCT design, reducing the potential for contamination between treatment arms that would be present were individuals randomized. We enrolled schools over 13 months beginning in October 2004 and used computer-generated random number sequences to randomize, within pairs, one school to the HIV/STI risk-reduction intervention and one to the control group. Recruiters, following a standardized scripted recruitment protocol, announced the study at the schools and distributed cover letters and parent/guardian consent forms to Grade 6 learners. During recruitment, school personnel, potential participants, and recruiters were masked to the schools' randomized intervention assignment. The nature of the intervention precluded masking the facilitators and participants to the group assignment during the interventions.

Interventions

As described elsewhere (L. S. Jemmott et al., 2014), we developed the interventions based on social–cognitive theory (Bandura, 1986) and the theory of planned behavior (Ajzen, 1991), integrated with qualitative information from extensive formative research with the target population (O'Leary et al., 2012). Each intervention included 12 modules, each lasting 1 hr, with two modules delivered during each of six sessions on consecutive school days. Sessions involved games, brainstorming, role-playing, group discussions, and comic workbooks with a series of characters and storylines. Using standardized manuals, male and female adult cofacilitators implemented each intervention in mixed-sex small groups of nine to 16 adolescents. Twenty-one women and 22 men ages 27–56 years (M = 42 years) bilingual in English and Xhosa served as cofacilitators (L. S. Jemmott et al., 2014). Fifty percent had a bachelor's degree, 65% previously worked as teachers, and 63% previously taught HIV education. We randomly assigned them to an 8-day training to implement one of the two interventions, a training in which trainers modeled the intervention activities and facilitators learned their intervention and practiced implementing it with feedback.

The HIV/STI risk-reduction intervention was designed to (a) increase HIV/STI risk-reduction knowledge, (b) enhance outcome

expectancies (Bandura, 1986) supporting abstinence and condom use, and (c) increase skills and self-efficacy (Ajzen, 1991; Bandura, 1986) to use condoms and to negotiate abstinence and condom use. Table 1 includes the specific theoretical constructs the intervention targeted. To facilitate parent–child discussions of sexual matters, we gave the learners take-home assignments to complete with a parent. The health-promotion control intervention (J. B. Jemmott et al., 2011) included activities similar to the HIV/STI risk-reduction intervention, but targeting physical activity and fruit and vegetable consumption, behaviors linked to chronic diseases that are leading causes of death in South Africa (Joubert et al., 2007; Schneider, Norman, Steyn, & Bradshaw, 2007).

Procedure

We enrolled in the trial Grade 6 learners who completed the preintervention questionnaire and attended Session 1 of the intervention. They completed immediate-post and 3-, 6-, and 12-month postintervention questionnaires by December 2006. The initial informed-consent process covered activities through the 12-month follow-up. Accordingly, we located the learners, then attending more than 200 secondary schools, and gave them parent/guardian consent forms and cover letters explaining the continuation of the trial and inviting their parents or guardians to a meeting where they could ask questions about the follow-up study.

We began 42-month data collection in April 2008 and completed 54-month data collection in June 2010. As compensation, learners received a notebook, a pen, and a pencil for the 3-month follow-up; a T-shirt for the 6-month follow-up; a backpack for the 12-month follow-up; an umbrella (if female) or a cap (if male) for the 42-month follow-up; and a jacket for the 54-month follow-up. We held the intervention and data collection sessions except the 42- and 54-month follow-ups at the learners' schools during the extracurricular period at the end of the school day. We held the 42- and 54-month follow-ups on Saturdays at one of the 18 schools, a centrally located school with suitable plumbing facilities; transportation was provided to the sessions.

Measures

The primary outcome was a binary variable indicating whether the learner reported having unprotected vaginal intercourse in the past 3 months. We defined vaginal intercourse as "your penis in a female's vagina" (male version) or "a boy's penis in your vagina" (female version). We coded the responses 1 for learners reporting not having vaginal sex or using a condom during vaginal sex and 2 for those reporting vaginal sex without using a condom. Secondary behavioral outcomes included sexual experience (i.e., whether they ever had vaginal sex) and behaviors in the past 3 months: vaginal sex, multiple partners, heterosexual anal sex, consistent condom use, frequency of condom use, condom use at last sex, and talking to parents about condoms and about not having sex. We defined anal intercourse using the term "anus/behind." Condom use measures excluded learners not reporting vaginal sex in the past 3 months. Consistent condom use was report of using condoms 100% of the time. Frequency of condom use was on a scale from 1 (*never*) to 5 (*always*).

Additional secondary outcomes included potential mediators—theoretical constructs the HIV risk-reduction intervention targeted—and biologically confirmed STIs. The number of items, coefficient alpha, and mean (*SE*) by intervention condition and data collection period for each theoretical construct are shown in Table 1. HIV risk-reduction knowledge (J. B. Jemmott, Jemmott, Braverman, & Fong, 2005) and its subscales on cultural myths (J. B. Jemmott et al., 2014) and condom use knowledge (J. B. Jemmott et al., 2005) are the sum of the correctly answered true–false questions. We assessed three types of condom use outcome expectancies. Hedonistic outcome expectancy concerns the belief that using condoms will not interfere with sexual enjoyment (J. B. Jemmott et al., 1998, 2005, 2007). An example item is "When a condom is used, sex is more fun." Prevention outcome expectancy is the belief that condoms can reduce the risk of pregnancy and HIV/STI (J. B. Jemmott et al., 1998, 2007). An example item is "Condoms help prevent AIDS." Expected parental approval of condom use is the participants' belief that their mother and father would approve of their using condoms (J. B. Jemmott et al., 2007). Items were rated on scales from 1 (*disagree strongly*) to 5 (*agree strongly*); the mean is the score.

