Haverford College

Haverford Scholarship

2012

Moderation and Mediation of an Effective HIV Risk-Reduction Intervention for South African Adolescents

Ann O'Leary

John B. Jemmott

Loretta S. Jemmott

Zolani Ngwane
Haverford College, zngwane@haverford.edu

Follow this and additional works at: https://scholarship.haverford.edu/anthropology_facpubs

Repository Citation

ORIGINAL ARTICLE

Moderation and Mediation of an Effective HIV Risk-Reduction Intervention for South African Adolescents

Ann O'Leary, Ph.D. · John B. Jemmott III, Ph.D. ·
Loretta Sweet Jemmott, Ph.D. ·
Scarlett Bellamy, Ph.D. · Zolani Ngwane, Ph.D. ·
Larry Icard, Ph.D. · Lynnette Gueits, MHS

Abstract

Background "Let Us Protect Our Future" is a sexual risk-reduction intervention for sixth-grade adolescents in South Africa. Tested in a cluster-randomized controlled trial, the intervention significantly reduced self-reported intercourse and unprotected intercourse during a 12-month follow-up period.

Purpose The present analyses were conducted to identify moderators of the intervention's efficacy as well as, which theory-based variables mediated the intervention's effects.

Methods Intervention efficacy over the 3-, 6-, and 12-month follow-up was tested using generalized estimating equation models.

Results Living with their father in the home, parental strictness, and religiosity moderated the efficacy of the intervention in reducing unprotected intercourse. Self-efficacy to avoid risky situations and expected parental disapproval of their having intercourse, derived from Social Cognitive Theory, significantly mediated the intervention's effect on abstinence.

Conclusions This is the first study to demonstrate that Social Cognitive variables mediate the efficacy of a sexual risk-reduction intervention among South African adolescents.

Keywords HIV prevention · Behavioral intervention · Adolescents · South Africa · Moderation · Mediation

Introduction

"Let Us Protect Our Future" is an intervention to reduce the risk of human immunodeficiency virus (HIV), acquired immunodeficiency syndrome (AIDS), and sexually transmitted diseases (STDs) among sixth-grade South African adolescents. In a cluster-randomized controlled trial, a significantly smaller percentage of adolescents who received the HIV risk-reduction intervention reported having vaginal intercourse in the prior 3 months and unprotected vaginal intercourse in the prior 3 months compared with adolescents in the health-promotion control intervention [1]. The trial's results were particularly important in the South African context because South Africa has the largest number of HIV-infected individuals in the world [2], an estimated 5,700,000. About 18.8 % of South Africans 15–49 years of age are living with HIV [3], and new HIV infections are being driven by the high incidence in those 15–24 years of age, particularly women. It is estimated that more than one-half of all South African 15-year olds in 2006 will not survive to age 60 years [4]. Young adolescents, before or just after the initiation of sexual activity, are singularly important for intervention because they are highly vulnerable and because they have not established habitual patterns

A. O'Leary (✉)
Prevention Research Branch, Division of HIV/AIDS Prevention,
National Center for HIV, Hepatitis, STD, and TB Prevention,
Centers for Disease Control and Prevention,
1600 Clifton Road, MS E-37,
Atlanta, GA 30333, USA
e-mail: aao0@cdc.gov

J. B. Jemmott III, · L. S. Jemmott · S. Bellamy · L. Gueits
University of Pennsylvania,
Philadelphia, PA, USA

Z. Ngwane
Haverford College,
Haverford, PA, USA

L. Icard
Temple University,
Philadelphia, PA, USA

of sexual behavior. A nationally representative survey of black South Africans 18–24 years of age revealed that the median age at sexual debut was 16 years [5]. While several behavioral risk reduction interventions for adolescents have been developed in North America [6], no comparable adolescent intervention had been evaluated for behavior change in South Africa prior to this trial. Of the HIV risk-reduction interventions developed for adolescents in North America, few [7, 8] have reported moderation or mediation analyses. We selected potential moderators and mediators on the basis of existing literature and formative research conducted within the culture.

Moderation and mediation analysis are ways to examine more closely the results of successful intervention trials and to suggest possible improvements to interventions. Moderators are participant characteristics that are generally stable across time, not changed by the intervention, but associated with differential responses to the intervention [9]. Moderator analysis may thus suggest changes to the intervention to make it more effective with the groups responding less positively. Mediation analysis [9, 10] provides a method for identifying which components of multifaceted behavioral interventions are responsible for efficacy. The results of mediation analyses can be used to adapt interventions or to develop more efficient interventions because ineffective components can be removed, making the resulting intervention more cost-effective. Identifying mediators for specific populations and behaviors can also, in turn, contribute to theory. For example, a mediation analysis of an effective HIV risk-reduction intervention for adult women [11] revealed that self-efficacy was more important than partner resistance in accounting for condom use in the intervention group.

Social Cognitive Theory and Sexual Risk Reduction Interventions

In Social Cognitive Theory [12], two classes of behavior-change determinants are described. "Outcome expectancies" are the results people expect if they perform a particular behavior successfully. These are specific to the behavior to be changed, as well as other factors such as gender, age, and other person characteristics. Motivation to perform a behavior is largely based on outcome expectancies such as expected health outcomes, social reactions, etc. "Self-efficacy" is the confidence people have that they can succeed in performing a behavior despite meeting challenges and setbacks and determines behavioral choice, effort, and persistence. Outcome expectancies can be addressed in interventions by providing factual information, testimonials, and narrative components. Self-efficacy and skills are developed when facilitators model behaviors and participants practice them with feedback and, if necessary, problem-solving.

Several studies have revealed the importance of Social Cognitive Theory factors in adolescent sexual behavior. Self-efficacy has generally been assessed for condom use and indeed is associated with sexual behavior intentions and condom use [8, 13–15]. Self-efficacy to refuse sex has also been assessed, although it did not mediate the effects of an HIV risk-reduction intervention that obtained a significant delay in sexual debut [7]. Of possible outcome expectancies, the belief that condoms make sex less enjoyable [14, 15] and that sexual partners will be upset by condom requests [16] are associated with reduced likelihood of condom use.