We assessed three types of condom use self-efficacy. Negotiation self-efficacy is the learners' belief that they can convince their partner to use condoms (J. B. Jemmott et al., 2005, 2007). An example item is "I can get my partner to use a condom, even if he or she doesn't want to." Technical skill self-efficacy is learners' belief that they know how to use condoms (J. B. Jemmott et al., 1998, 2005, 2007). An example item is "I can use a condom, even if the room is dark." Impulse control self-efficacy is the learners' belief that they can control themselves sufficiently when sexually excited to use a condom (J. B. Jemmott et al., 1998, 2005). An example item is "If I am sexually aroused, I can stop before sex to use a condom." Learners rated items composed of self-efficacy on scales from 1 (*disagree strongly*) to 5 (*agree strongly*); the mean is the score.

We assessed three abstinence or sexual intercourse outcome expectancies. Abstinence–career goals outcome expectancy is the belief that practicing abstinence will facilitate achieving career goals (Jemmott et al., 1998). Abstinence–prevention outcome expectancy is the belief that practicing abstinence prevents pregnancy and HIV/STI (Jemmott et al., 1998). Expected parental approval of sex is the learners' belief that their mother and father would approve of their having sex. This scale was related to increased odds of reporting sexual intercourse in pilot data (O'Leary et al., 2012). Items were rated on scales from 1 (*disagree strongly*) to 5 (*agree strongly*); the mean is the score. We measured two types of abstinence or sexual intercourse self-efficacy: self-efficacy to refuse sex and to avoid sexual-risk situations. Items were rated on 4-point scales from 1 (*not at all sure*) to 4 (*completely sure*); the mean is the score. An example item for self-efficacy to refuse sex is "How sure are you that you could refuse to have sex with a person even if you loved him?" (female version). An example of an item measuring self-efficacy to avoid sexual risk situations is "How sure are you that you could refuse a ride offered to you by a person that you thought might want to have sex with you?" Both scales were related to reduced intention for sexual intercourse in pilot data (O'Leary et al., 2012).

After completing the 42- and 54-month postintervention questionnaires, learners provided a first-pass urine specimen and a blood specimen, which were delivered to the STI Reference Centre of the National Institute for Communicable Diseases, Johannes-

Table 1
Empirical Mean (SE) of Theoretical Constructs, Longitudinally Up to 54 Months Postintervention, by Intervention Arm and Assessment Period, Mdantsane and Berlin, South Africa, 2004–2010

	Baseline		Immediate post		3 months		6 months		12 months		42 months		54 months	
Theoretical construct	HIV (n = 562)	Health (n = 495)	HIV (n = 562)	Health (n = 495)	HIV (n = 544)	Health (n = 485)	HIV (n = 547)	Health (n = 483)	HIV (n = 545)	Health (n = 477)	HIV (n = 508)	Health (n = 449)	HIV (n = 520)	Health (n = 456)
Constructs relevant to abstinence and condom use														
HIV risk-reduction knowledge (16 items)	6.70 (0.09)	6.88 (0.10)	9.74 (0.11)	7.40 (0.14)	8.24 (0.13)	6.86 (0.13)	8.46 (0.13)	6.78 (0.13)	8.53 (0.14)	7.22 (0.14)	9.26 (0.13)	8.51 (0.14)	9.61 (0.13)	8.76 (0.14)
Cultural myths (4 items)	1.14 (0.05)	1.18 (0.05)	1.91 (0.06)	1.39 (0.07)	1.76 (0.06)	1.46 (0.07)	1.78 (0.07)	1.45 (0.07)	1.87 (0.07)	1.59 (0.07)	2.43 (0.06)	2.17 (0.07)	2.43 (0.07)	2.14 (0.07)
Constructs relevant to condom use														
Condom use knowledge (3 items)	1.23 (0.05)	1.30 (0.05)	2.05 (0.03)	1.24 (0.05)	1.56 (0.04)	1.00 (0.05)	1.64 (0.04)	1.00 (0.05)	1.63 (0.04)	1.11 (0.05)	1.75 (0.04)	1.47 (0.05)	1.98 (0.04)	1.78 (0.05)
Condom use hedonistic outcome expectancy (4 items; α = .65)	3.85 (0.04)	3.82 (0.05)	4.07 (0.04)	3.93 (0.04)	4.06 (0.04)	3.82 (0.05)	4.06 (0.04)	3.83 (0.04)	4.15 (0.04)	3.89 (0.04)	3.97 (0.03)	3.80 (0.04)	4.01 (0.03)	3.86 (0.04)
Condom use prevention outcome expectancy (3 items; α = .89)	3.70 (0.06)	3.63 (0.07)	4.42 (0.04)	4.00 (0.05)	4.29 (0.04)	4.05 (0.05)	4.29 (0.04)	4.14 (0.05)	4.26 (0.04)	4.25 (0.04)	4.56 (0.03)	4.53 (0.03)	4.52 (0.03)	4.55 (0.03)
Perceived parent approval of condom use (2 items; α = .90)	3.32 (0.07)	3.24 (0.07)	3.71 (0.06)	3.14 (0.07)	3.66 (0.06)	3.25 (0.07)	3.73 (0.06)	3.37 (0.07)	3.69 (0.06)	3.56 (0.07)	4.37 (0.05)	4.32 (0.05)	4.43 (0.04)	4.46 (0.04)
Condom technical skill self-efficacy (3 items; α = .82)	2.87 (0.06)	2.87 (0.06)	3.10 (0.05)	2.84 (0.06)	3.16 (0.05)	3.03 (0.06)	3.20 (0.05)	3.08 (0.06)	3.30 (0.05)	3.13 (0.05)	3.75 (0.04)	3.65 (0.04)	3.86 (0.04)	3.81 (0.04)
Condom use negotiation self-efficacy (4 items; α = .93)	3.39 (0.06)	3.40 (0.07)	3.87 (0.05)	3.34 (0.06)	3.81 (0.05)	3.51 (0.06)	3.75 (0.05)	3.53 (0.05)	3.84 (0.05)	3.59 (0.06)	4.27 (0.03)	4.13 (0.04)	4.28 (0.03)	4.22 (0.03)
Condom use impulse control self-efficacy (3 items; α = .74)	3.18 (0.06)	3.17 (0.06)	3.85 (0.05)	3.35 (0.06)	3.84 (0.05)	3.51 (0.06)	3.86 (0.05)	3.61 (0.06)	3.94 (0.05)	3.69 (0.05)	4.15 (0.04)	4.02 (0.04)	4.13 (0.04)	4.06 (0.04)

(*table continues*)

Table 1 (*continued*)

Theoretical construct	Baseline		Immediate post		3 months		6 months		12 months		42 months		54 months	
	HIV (n = 562)	Health (n = 495)	HIV (n = 562)	Health (n = 495)	HIV (n = 544)	Health (n = 485)	HIV (n = 547)	Health (n = 483)	HIV (n = 545)	Health (n = 477)	HIV (n = 508)	Health (n = 449)	HIV (n = 520)	Health (n = 456)
Constructs relevant to abstinence														
Abstinence–career goals outcome expectancy (4 items; α = .83)	3.14 (0.06)	2.93 (0.06)	4.13 (0.04)	3.64 (0.05)	4.09 (0.04)	3.74 (0.05)	4.18 (0.04)	3.85 (0.05)	4.18 (0.04)	3.95 (0.05)	3.70 (0.05)	3.65 (0.05)	3.54 (0.04)	3.51 (0.05)
Abstinence–prevention outcome expectancy (2 items; α = .88)	3.42 (0.06)	3.36 (0.07)	4.06 (0.04)	3.74 (0.06)	4.01 (0.05)	3.87 (0.05)	4.08 (0.04)	3.96 (0.05)	4.16 (0.04)	4.04 (0.05)	4.00 (0.04)	3.95 (0.05)	3.85 (0.04)	3.88 (0.05)
Perceived parent approval of sexual intercourse (2 items; α = .88)	1.43 (0.03)	1.41 (0.03)	1.41 (0.03	1.51 (0.04)	1.34 (0.03)	1.42 (0.04)	1.33 (0.03)	1.50 (0.04)	1.31 (0.03)	1.40 (0.03)	1.35 (0.03)	1.40 (0.05)	1.49 (0.03)	1.61 (0.04)
Self-efficacy to refuse sexual intercourse (5 items; α = .92)	2.18 (0.05)	2.14 (0.05)	2.61 (0.04)	2.37 (0.05)	2.74 (0.05)	2.47 (0.05)	2.84 (0.05)	2.57 (0.05)	2.97 (0.05)	2.72 (0.03)	3.08 (0.04)	2.91 (0.04)	3.11 (0.04)	3.01 (0.04)
Self-efficacy to avoid sexual risk situations (4 items; α = .91)	1.93 (0.05)	1.89 (0.05)	2.63 (0.05)	2.33 (0.05)	2.79 (0.05)	2.50 (0.05)	2.88 (0.05)	2.57 (0.05)	2.96 (0.05)	2.68 (0.05)	3.18 (0.04)	2.96 (0.05)	3.27 (0.04)	3.09 (0.05)

burg, South Africa. Urine specimens were assayed for CT and GC using the Aptima Combo Assay (Hologic Gen-Probe, San Diego, CA) and TV using the Aptima *Trichomonas vaginalis* Assay (Hologic Gen-Probe, San Diego, CA). Sera were tested for HSV-2 using the HerpeSelect 2 ELISA IgG assay (Focus Diagnostics, Cypress, CA). Participants testing positive for curable STIs (CT, GC, or TV) received directly observable single-dose antimicrobial treatment and risk-reduction counseling per Centers for Disease Control and Prevention recommendations. Those testing seropositive for HSV-2 were counseled, given a short course of acyclovir for flare-ups, and referred for treatment for future flare-ups.

Statistical Analysis

The a priori unit of inference was the individual (J. B. Jemmott, Jemmott, O'Leary, et al., 2010). A sample size calculation was performed to detect an effect of $d = 0.25$ standard deviations (Cohen, 1988) on the a priori primary outcome unprotected intercourse, adjusting for the expected variance inflation due to clustering (Donner & Klar, 2000). Assuming $\alpha = .05$, a two-tailed test, intraclass correlation (ICC) coefficient = .00864 based on unpublished pilot data, 20% attrition, and $N = 1{,}100$ Grade 6 learners enrolled in the trial from 16 schools with an average of 67 learners in each school, the trial was estimated to have 80% power to detect $d = 0.25$ effect of the intervention.