Because expected outcomes and barriers to behavior change vary depending on the behavioral outcome sought and the population being considered, scales must be developed whenever a new behavior or population is under study. In the parent study, our primary outcome variable was frequency of unprotected sex, which is in turn determined by (a) having sex and (b) using condoms (or not) [17]. While we included outcome expectancy and self-efficacy scales for condom use, we found that few participants had sex, which limited out ability to examine mediation of condom use during the study since only sexually active participants can be included in condom use analyses. Moreover, unprotected sex is a combination variable, as described above. Mediators for these two behaviors, avoiding sex and using condoms, are likely to differ. For mediation analyses, we therefore focused on the primary contributor to sexual risk in the study, namely, having sex or being abstinent. Outcome expectancies related to abstinence [17] included expectations regarding prevention of HIV and pregnancy; expectations regarding career development opportunities; and expectations regarding parental approval or non-approval of the child having sex.

Self-efficacy was assessed in two domains relevant to abstinence: Self-efficacy to refuse sex and self-efficacy to avoid risky situations, such as accepting a gift from a person who would then expect sex. Each of these has the potential to contribute to abstinence. In addition to these theoretically derived potential mediators, we measured two aspects of basic knowledge about HIV/AIDS. One assessed cultural myths about HIV that we learned of in the course of our formative research. The other assessed basic facts about HIV transmission.

The Importance of Parents in the Sexual Behavior of Adolescents

Adolescents occupy a position poised between their parents and their peers as major sources of influence. During and just prior to the teenage years, relationships with parents have been shown to influence sexual behavior of ethnic

minority adolescents in the USA in at least two ways. Parental monitoring of adolescents' activities has been found to be protective against problem behavior [18], as has parental strictness [19, 20].

Father presence in the home has been shown to be an important factor in adolescent development. In the USA, absence of the father in the household has been linked to earlier sexual debut [21, 22]. Adolescents who live with their fathers feel greater attachment to them and are less likely to be judged by teachers as having behavioral problems at school [23]. Even when not close to their fathers, adolescents with fathers living in the home have better grades and engage in less violence and less substance use [24], and even male figures who are not fathers (e.g., "uncles") serve supportive roles in the lives of male youth in single-parent households [25]. Recognizing the importance of parents in the sexual behavior of adolescents, several sexual risk reduction interventions for youth have included, or focused exclusively, on parents [26]. Another factor related to the family is religiosity, which has been shown to be related to adolescent sexual behavior [19] as well as other "problem behaviors such as substance abuse and truancy" [27].

Purpose of the Present Study

The present analyses were performed to identify, first, which baseline participant characteristics were associated with strength of response to the intervention (moderation), and, second, which theory-derived variables mediated the effect of the intervention. Moderation analyses were performed using two sexual behavior outcomes: abstinence and unprotected intercourse in the past 3 months. Mediation analyses used only the abstinence outcome because as discussed above unprotected sex is a combination variable that is affected both by abstinence and by condom use and therefore unlikely to be mediated in a clear way.

Methods

Design

Methods for the present study are described in detail elsewhere [1]. The study was conducted in Mdantsane, an urban township (population, 177,816), and Berlin (population, 2,271) a neighboring rural settlement, near East London in Eastern Cape Province, South Africa, where isiXhosa is the language spoken in the home for 95.1 % of the population. We used a cluster-randomized controlled design to test an HIV risk reduction intervention against a health-promotion attention control. Eighteen schools were randomized in matched pairs (9 pairs randomly selected from 17) to the intervention conditions. The intervention and an attention-control health promotion intervention were developed based on Social Cognitive Theory and formative research.

For the present and the parent study, extensive formative research was conducted to identify the relevant Social Cognitive Theory factors to employ in the intervention and to assess for the present analyses. We conducted 9 focus groups with 89 isiXhosa-speaking sixth-grade students, 4 focus groups with 34 parents of sixth-grade students, and 1 focus group with 12 teachers of sixth-grade students.

Both interventions consisted of twelve 1-h modules, with two modules delivered during each of six sessions on six consecutive school days. Both interventions were highly structured and implemented in mixed-sex small groups by male and female adult isiXhosa-speaking cofacilitator pairs using standardized intervention manuals. We conducted three pilot tests of the interventions with 116 grade 6 learners. The interventions were pilot tested in English in Mdantsane, translated into isiXhosa, back-translated from isiXhosa to English, pilot tested in isiXhosa in Mdantsane and Berlin, and delivered in isiXhosa 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 utilize video, an often-used strategy in efficacious interventions conducted in the USA. We, therefore, used comic workbooks—six issues, one for each session—using 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. The facilitators were selected based on oral and performance-based interviewing. We randomly assigned them to an 8-day training to implement one of the two interventions. In this way, we randomized facilitators' characteristics across interventions.

We designed the sexual risk-reduction intervention to (a) increase knowledge of HIV and other STDs, (b) enhance expected outcomes that support abstinence and condom use, and (c) increase skills and self-efficacy 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 learners 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, 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 [28]. 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.

Participants

To recruit participants, isiXhosa-speaking community members made announcements at the selected schools and distributed letters and consent forms for parents/guardians to all grade 6 learners [1]. 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, grade 6 learners who had written parent/guardian consent were eligible to participate. At the other six schools, where there were too few classrooms to accommodate all learners who had consent, we randomly selected learners as eligible from among those with consent. Of the 1,898 grade 6 learners enrolled at the schools, 1,396 or 73.6 % returned signed consent forms, 1,118 were eligible to participate, and 1,057 or 94.5 % participated, 558 girls and 499 boys. Their age ranged from 9 to 18 years, with a mean (SD) of 12.4 (1.2); 7.6 % resided in Berlin, and the others resided in Mdantsane. Retention at follow-up assessments was excellent: 1,029 (97.4 %) completed the 3-month follow-up, 1,030 (97.4 %) completed the 6-month follow-up, 1,022 (96.7 %) completed the 12-month follow-up, and 1,043 (98.7 %) attended at least one follow-up. The percentage that attended at least one follow-up did not differ between the HIV/STD risk-reduction (98.8 %) and control interventions (98.6 %).