We also performed a power analysis for the intervention's effect on STIs, a secondary outcome introduced 42 and 54 months postintervention. In studies in schools and other nonclinic settings, some adolescents will be sexually experienced and therefore at risk of STI, whereas others will not be sexually experienced and hence not at risk. Based on prior research (Richter, 2005; Simbayi et al., 2004), we considered three estimates of the percentage of learners who would be sexual experienced: 76.5% ($n = 809$), 51.3% ($n = 542$), and 38.3% ($n = 405$) of the original 1,057 learners. Assuming that 15.4% of the sexually experienced learners in the absence of an intervention would test positive for CT, GC, or TV, $\alpha = .05$, a two-tailed test, ICC = .009, attrition = 20%, and a reduction in STI rates from 15.4% in the control group to 8.0% in the intervention group, the estimated power was .84 if 51.3% were sexually experienced, .95 if 76.5% were sexually experienced, and .72 if 38.3% were sexually experienced.

In the primary analyses, the efficacy of the HIV/STI intervention compared with the control intervention on behavioral outcomes over the 3-, 6-, 12-, 42-, and 54-month follow-ups was tested using generalized estimating equation models, adjusting for longitudinal repeated measurements on learners clustered within schools (Fitzmaurice, Laird, & Ware, 2004; Liang & Zeger, 1986). Robust standard errors were used, and an exchangeable working correlation matrix was specified. The models included time-independent covariates, baseline measure of the criterion, time (five categories representing 3-, 6-, 12-, 42-, and 54-month follow-up), intervention condition, and the Intervention Condition × Time interaction. In models for theoretical constructs, time had six categories because the immediate-post assessment was included. We report estimated intervention effects averaged over all postintervention assessments constructed from appropriate "estimate" statements from fitted generalized estimating equation models.

We used Intervention Condition × Time interaction contrasts to test whether the effect of the intervention was significantly different 42 and 54 months postintervention compared with 3, 6, and 12 months postintervention. In analyses of condom use, baseline condom use was not included because too few learners reported vaginal intercourse at baseline. We intended to examine the efficacy of the intervention on STIs, restricting the analysis to learners who reported sexual experience, but found that some learners reporting no sexual experience tested positive for STIs; accordingly, we also report analyses for those reporting no sexual experience. Analyses focused on any curable STI and HSV-2 separately and controlled for gender, a strong correlate of STIs, including HIV, in this setting. We tested the intervention effects on report of sexual inexperience by the 54-month follow-up using logistic regression not controlling for baseline sexual experience because the analysis was restricted to those sexually inexperienced at baseline. We used an intent-to-treat mode with participants analyzed based on their intervention assignment, regardless of the number of intervention or data collection sessions attended. We used chi-square and t tests to analyze attrition. Analyses were completed using SAS Version 9.

Results

More than 90% of 1,057 learners attended each follow-up session (see Figure 1). The percentage that attended at least one follow-up did not differ between the HIV/STI risk-reduction (99.5%) and control interventions (99.2%), $p = .583$. Attending a follow-up was unrelated to sex, father's presence in the household, residing in the semirural area, or sexual behavior at baseline. However, only 171 (97.7%) of learners ages 14–18 years at baseline returned for a follow-up compared with 631 (99.5%) of those ages 12–13 and 248 (100%) of those ages 9–11, $p = .011$.

Unprotected vaginal sex in the past 3 months increased over the follow-up period (see Table 2). A smaller percentage of learners in the HIV/STI risk-reduction intervention schools reported having unprotected vaginal sex averaged over the postintervention period compared with their counterparts in control schools ($d = 0.15$), controlling for baseline unprotected vaginal sex (see Table 3). The Intervention Condition × Time interaction contrast was nonsignificant, indicating that the effect was not significantly different at 42 and 54 months postintervention compared with 3, 6, and 12 months postintervention.

The intervention also had effects on two secondary behavioral outcomes, decreasing the odds of heterosexual anal sex ($d = 0.16$) and increasing the odds of talking to parents about not having sex ($d = 0.14$) averaged over the postintervention period in HIV/STI risk-reduction intervention participants compared with controls, effects that were not smaller 42 and 54 months postintervention compared with 3, 6, and 12 months postintervention. Two effects approached significance: nonsignificantly lower odds of self-reported vaginal sex ($d = 0.11$) and multiple partners ($d = 0.10$), effects that were smaller at the 42- and 54-month follow-ups compared with the first 12 months. There were no significant differences between the interventions in measures of condom use and talking to parents about condom use.

The intervention had the hypothesized effect on each theoretical construct (see Table 4). Its effect on condom use hedonistic expectancy, condom use technical skills, expected parental approval of sex, self-efficacy to refuse sex, and self-efficacy to avoid sexual risk situations was not smaller 42 and 54 months postintervention compared with the first 12 months of follow-

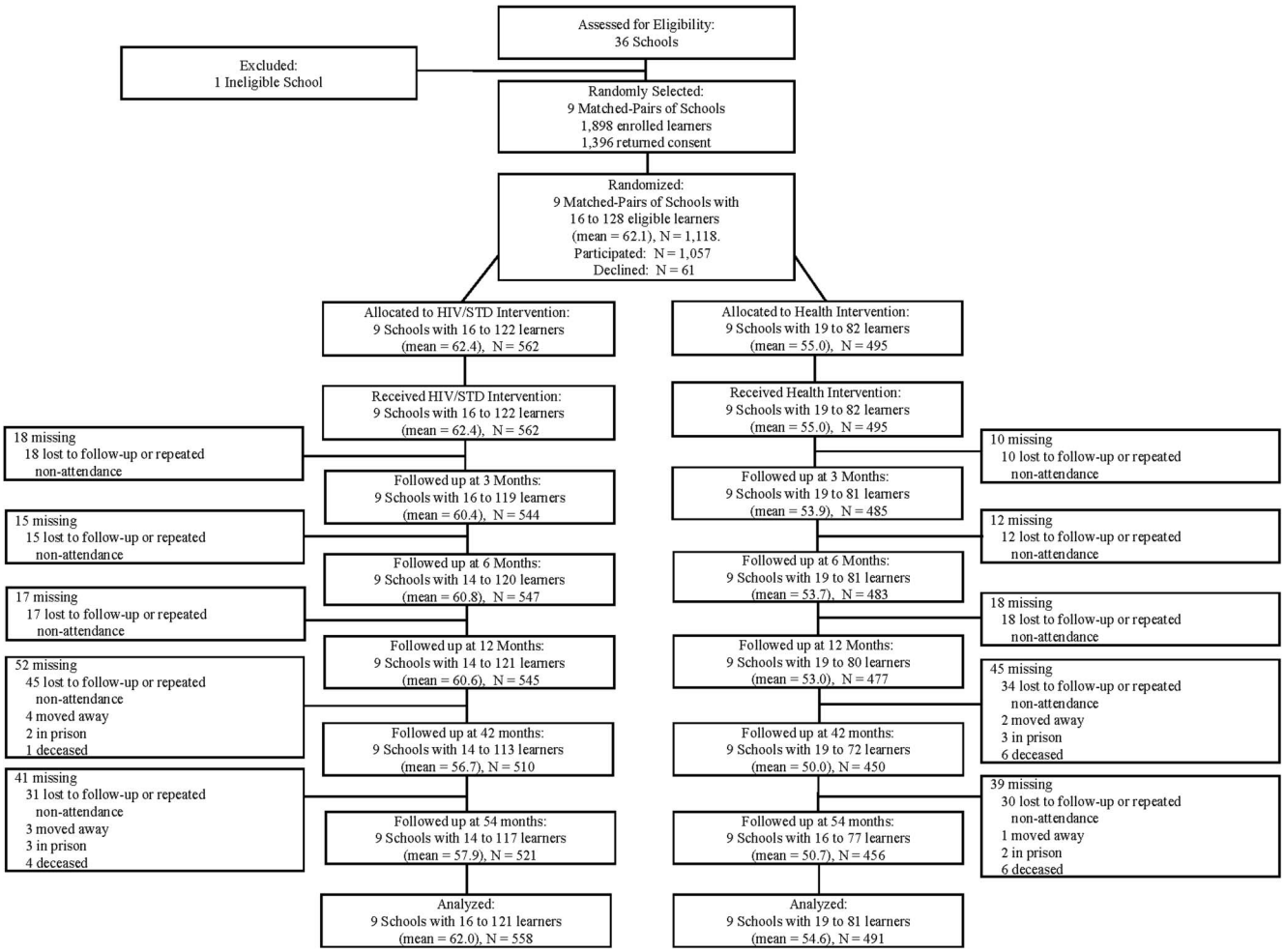

Figure 1. Progress of participating schools and Grade 6 learners through the trial, Mdantsane and Berlin, South Africa, 2004–2010.

up, whereas its effect on HIV/STI knowledge, cultural myths, condom use knowledge, condom use prevention outcome expectancy, expected parental approval of condom use, condom use impulse control, abstinence–career goal outcome expectancy, and abstinence–prevention outcome expectancy was smaller 42 and 54 months postintervention compared with the initial follow-ups. Even though the effect was smaller at long-term follow-up on the three knowledge variables and condom use impulse control, it was still significant (see Table 4).

We treated all learners testing positive for a curable STI. Table 2 presents the percentages of learners testing positive for STIs. Of those reporting sexual experience at 42 months, 123 (21.1%) tested positive for a curable STI, as did 29 (7.7%) of those reporting no sexual experience ($p < .001$). At 54 months, the figures were 119 (19.6%) and 11 (6.0%), respectively ($p < .001$). In the analyses on self-reported sexually experienced learners, the intervention effect on curable STIs averaged over the 42- and 54-month follow-ups was nonsignificant, OR = 0.91, 95% CI [0.73, 1.12]. The Intervention Condition × Time interaction was significant, $p = .022$. The intervention reduced curable STIs at 42-month follow-up, OR = 0.71, 95% CI [0.54, 0.95], but not at 54-month follow-up, OR = 1.15, 95% CI [0.84, 1.57]. The analysis on HSV-2 serostatus revealed no significant intervention effect or interaction, $ps > .66$. In the analyses on self-reported sexually inexperienced learners, the intervention's effects on curable STIs and HSV-2 and the Intervention-Condition x Time interactions were nonsignificant, $ps > .18$.