Measures

Assessments were conducted before, immediately post, and 3, 6, and 12 months post-intervention via confidential questionnaires that were written in isiXhosa following translation and back-translation from English. Adults from the community who were bilingual in isiXhosa and English and blind to the participants' intervention assignment implemented a read-aloud procedure: Learners completed questionnaires at their desks while data collectors read the questions aloud.

The process of developing the questionnaire involved conducting focus groups to elicit salient beliefs relevant to Social Cognitive Theory. Thus, participants were asked questions about the consequences of abstinence and sexual involvement to identify outcome expectancies. Questions also addressed barriers to abstinence that an intervention could target to build skill and self-efficacy to surmount

those barriers that were amenable to change. We then either adapted existing measures or items that had been employed in previous studies or developed new measures unique to this study based on the information collected. The outcome expectancies about abstinence were similar to those we had observed in previous research, and so we adapted measures used in previous studies. For self-efficacy, we developed new measures because the barriers were different from those we had previously observed. We created new HIV knowledge items that pertained to cultural myths about HIV transmission that we had identified in focus groups and that the intervention targeted. Parental norms, strictness, parental monitoring, and religiosity were all measured with questions used in previous studies.

The questionnaire was first prepared in English and pilot tested, which suggested the need to reword some of the questions so that they were more appropriate to the population and retained the intended meaning (American English versus South African English). The questionnaire was then translated into isiXhosa, back translated into English, and any discrepancies were resolved. We then pilot tested it in isiXhosa with 64 (31 girls and 33 boys) sixth grade learners from Mdantsane and Berlin to determine whether they understood the questions and response choices and to solicit their recommendations regarding question phrasing. Some wording changes were necessary to ensure clarity. For instance, the meaning of whether a referent would "approve" their behavior was not clear. A clearer wording would be whether a referent would "agree" that they should engage in the behavior. We then pilot tested the measures with a new sample (Jemmott et al., unpublished data analysis, 2004) that included 165 isiXhosa-speaking adolescents (99 girls, 63 boys; 3 did not report sex) ages 11–15 years (mean= 13.1; SD=1.1).

Sexual Behavior

Sexual behavior in the preceding 3 months included whether any vaginal sex was experienced, whether any unprotected sex was experienced, whether condoms were used, and whether sex was engaged in with more than one partner. At baseline, few participants reported having had sex within this time frame: 3.3 % reported any sexual experience at baseline. By the 12-month follow-up, this percentage had risen to 25.6 %.

Moderator Variables

In addition to gender and age, the following baseline factors were examined for moderation effects. Parental presence was assessed with two separate questions. Participants reported whether their mother was present in the home and whether their father was present. Parental monitoring was

assessed with a six-item scale ranging from 1 (Never) to 5 (Always). An example item is: "When school is out I go someplace where I am watched by an adult." Items were averaged to create the scale. Coefficient alpha for this scale was 0.90. In the pilot survey, adolescents scoring higher in parental monitoring were less likely to report ever having sexual intercourse, $r(162)=-.19$, $p=.01$, were less likely to report sexual intercourse in the past 3 months, $r(163)=-.19$, $p=.01$, reported a lower intention to have sexual intercourse in the next 3 months, $r(163)=-.33$, $p<.0001$, and were more likely to be girls than boys, $r(159)=.29$, $p=.0002$.

Parental strictness was assessed with a five-item scale using a four-point scale (1=not at all to 4=very strict). An example item is: "How strict have your parents been about making you do chores?" Items were averaged to create the scale. Coefficient alpha for this scale was 0.84. In the survey, adolescents scoring higher in parental strictness scored higher in abstinence prevention outcome expectancy, $r(162)=.17$, $p=.03$, self-efficacy to refuse sex, $r(162)=.29$, $p=.0002$, self-efficacy to avoid risky situations, $r(162)=.23$, $p=.004$, and lower in expected parental approval of sex, $r(161)=-.15$, $p=.05$, and intention to have sex in the next 3 months $r(162)=-.17$, $p=.03$.

Religiosity was assessed with a seven-item scale asking how often certain activities were performed, on a scale from 1 (Never) to 5 (Once a week or more). These were the following: go to church, worship services, or other religious activities; read the bible or other religious works; listen to worship music; listen to religious radio stations; watch religious television programs; say grace or pray before you eat; and pray before you go to bed. Items were averaged to create the scale. Coefficient alpha for this scale was 0.80. In the pilot survey, adolescents scoring higher in religiosity were less likely to report ever having sexual intercourse, $r(161)=-.25$, $p=.001$, were less likely to report sexual intercourse in the past 3 months, $r(162)=-.23$, $p=.002$, reported a lower intention to have sexual intercourse in the next 3 months, $r(162)=-.17$, $p=.03$, and were more likely to be girls than boys, $r(159)=.27$, $p=.0006$.

Mediator Variables

The following potential mediators were taken from Social Cognitive Theory as described above. Abstinence prevention outcome expectancy, the belief that abstinence prevents HIV/AIDS and pregnancy, was assessed with two items that had a five-point response scale going from 1 (disagree strongly) to 5 (agree strongly). They were "If I have sex in my teen years, I am likely to become (get a female) pregnant," and "If I have sex, I am likely to get AIDS." Coefficient alpha for this scale was 0.88. A randomized controlled trial found that an abstinence-based intervention increased this belief in young African American adolescents [17]. In

the pilot survey, abstinence prevention outcome expectancy was associated with a lower intention to have sexual intercourse in the next 3 months, $r(163)=-.17$, $p=.03$ and higher HIV risk reduction knowledge scores, $r(163)=.20$, $p=.01$.