Discussion

These results, obtained more than 4 years postintervention, indicate that the Let Us Protect Our Future intervention had significant effects on South African early adolescents. Averaged over the 54-month follow-up period, the intervention reduced self-reported unprotected vaginal sex and heterosexual anal sex and increased self-reported talking to parents about not having sex compared with the control group. Moreover, nonsignificant Intervention Condition × Time interaction contrasts revealed that these effects were not smaller during the longer term compared with shorter term follow-ups.

The intervention's effects on reports of vaginal sex and multiple partners were smaller at long-term compared with short-term

Table 2

Empirical Distribution of Self-Reported Behaviors and Biologically Confirmed Curable Sexually Transmitted Infections and Herpes Simplex Virus 2 Seropositivity, Longitudinally Up to 54 Months Postintervention, by Intervention Arm and Assessment Period, Mdantsane and Berlin, South Africa, 2004–2010

	Baseline		3 months		6 months		12 months		42 months		54 months	
Behavior	HIV (n = 562)	Health (n = 495)	HIV (n = 544)	Health (n = 485)	HIV (n = 547)	Health (n = 483)	HIV (n = 545)	Health (n = 477)	HIV (n = 508)	Health (n = 449)	HIV (n = 520)	Health (n = 456)
Unprotected vaginal intercourse, *n/N* (%)	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)	81/508 (18.04)	98/449 (19.29)	132/519 (25.43)	126/455 (27.69)
Vaginal intercourse, *n/N* (%)	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)	182/506 (35.97)	140/448 (31.25)	256/516 (49.61)	214/449 (47.66)
Multiple sexual partners, *n/N* (%)	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)	58/502 (11.55)	45/449 (10.02)	82/514 (15.95)	66/448 (14.29)
Sexually inexperienced, *n/N* (%)	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)	212/505 (41.98)	205/449 (45.66)	138/519 (26.59)	133/454 (29.30)
Heterosexual anal intercourse, *n/N* (%)	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)	26/508 (5.12)	30/448 (6.70)	35/520 (6.73)	51/456 (11.18)
Consistent condom use, *n/N* (%)									113/182 (62.09)	78/139 (56.12)	161/258 (62.40)	127/216 (58.80)
Mean (*SE*) frequency of condom use									3.34 (0.11)	3.04 (0.13)	3.26 (0.09)	3.18 (0.11)
Condom use at last vaginal intercourse, *n/N* (%)									212/290 (73.10)	165/236 (69.92)	282/377 (74.80)	228/312 (73.08)
Talked to parents about condoms, *n/N* (%)	49/529 (9.26)	60/495 (12.12)	183/544 (33.64)	158/485 (32.58)	179/547 (32.72)	151/482 (31.33)	177/545 (32.48)	158/477 (33.12)	250/510 (49.02)	212/449 (47.22)	259/521 (49.71)	212/455 (46.59)
Talked to parents about not having sex, *n/N* (%)	216/528 (40.91)	225/495 (45.45)	314/544 (57.72)	245/485 (50.52)	316/547 (57.77)	256/482 (53.11)	319/545 (58.53)	265/477 (55.56)	322/510 (63.14)	277/450 (61.56)	311/521 (59.69)	249/455 (54.73)
Any curable STI detected, *n/N* (%)												
Reported sexual experience									56/316 (17.72)	67/267 (25.09)	68/327 (20.80)	51/281 (18.51)
Reported no sexual experience									21/193 (10.88)	8/183 (4.37)	7/98 (7.14)	4/86 (4.65)
Herpes simplex virus 2 seropositivity												
Reported sexual experience									28/314 (8.92)	21/267 (7.87)	40/325 (12.31)	31/280 (11.07)
Reported no sexual experience									11/193 (5.70)	7/183 (3.83)	10/197 (10.31)	4/84 (4.76)

Note. All behaviors are reported for the past 3 months except sexual experience, which is ever in life.

Table 3
Generalized Estimating Equation Empirical Significance Tests, Odds Ratios, (and 95% Confidence Intervals) for the Overall Intervention Effect (3, 6, 12, 42, 54 Months Postintervention), Short-Term Intervention Effect (3, 6, 12 Months Postintervention), and Long-Term Intervention Effect (42 and 54 Months Postintervention) on Self-Reported Behaviors Adjusted for Baseline Prevalence, Mdantsane and Berlin, South Africa, 2004–2010

Behavior	Overall intervention effect		Short-term intervention effect		Long-term intervention effect		Intervention condition × Time interaction contrast
	OR [95% CI]	*p*	OR [95% CI]	*p*	OR [95% CI]	*p*	*p*
Unprotected vaginal intercourse	0.42 [0.22, 0.84]	.013	0.51 [0.30, 0.85]	.012	0.95 [0.58, 1.54]	.820	.101
Vaginal intercourse	0.61 [0.36, 1.05]	.076	0.62 [0.42, 0.94]	.022	1.31 [0.86, 2.19]	.212	.034
Multiple sexual partners	0.52 [0.24, 1.12]	.095	0.50 [0.28, 0.89]	.018	1.31 [0.71, 2.44]	.386	.035
Sexually in-experienced			1.05 [0.76, 1.45]	.775	0.83 [0.48, 1.45]	.508	
Heterosexual anal intercourse	0.31 [0.13, 0.75]	.009	0.60 [0.34, 1.05]	.073	0.40 [0.17, 0.91]	.030	.147
Consistent condom use					1.47 [0.79, 2.71]	.221	
Frequency of condom use					1.59 [0.91, 2.77]	.105	
Condom use at last vaginal intercourse					1.25 [0.72, 2.17]	.426	
Talked to parents about condoms	1.21 [0.86, 1.71]	.279	1.20 [0.80, 1.79]	.390	1.28 [0.83, 1.96]	.264	.885
Talked to parents about not having sex	1.52 [1.07, 2.16]	.021	1.66 [1.11, 2.48]	.014	1.38 [0.89, 2.15]	.147	.251