Abstinence career opportunities outcome expectancy, the belief that becoming sexually active might interfere with career trajectories, was assessed with four items that had a five-point response scale going from 1 (disagree strongly) to 5 (agree strongly). They were "If I have sex during my teen years, then I am less likely to matriculate," "If I have sex before I matriculate, then I am less likely to have the career that I am hoping for," "If I do not have sex before I matriculate, then I will matriculate," and "If I do not have sex before I matriculate, I will be able focus on getting a good job." Coefficient alpha for this scale was 0.83. This scale is an adaptation of the abstinence goal-attainment scale that was increased by an abstinence-based intervention in a randomized controlled trial with young African-American adolescents [17]. Matriculate was substituted for high school and two additional items were added to strengthen the alpha, which was low in pilot testing with South African adolescents. This factor was addressed in the HIV risk reduction intervention through discussions of the benefits of abstinence. In the pilot survey, abstinence career opportunities outcome expectancy was associated with a lower intention to have sexual intercourse in the next 3 months, $r(163)=.18$, $p=.02$.

Expected parental approval of the child's having sex was assessed with two items, using a five-point response format going from 1 (disagree strongly) to 5 (agree strongly). They were as follows: "My mother would think it is okay for me to have sex in the next 3 months" and "My father would think it is okay for me to have sex in the next 3 months." Coefficient alpha for this scale was .88. This factor was addressed in the HIV risk reduction intervention activities by giving the children homework assignments that required them to have conversations with parents about subjects including sex. We included this activity in response to qualitative preliminary data indicating that while parents and children wished to discuss issues like sex with each other, they were uncertain as to how to begin. In the pilot survey, expected parental approval of the child's having sex was associated with self-reported sexual intercourse in the past 3 months, $r(162)=.18$, $p=.02$, intention to have sexual intercourse in the next 3 months, $r(162)=.55$, $p<.0001$, and older age, $r(162)=.17$, $p=.03$.

Self-efficacy to refuse sexual advances (as a way to achieve abstinence) was assessed with a five-item scale that asked, "How sure are you that you could refuse to have sex with…?" Responses ranged from 1 (not at all sure) to 4 (Completely sure). An example item is: "How sure are you that you could refuse to have sex with a person even if you loved him?" Coefficient alpha for the scale was .92. This

was addressed in the HIV risk reduction intervention by having the participants practice sex refusal, with feedback, in role plays. In the pilot survey, self-efficacy to refuse sexual advances, r(163)=−.25, p=.001, was associated with a lower intention to have sexual intercourse in the next 3 months.

Self-efficacy to avoid risky situations that could lead to sex was assessed with a four-item scale that asked "How sure are you that you could refuse _____ offered to you by a person that you thought might want to have sex with you?" Responses ranged from 1 (not at all sure) to 4 (Completely sure). An example item is: "How sure are you that you could refuse a meal offered to you by a person that you thought might want to have sex with you?" Thus, like "Self-efficacy to refuse sex," this measure also involved refusal, but not of sex per se but rather of events that often lead to sex and even rape. Coefficient alpha for the scale was 0.92. The HIV/STD risk reduction intervention addressed this with a "Long Walk Home" exercise in which dangers lurked and had to be avoided by a child on her way home from school. In the pilot survey, self-efficacy to avoid risky situations that could lead to sex, r(163)=−.23, p=.003, was associated with a lower intention to have sexual intercourse in the next 3 months.

HIV risk-reduction knowledge was tapped with eight true–false items. Examples include the following: "A pregnant women who has HIV or AIDS can give it to her baby," and "There is a good chance you will get AIDS if you share a sink, shower, or toilet seat with someone who has AIDS." This factor was addressed in the HIV risk reduction intervention by providing accurate information and discussion.

A scale comprising four belief items identified in preliminary research to be held by some amaXhosa individuals was used to measure cultural myths regarding HIV transmission. The response format was True, False, or Don't Know. Two examples are: "People who are jealous of you can give you AIDS by putting a curse on you," and "One way to get AIDS is if you don't do good by your ancestors." In the pilot survey, higher HIV risk-reduction knowledge scores were associated with greater rejection of cultural myths about transmission, r(163)=.45, p<.0001, and a lower intention to have sexual intercourse in the next 3 months, r(163)=−.22, p=.006.

Statistical Analysis

Unprotected sex was chosen as the primary outcome of the intervention trial, a priori. This makes sense as a test of an intervention focusing both on abstinence and on condom use, since both can contribute to changes in this variable and since it is directly related to HIV risk [17]. It is also a suitable outcome for moderation analyses. However, unprotected intercourse is not a useful outcome to use for

mediation analyses, precisely because of the combination of behaviors that contribute to it. As mentioned above, one would expect the mediators of abstinence and of condom use to differ.

Generalized estimating equations (GEE) were used to accommodate repeated measures data from the entire 12-month follow-up period [29, 30]. Specifically, GEE models were employed to examine the potential effects of moderators by determining whether there were significant "moderator×intervention" effects in models, which included main effects of the intervention and moderators. In mediation analyses, we examined each mediator separately. We also tested one mediator for a gender interaction based on an a priori hypothesis that self-efficacy to avoid risky situations might be especially important for girls. The outcome measures were abstinence in the prior 3 months and unprotected sex in the same time period. We selected these outcomes because abstinence was responsible for the effect of the intervention on unprotected sex, as discussed above. Since abstinence was a major goal of the intervention, we had developed numerous outcome expectancy scales for potential mediators of abstinence; scales for condom use were not useful due to the low prevalence of use. Outcome expectancies for abstinence included expected career outcomes, expected HIV and pregnancy prevention, and expected parental approval of abstinence. We also developed scales for self-efficacy to refuse sex and self-efficacy to avoid risky situations.