Note. OR (HIV intervention vs. health control) is adjusted for baseline prevalence of the behavior, except sexually inexperienence is not adjusted for baseline prevalence and excludes those not sexually inexperienced at baseline.

follow-up, and its effects averaged over the follow-up period revealed only nearly significant trends toward reductions in vaginal sex and multiple partners. The attenuation of the intervention's effects on some behavioral outcomes after more than 4 years is perhaps not surprising; the durability of its effects on unprotected vaginal sex, heterosexual anal sex, and talking to parents about not having sex is surprising. In this connection, some might argue that the intervention, based on a Western theoretical model, social–cognitive theory, implemented in sub-Saharan Africa, would have little effect on behavior. Contrary to this, its effects were similar to those in a meta-analytic review of HIV risk-reduction interventions with adolescents, although none of the trials reviewed had a follow-up as long as 54 months postintervention (Johnson, Scott-Sheldon, Huedo-Medina, & Carey, 2011).

The intervention also had a significant effect averaged over the postintervention period on each theoretical construct. Moreover, its effects on several of them, including condom use hedonistic outcome expectancy, condom use technical skills, expected parent approval of sex, self-efficacy to refuse sex, and self-efficacy to avoid sexual risk situations, did not decrease at long-term compared with short-term follow-up. Interestingly, two of these theoretical constructs, expected parent approval of sex and self-efficacy to avoid sexual risk situations, mediated the intervention's efficacy over the first 12 months postintervention (O'Leary et al., 2012). That effects on these constructs endured may well account for the continued efficacy of the intervention, a possibility that future mediation analyses must explore.

In the planned analysis on learners reporting sexual experience, the intervention did not reduce curable STIs or HSV-2 averaged over the 42- and 54-month follow-ups. However, its effect on curable STIs differed significantly at the two follow-ups. It reduced curable STIs 42 months, but not 54 months, postintervention. Reducing STIs is important because having an STI increases the risk of coinfection with HIV (Fleming & Wasserheit, 1999). STIs detected 42 months postintervention are a measure of prevalence because when the learners contracted the STIs is unknown. In contrast, STIs detected 54 months postintervention are a measure of 1-year incidence because we treated all curable STIs detected 42 months postintervention. Thus, the intervention had an effect on curable STIs sometime between the intervention's culmination and the 42-month assessment, an effect that did not persist sufficiently to affect STI incidence at 54-month follow-up. Although some learners reporting no sexual experience tested positive for STI, analyses revealed no significant intervention or Intervention Condition × Time interaction effects on curable STIs or HSV-2 in learners reporting no sexual experience.

A few other studies on youth in sub-Saharan Africa have found intervention-induced behavior change (Michielsen et al., 2010; Paul-Ebhohimhen, Poobalan, & van Teijlingen, 2008), but the follow-up periods were generally shorter than 1 year and rarely 2 or more years, and none targeted early adolescents. Notably, one cluster RCT found a decreased HSV-2 incidence during a 2-year follow-up period and, in men, decreased transactional sex and problem drinking (Jewkes et al., 2008). Another intervention study, employing a 9-year follow-up, reported no effects on HIV or HSV-2 incidence or self-reported behavior (Doyle et al., 2010).

We are unaware of any other RCT reporting effects of an HIV/STI risk-reduction intervention on sub-Saharan African early adolescents over 4.5 years. Indeed, we are not aware of any other trials that have tested an HIV/STI risk-reduction intervention 1-year postintervention period compared with longer term follow-up, and most meta-analyses have not investigated whether intervention efficacy varies over time. Although a meta-analysis (Johnson et al., 2011) reported that the length of postintervention follow-up did not affect effect size estimates, such review-generated evidence as opposed to study-generated evidence (Cooper, 1989) is correlational, not addressing whether the effects within trials are significantly smaller at long-term follow-up because length of follow-up may be related to other aspects of trials, complicating interpretation. Future trials, like the present trial, reporting statistical tests comparing short-term and long-term follow-up results, are needed to provide the data for meta-analyses on the whether the size of intervention effects varies over time.