Moderation

Potential moderators of the intervention effect determined a priori were gender, age, the presence of mothers and fathers in the home, parental monitoring, strictness, and religiosity. Moderators of intervention effect (HIV/STD Risk Reduction intervention compared to the health promotion control) were assessed by determining whether the"moderator×intervention" interaction effect was significant in a model including intervention and moderator main effects. As a general analytic strategy, intervention efficacy over the 3-, 6-, and 12-month follow-ups was tested using generalized estimating equation (GEE) models, properly adjusting for nested longitudinal repeated measurements on participants within schools [29, 30]. This analytic strategy accounted for the correlation among adolescents within schools assessed longitudinally. The models were fit and estimated odds ratios and corresponding 95 % confidence intervals are presented for binary measures; mean differences and corresponding 95 % confidence intervals are presented for continuous measures to compare outcomes across intervention conditions. When candidate moderators were categorical (e.g., gender, live with mother, live with father, and age group) and there was statistical evidence of moderation of intervention

effects, those effects were estimated separately at each level of the moderator. When candidate moderators were continuous (e.g., parental monitoring, strictness and religiosity) and there was statistical evidence of moderation of intervention effects, to illustrate the nature of the differing intervention effects, three levels of the continuous moderator were constructed corresponding to "low," "medium," and "high" levels as recommended by Aiken and West [31]. Robust standard errors were employed, and an independent working correlation matrix was specified. Intention-to-treat analyses were performed so that adolescents were included on the basis of their intervention assignment, regardless of the number of intervention or data-collection sessions attended. All analyses were completed using SAS Version 9. Hypotheses were tested with two-sided tests using significance criterion $p<0.05$.

Mediation

We assessed mediation using a "product of coefficients" approach [10] where an α path (effect of the intervention on the potential mediator) and a β path (effect of the potential mediator on the outcome of interest) were estimated independently in a GEE framework that contained both effects. The product of α and β ($\alpha\beta$) was then used to determine whether mediation was present. The product, $\alpha\beta$, represents the indirect or mediated effect of the intervention on the outcome of interest. Specifically, we present two statistical evaluations of mediation: a "Z" statistic and corresponding p value [10] testing the null hypothesis that $\alpha\beta=0$ (e.g., no mediation) as well as asymmetric confidence intervals for $\alpha\beta$, which accommodate the non-normal distribution of a 'product' statistic. MacKinnon et al. [10] present a comparison of these and other mediation approaches. All models were fit using a GEE approach, properly adjusting for the longitudinal correlation of measuring learners (e.g., outcomes and potential mediators) repeatedly over time and for clustering from learners enrolled in the same school.

Additionally, we explored whether or not "gender" might be an effect modifier for the "self-efficacy to avoid risky sexual situations" mediator, by examining the "gender × mediator" interaction. All hypothesis tests presented are two-sided, alpha=0.05 level tests and all were performed using SAS Version 9.

Results

Moderation

Generalized estimating equations analyses, adjusting for clustering from 18 schools, revealed that averaged over the three follow-ups a significantly smaller percentage of HIV/STD risk-reduction intervention participants reported having unprotected vaginal intercourse in the prior 3 months (OR=0.51; 95 % CI, 0.30–0.85) and vaginal intercourse in the prior 3 months (OR=0.62; 95 % CI, 0.42–0.94), when adjusted for baseline prevalence, compared with health-promotion control participants.

Results for the moderation analyses can be found in Table 1. Summary measures (odds ratios and 95 % CIs) at each level of each potential moderator as well as "beta" coefficients for moderator effects (e.g., "moderator × intervention" interaction beta's) and corresponding p values evaluating moderator effects are presented. There were four significant findings. Two of these findings were related to whether adolescents were living with their fathers. The HIV risk-reduction intervention compared to the health control caused a significantly greater reduction in self-reported vaginal intercourse in the past 3 months (OR=0.42 vs. 1.04, respectively; $p=.03$) among adolescents who reported living with their fathers than among adolescents who did not live with their fathers. Similarly, the intervention effect on unprotected sex was stronger ($p=.05$) among adolescents who reported living with their fathers (OR=0.32), compared with adolescents who did not report living with their fathers (OR=0.94). Perceived parental strictness was also a significant moderator of the intervention effect for unprotected intercourse (interaction beta=−0.97, $p=.03$). The ORs for adolescents "high," "medium," and "low" in strictness scores were 0.43, 1.00, and 0.22, respectively, suggesting that the intervention effect was most protective among adolescents who perceived their parents as being less strict and least protective among those who perceived their parents as moderately strict. Religiosity was also a significant moderator of the effect of the intervention on unprotected sex (interaction beta=−0.71, $p=0.01$). Inspection of the effect of the intervention for "high," "medium," and "low" religiosity scores (ORs=0.32, 0.59, 0.61, respectively) suggests that the intervention effect was greater among those adolescents with higher religiosity scores.

Mediation

Table 2 presents mediator and outcome summaries, by intervention, at each assessment point (i.e., baseline and 3, 6, and 12 months post-intervention). Means and standard errors are presented for each potential mediator and the number and percentage of adolescents reporting sexual intercourse in the past 3 months. Table 3 displays the mediation results where each potential mediator was assessed independently using a GEE approach in a model that included the intervention effect (α path), the mediator effect on the outcome (β path) and follow-up time. The product of α and β ($\alpha\beta$) with its corresponding asymmetric confidence limit (ACL) were used to determine mediation [32] of

Table 1 Moderators of intervention effects (estimated odds ratios) for vaginal intercourse and unprotected vaginal intercourse in the past 3 months

Moderator		Vaginal intercourse in past 3 months		Unprotected intercourse in past 3 months	
		Intervention effect odds ratio (CI)[b]	Moderator effect (p value)[c]	Intervention effect odds ratio (CI)	Moderator effect (p value)
Gender	Boys	0.65 (0.43, 0.99)	0.00 (>0.99)	0.53 (0.31, 0.91)	−0.01 (0.99)
	Girls	0.65 (0.16, 2.72)		0.53 (0.09, 3.22)	
Live with mother	Yes	0.36 (0.15, 0.90)	−0.67 (0.19)	0.49 (0.16, 1.52)	−0.06 (0.93)
	No	0.71 (0.45, 1.13)		0.52 (0.29, 0.95)	
Live with father	Yes	0.42 (0.25, 0.73)	0.90 (0.03)	0.32 (0.15, 0.65)	1.10 (0.05)
	No	1.04 (0.55, 1.97)		0.94 (0.42, 2.16)	
Age group	1: 9–11	0.63 (0.19, 2.07)	2 vs. 1: 0.20	0.25 (0.03, 2.33)	2 vs. 1: 1.05
	2: 12–13	0.77 (0.46, 1.29)	3 vs. 1: −0.33 (0.54)	0.70 (0.36, 1.37)	3 vs. 1: 0.32 (0.35)
	3: 14–18	0.45 (0.21, 1.00)		0.34 (0.13, 0.86)	
Parental monitoring[a]	High	0.65 (0.35, 1.19)	0.63 (0.19)	0.41 (0.18, 0.96)	0.15 (0.82)
	Medium	0.91 (0.45, 1.86)		1.14 (0.49, 2.65)	
	Low	0.36 (0.16, 0.85)		0.23 (0.07, 0.73)	
Strictness[a]	High	0.58 (0.31, 1.09)	−0.45 (0.23)	0.43 (0.17, 1.07)	−0.97 (0.03)
	Medium	0.80 (0.46, 1.40)		1.00 (0.48, 2.06)	
	Low	0.40 (0.04, 3.97)		0.22 (0.01, 3.68)	
Religiosity[a]	High	0.50 (0.21, 1.14)	−0.33 (0.13)	0.32 (0.10, 0.98)	−0.71 (0.01)
	Medium	0.74 (0.43, 1.28)		0.59 (0.29, 1.20)	
	Low	0.57 (0.24, 1.34)		0.61 (0.21, 1.81)	

[a] Beta coefficients presented for continuous moderators (parental monitoring, strictness and religiosity); for illustration purposes only, estimated odds ratios are presented for "low" "medium" and "high" values of these moderators where "low" corresponds to values less than the 25th percentile; "medium" corresponds to values between the 25th and 75th percentiles and "high" corresponds to values greater than the 75th percentile

[b] Intervention effect=estimated odds ratio (risk reduction vs. health promotion)

[c] Moderator effect=estimated interaction beta coefficient ("moderator×intervention")

sexual intercourse in the past 3 months. Here, mediation is indicated when the ACL does not contain zero.

There were two significant mediators of abstinence from sexual intercourse in the past 3 months, namely, expected parental approval of sexual intercourse [$\alpha\beta$=−0.088, ACL= (−0.147, −0.029)] and self-efficacy to avoid risky situations [$\alpha\beta$=−0.069, ACL=(−0.120, −0.018)]. In addition, the "mediator×gender" interaction for "self-efficacy to avoid risky situations" was significant. Specifically, "self-efficacy to avoid risky situations" was stronger mediator of intervention efficacy among girls (beta=−6.01) than among boys (beta=−2.13), adjusting for baseline levels of the mediator and outcome variables.

Discussion

The results of these analyses point to the importance of parents and their opinions for these sixth grade children in South Africa. Among the moderators, the father being present in the home was a significant predictor of a stronger positive response to the intervention for both outcomes examined, any sex in the last 3 months and any unprotected sex in the last 3 months. Parental strictness and child

religiosity were also associated with more positive responses to the intervention for the unprotected sex outcome. In addition, a significant mediator of the intervention was expected parental approval/disapproval of the child having sex. Clearly, at the age of our participants, parents, and in South Africa especially, fathers are very influential in children's decision making. Interestingly, even though the father's presence in the home moderated the intervention's efficacy, the parent-related variable of parental monitoring did not. While parental strictness and religiosity would be difficult or impossible to change (as is typically the case with moderators), parents do have the ability (with help from the intervention in this case) to convey their disapproval of their children's early engagement in sexual activity. Future work may focus on alternative motivations, beyond religious beliefs, for avoiding sexual intercourse.

Several theoretical constructs from Social Cognitive Theory were used to design the intervention, whose outcomes can be found elsewhere [1]. We also incorporated findings from preliminary elicitation research with members of the Eastern Cape communities in which we conducted the research. Indeed, we were successful in operationalizing these constructs into intervention activities, and the intervention had significant influences over the 12-month follow-up on

Table 2 Mediator and outcome summaries at study time points for HIV and Health Promotion interventions

	Baseline		3 months		6 months		12 months	
	HIV/STD intervention $N=562$	Health intervention $N=495$	HIV/STD intervention $N=544$	Health intervention $N=485$	HIV/STD intervention $N=547$	Health intervention $N=483$	HIV/STD intervention $N=545$	Health intervention $N=477$
Mediators (mean±SE)								
Abstinence prevention expectancy	3.42±0.06	3.36±0.07	4.01±0.05	3.87±0.05	4.08±0.04	3.96±0.05	4.16±0.04	4.04±0.05
Abstinence career opportunity expectancy	3.14±0.06	2.93±0.06	4.09±0.04	3.74±0.05	4.18±0.04	3.85+/− 0.05	4.18±0.04	3.95±0.05
Expected parental approval of sexual intercourse	1.43±0.03	1.41±0.03	1.34±0.03	1.42±0.04	1.33±0.03	1.50±0.04	1.31±0.03	1.40±0.03
Self-efficacy to refuse sex	2.18±0.05	2.14±0.05	2.74±0.05	2.47±0.05	2.84±0.05	2.57±0.05	2.97±0.05	2.72±0.05
Self-efficacy to avoid risky sexual situations	1.93±0.05	1.89±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
HIV risk-reduction knowledge	3.94±0.03	3.91±0.03	4.64±0.03	4.14±0.03	4.78±0.03	4.06±0.04	4.81±0.04	4.25±0.04
Cultural myths regarding HIV transmission	1.14±0.05	1.18±0.05	1.76±0.06	1.46±0.07	1.78±0.07	1.45±0.07	1.87±0.07	1.59±0.07
Outcome [N(%)]								
Sex in the past 3 months	7 (1.25)	5 (1.01)	18 (3.31)	35 (7.22)	31 (5.67)	33 (6.85)	27 (4.95)	37 (7.77)

each of them. We also succeeded in assessing these constructs with psychometrically sound scales. These are both prerequisites for meaningful mediation analyses of intervention effects.