Table 4

Generalized Estimating Equation Empirical Significance Tests, Mean Differences, (95% Confidence Intervals) for the Overall Intervention Effect (Immediate-Post and 3, 6, 12, 42, 54 Months Postintervention), Short-Term Intervention Effect (Immediate-Post and 3, 6, 12 Months Postintervention), and Long-Term Intervention Effect (42 and 54 Months Postintervention) and on Theoretical Constructs Adjusted for Baseline Theoretical Construct Score, Mdantsane and Berlin, South Africa, 2004–2010

	Overall intervention effect		Short-term intervention effect		Long-term intervention effect		Intervention condition × Time interaction contrast
Theoretical construct	Mean difference [95% CI]	*p*	Mean difference [95% CI]	*p*	Mean difference [95% CI]	*p*	*p*
Constructs relevant to abstinence and condom							
HIV risk-reduction knowledge	2.78 [2.22, 3.35]	<.001	3.43 [2.82, 4.04]	<.001	1.59 [0.93, 2.25]	<.0001	<.0001
Cultural myths	0.66 [0.38, 0.94]	<.001	0.71 [0.43, 1.05]	<.001	0.56 [0.22, 0.90]	.0012	.0224
Constructs relevant to condom use							
Condom use knowledge	1.02 [0.84, 1.21]	<.001	1.29 [1.08, 1.50]	<.001	0.49 [0.27, 0.71]	<.001	<.001
Condom use hedonistic outcome expectancy	0.39 [0.25, 0.54]	<.001	0.43 [0.26, 0.60]	<.001	0.31 [0.15, 0.48]	<.001	.850
Condom use prevention outcome expectancy	0.28 [0.14, 0.43]	<.001	0.42 [0.23, 0.61]	<.001	0.01 [−0.13, 0.15]	.877	<.001
Perceived parent approval of condom use	0.45 [0.22, 0.67]	<.001	0.67 [0.39, 0.96]	<.001	0.03 [−0.17, 0.23]	.761	<.001
Condom use technical skill self-efficacy	0.28 [0.08, 0.49]	.006	0.35 [0.10, 0.60]	.006	0.16 [−0.04, 0.35]	.114	.295
Condom use negotiation self-efficacy	0.50 [0.31, 0.69]	<.001	0.66 [0.42, 0.90]	<.001	0.20 [0.04, 0.36]	.015	.097
Condom use impulse control self-efficacy	0.51 [0.33, 0.70]	<.001	0.68 [0.44, 0.92]	<.001	0.20 [0.03, 0.37]	.023	<.001
Constructs relevant to abstinence							
Abstinence–career goal outcome expectancy	0.49 [0.33, 0.65]	<.001	0.70 [0.51, 0.90]	<.001	0.09 [−0.13, 0.31]	.442	<.001
Abstinence–prevention outcome expectancy	0.23 [0.06, 0.40]	.008	0.35 [0.14, 0.55]	<.001	0.02 [−0.18, 0.23]	.823	.004
Perceived parent approval of sexual intercourse	−0.21 [−0.33, −0.09]	<.001	−0.23 [−0.37, −0.10]	<.001	−0.18 [−0.34, −0.01]	.034	.880
Self-efficacy to refuse sexual intercourse	0.41 [0.22, 0.60]	<.001	0.51 [0.29, 0.73]	<.001	0.26 [0.06, 0.46]	.009	.166
Self-efficacy to avoid sexual risk situations	0.51 [0.30, 0.71]	<.001	0.57 [0.34, 0.81]	<.001	0.40 [0.19, 0.61]	<.001	.285

Note. The mean difference is HIV intervention minus health control mean difference controlling for baseline scores.

A common concern about providing HIV education, including information about condoms, to young sexually inexperienced adolescents is that such education would encourage them to have sex. The present study in which only 3.3% of young adolescents reported sexual experience before the intervention (J. B. Jemmott, Jemmott, O'Leary, et al., 2010) should allay that concern. The adolescents who received the HIV/STI risk-reduction intervention were less likely to report unprotected vaginal sex during a 54-month postintervention period than were their counterparts in the control group, a finding suggesting that intervening with adolescents before they are sexually active is salubrious, causing reductions in their sexual risks.

The strengths of this study include the attention-matched control group, random selection of schools, long-term follow-up, high retention rates, biological markers, generalized epidemic setting, and the cluster RCT design, which increased internal validity while decreasing risk of contamination between arms. The use of self-reports is a limitation. The fact that some learners reporting no sexual experience tested positive for STI suggests socially desirable responding, but the significant relation between self-reported sexual experience and STIs 42 and 54 months postintervention reassures that results were not entirely due to socially desirable responding. Moreover, the robust and consistent results for intervention effects on theoretical constructs lend credence to the validity of the data. The intervention reduced unprotected vaginal sex, but did not increase condom use. Analyses of the intervention's effects on condom use had less power than did analyses on other outcomes: Data from the first three follow-ups were excluded from the condom use analyses because too few learners reported having sex, as were data from learners who did not report sex at 42-month or 54-month follow-up, whereas analyses on other outcomes included all learners, irrespective of whether they had sex. Therefore, we may have underestimated the intervention's effects on condom use. Another limitation is that the results may not generalize to all South African adolescents. Unknown is whether the intervention would continue to be efficacious if implemented by teachers in classrooms across South Africa. A challenge for the future is whether the characteristics of the interven-

tion and its effects can be maintained with implementation in the real world, important questions implementation research will have to answer.

Nonetheless, the fact that adolescents who received only 12 hr of intervention in Grade 6, when few reported sexually experience, retained risk-reduction knowledge, self-efficacy, and outcome expectancies and were continuing to engage in safer sexual behavior during a 54-month follow-up period is quite extraordinary. The HIV epidemic is having devastating effects in South Africa, the country with the most people living with HIV. These results indicate that intervening early, before the initiation of sexual activity, can have long-lasting effects on behavior—necessary effects should we hope to see an AIDS-free generation.

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