Our mediation outcome, abstinence in the previous 3 months, was mediated by two factors. One of these was self-efficacy to avoid risky situations such as being offered something desirable when accepting it was likely to lead to pressure for sex or rape. This factor was included primarily with girls in mind, since girls are more often the target of solicitation attempts. Indeed, this was a stronger mediator for girls than boys. Interestingly, self-efficacy for sex refusal did not prove to be a significant mediator. This may be because for people as young as our participants, avoiding situations that may predispose to confrontation may be a more reasonable strategy than one actually involving confrontation and refusal with a prospective partner.

The second significant mediator of this outcome was the belief that parents would/would not approve of the child's being sexually active. Again, for children as young as our

participants, perceptions of parents' opinions are likely to be influential; the intervention also discussed respect for parents' wishes as a benefit of abstinence. It is notable that this factor may have been able to mediate the intervention only because we included the parent–child homework activity, in response to elicitation research with parents and children demonstrating that both parties wished for discussion of sex but "didn't know how."

What are the implications of these findings for the "Let us Protect Our Future" intervention? The findings suggest that inclusion of parents, especially fathers, in homework and/or other activities may be particularly important. Unless children and their parents discuss sexual issues, it may be unclear to the children what their parents' level of approval of sex is, and this was an important mediator of the intervention's efficacy. In terms of skill building, focusing on avoiding risky situations, as illustrated by the "long walk home" game, may be more effective than practicing refusal of sex in the face of a confrontation. In light of the potential

Table 3 Mediation analysis of intervention effect (HIV/STD versus health promotion intervention on self-reported sexual intercourse in the past 3 months at 3, 6, and 12-month follow-up, adjusting for baseline mediator values)

Mediator	Intervention effect on mediator		Mediator effect on outcome		Mediated effect		
	α path (SE)	p value	β path (SE)	p value	$\alpha\beta$ product (95 % ACL)	Z	p value
Abstinence prevention expectancy	0.123 (0.055)	.0266	−0.132 (0.065)	.0427	−0.016 (−0.037, 0.005)	−1.496	.1346
Abstinence career opportunity expectancy	0.302 (0.052)	<.0001	−0.128 (0.079)	.1053	−0.039 (−0.087, 0.010)	−1.560	.1186
Expected parental approval of sex	−0.114 (0.036)	.0018	0.772 (0.089)	<.0001	−0.088 (−0.147, −0.029)	−2.945	.0032
Self-efficacy to refuse sex	0.255 (0.058)	<.0001	−0.112 (0.073)	.1238	−0.029 (−0.067, 0.010)	−1.451	.1467
Self-efficacy to avoid risky sexual situations	0.287 (0.062)	<.0001	−0.242 (0.074)	.0010	−0.069 (−0.120, −0.018)	−2.668	.0076
HIV risk-reduction knowledge	0.599 (0.081)	<.0001	0.003 (0.052)	.3124	0.002 (−0.002, 0.005)	1.001	.3169
Cultural myths regarding HIV transmission	0.324 (0.083)	.0001	−0.062 (0.061)	.3119	−0.020 (−0.061, 0.020)	−0.979	.3276

The outcome is self-reported sexual intercourse in the past 3 months. ACL is the 95 % asymmetric confidence limits for the estimated mediated effect

function of mediation analysis, to shorten and make more cost-effective multisession interventions, the present results suggest that reducing the intervention's focus on knowledge, condom use, and sex refusal would enhance efficiency without reducing efficacy. The danger in doing this lies in the possibility that as the participants get older, sex refusal and condom use become more common. We have been following the participants for an additional 4 years postintervention and thus will be able to report on such changes in the near future. In any case, we believe that any intervention that has been changed on the basis of mediation or moderation analyses should be retested in case complex interactions among mediators account for some of the intervention's efficacy.

A limitation of this study was its reliance on self-reported sexual behavior. Biological measures such as incidence of STDs were not feasible, given that 96.7 % of participants were sexually inexperienced at baseline. We also recognize that the intervention may not generalize to all South African adolescents, most notably those who do not speak isiXhosa, given that the intervention was delivered in this language.

The fact that western behavioral theory was used to design an intervention that was culturally competent and effective in a very different society is worthy of note. Moreover, such theory provided measures that were internally consistent and that enabled identification of significant intervention mediators in a very different cultural context. Even in the west, few HIV risk reduction trials have reported mediation analyses. The use of theory combined with extensive qualitative and quantitative formative research resulted in an intervention whose efficacy was similar to that of similar interventions delivered to American youth [33].

Moderation analysis provides a tool for identifying individuals who may be particularly primed to respond positively to interventions. It may suggest improvements to interventions to make them more effective with the groups responding less positively to the original version. Mediation analysis is an efficient and cost-effective method for obtaining suggestive evidence for essential and nonessential components of interventions. This information can be used to streamline interventions to be more cost effective, although we emphasize that the resulting interventions should be rigorously tested before assuming that their effectiveness would be equal to that of the original intervention. When intervention evaluations rely on self-reported outcomes, systematicity in data revealed by mediation analyses—particularly when some, but not all, variables are found to mediate—can provide reassurance that outcomes were not simply the result of socially desirable responding. As the field of Health Psychology matures, moderation and mediation analyses are more often being conducted [34]. Learning more about for whom interventions are effective, and about the mechanisms by which behavioral interventions are effective for targeted populations is likely to advance our understanding of biopsychosocial relationships and possibly contribute in turn to theory development and elaboration.

Conflict of interest statement The authors have no conflict of interest to disclose.

References

1. Jemmott JB, 3rd, Jemmott LS, O'Leary A, et al. School-based randomized controlled trial of an HIV/STD risk-reduction intervention for South African adolescents. Arch Pediatr Adolesc Med. 2010;164(10):923–9.

2. UNAIDS. AIDS epidemic update: December 2009. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS) and World Health Organization (WHO); 2010.

3. South African Department of Health. National HIV and syphilis antenatal sero-prevalence survey in South Africa 2005. 2006: Available from: http://www.doh.gov.za/docs/reports-f.html.

4. Dorrington RE, Johnson LF, Bradshaw D, Daniel T. The demographic impact of HIV/AIDS in South Africa: National and provincial indicators for 2006. Cape Town: Centre for Actuarial Research, South African Medical Research Council, and Actuarial Society of South Africa; 2006. Available from: http://www.mrc.ac.za/bod/DemographicImpactHIVIndicators.pdf.

5. Richter LM. Young people in South Africa: The status of youth report 2003. Pretoria: Human Sciences Research Council; 2005.

6. Marshall K, Crepaz N, O'Leary A. A systematic review of evidence-based behavioral interventions for African American youth at risk for HIV/STI infection, 1988–2007. In: McCree DH, Jones KT, O'Leary A, editors. African Americans and HIV/AIDS: Understanding and addressing the epidemic. New York: Springer; 2010. p. 151–80.

7. Coyle KK, Kirby DB, Marin BV, Gomez CA, Gregorich SE. Draw the line/respect the line: A randomized trial of a middle school intervention to reduce sexual risk behaviors. Am J Public Health. 2004;94(5):843–51.

8. Schmiege SJ, Broaddus MR, Levin M, Bryan AD. Randomized trial of group interventions to reduce HIV/STD risk and change theoretical mediators among detained adolescents. J Consult Clin Psychol. 2009;77(1):38–50.

9. Baron RM, Kenny DA. The moderator-mediator variable distinction in social psychological research: Conceptual, strategic, and statistical considerations. J Pers Soc Psychol. 1986;51(6):1173–82.

10. MacKinnon DP, Lockwood CM, Hoffman JM, West SG, Sheets V. A comparison of methods to test mediation and other intervening variable effects. Psychol Methods. 2002;7(1):83–104.

11. O'Leary A, Jemmott LS, Jemmott JB. Mediation analysis of an effective sexual risk-reduction intervention for women: The importance of self-efficacy. Health Psychol. 2008;27(2 Suppl):S180–4.

12. Bandura A. Social foundations of thought and action: A social cognitive theory. Englewood Cliffs: Prentice-Hall; 1986.

13. Jemmott LS, Jemmott JB, 3rd. Increasing condom-use intentions among sexually active black adolescent women. Nurs Res. 1992;41(5):273–9.

14. Jemmott JB, 3rd, Jemmott LS, Spears H, Hewitt N, Cruz-Collins M. Self-efficacy, hedonistic expectancies, and condom-use intentions among inner-city black adolescent women: A social cognitive approach to AIDS risk behavior. Journal of Adolescent Health. 1992;13(6):512–9.

15. Koniak-Griffin D, Stein JA. Predictors of sexual risk behaviors among adolescent mothers in a human immunodeficiency virus prevention program. J Adolesc Health. 2006;38(3):297e1–11.

16. National Institute of Mental Health Multisite HIV Prevention Trial Group. Social-cognitive theory mediators of behavior change in the National Institute of Mental Health Multisite HIV Prevention Trial. Health Psychol. 2001;20(5):369–76.

17. Jemmott JB, 3rd, Jemmott LS, Fong GT. Abstinence and safer sex HIV risk-reduction interventions for African American adolescents: A randomized controlled trial. Journal of the American Medical Association. 1998;279(19):1529–36.

18. Romer D, Stanton B, Galbraith J, Feigelman S, Black MM, Li X. Parental influence on adolescent sexual behavior in high-poverty settings. Arch Pediatr Adolesc Med. 1999;153(10):1055–62.

19. Jemmott LS, Jemmott JBr. Family structure, parental strictness, and sexual behavior among inner-city black male adolescents. Journal of Adolescent Research. 1992;7:192–207.

20. Jessor SL, Jessor R. Maternal ideology and adolescent problem behavior. Developmental Psychology. 1974;10:246–54.

21. Bohon C, Garber J, Horowitz JL. Predicting school dropout and adolescent sexual behavior in offspring of depressed and nondepressed mothers. J Am Acad Child Adolesc Psychiatry. 2007;46(1):15–24.

22. Mendle J, Harden KP, Turkheimer E, et al. Associations between father absence and age of first sexual intercourse. Child Dev. 2009;80(5):1463–80.

23. Williams SK, Kelly FD. Relationships among involvement, attachment, and behavioral problems in adolescence: Examining father's influence. Journal of Early Adolescence. 2005;25:168–96.

24. Booth A, Scott ME, King V. Father residence and adolescent problem behavior: Are youth always better off in two-parent families? Journal of Family Issues. 2010 1;31(5):585–605.

25. Richardson JB. The socially supportive role of the African American "uncle" in the lives of single-female headed households and at-risk African American youth. In: Johnson JW, editor. Social work with African American males: Health, mental health, and social policy. New York: Oxford University; 2010. p. 81–100.

26. Akers AY, Holland CL, Bost J. Interventions to improve parental communication about sex: A systematic review. Pediatrics. 2011;127(3):494–510.

27. Benson PL, Donahue MJ. Ten-year trends in at-risk behavior: A national study of black adolescents. Journal of Adolescent Research. 1989;4:125–39.

28. Jemmott JB, 3rd, Jemmott LS, O'Leary A, et al. Cognitive-behavioural health-promotion intervention increases fruit and vegetable consumption and physical activity among South African adolescents: A cluster-randomised controlled trial. Psychol Health. 2011;26(2):167–85.

29. Fitzmaurice GM, Laird NM, Ware JH. Applied longitudinal analysis. New York: Wiley; 2004.

30. Liang KY, Zeger SL. Longitudinal data analysis using generalized linear models. Biometrika. 1986;73(1):13–22.

31. Aiken LS, West SG. Multiple regression: Testing and interpretating interactions. Newbury Park: Sage; 1991.

32. Mackinnon DP, Lockwood CM, Williams J. Confidence Limits for the Indirect Effect: Distribution of the Product and Resampling Methods. Multivariate Behav Res. 2004;39(1):99.

33. Darbes L, Crepaz N, Lyles C, Kennedy G, Rutherford G. The efficacy of behavioral interventions in reducing HIV risk behaviors and incident sexually transmitted diseases in heterosexual African Americans. Aids. 2008;22(10):1177–94.

34. MacKinnon DP, Luecken LJ. How and for whom? Mediation and moderation in health psychology. Health Psychol. 2008;27(2 Suppl):S99–100.