

# Randomized Controlled Trial of a Safer Sex Intervention for High-Risk Adolescent Girls

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**Objective:** To determine the effect of an individualized safer sex intervention on condom use and recurrent sexually transmitted disease (STD) among female adolescents diagnosed as having an STD.

**Design:** Randomized controlled trial.

**Setting:** Urban children's hospital adolescent clinic and inpatient service.

**Participants:** One hundred twenty-three adolescents with cervicitis or pelvic inflammatory disease.

**Intervention:** Participants completed a questionnaire and then were randomized to receive standard STD education or to watch a videotape and have an individualized intervention session. Follow-up questionnaires were completed at 1, 3, 6, and 12 months. Intervention participants met with an educator at 1, 3, and 6 months to discuss interim sexual history and review the intervention.

**Main Outcome Measures:** Change in self-reported condom use and recurrence of STD. Other self-reported

behaviors, sexual risk knowledge, attitudes toward condoms, and condom use negotiation skills were also assessed.

**Results:** At 1 month, compared with control participants, intervention participants had increased sexual risk knowledge and more positive attitudes toward condoms and tended to use condoms more with a nonmain partner. At 6 months, fewer intervention participants than controls had sex with a nonmain sexual partner in the previous 6 months. At 12 months, intervention participants were less likely to have a current main partner and had a lower rate of recurrent STD than controls, but these differences were not significant.

**Conclusions:** This individualized safer sex intervention may improve condom use and decrease the number of partners among adolescent girls who have had an STD. Studies with larger samples are needed to determine definitive intervention effects on recurrent STD in this high-risk population.

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**S**EXUALLY TRANSMITTED diseases (STDs) are a major cause of morbidity among adolescent girls. Approximately two thirds of persons who acquire an STD each year are younger than 25 years,<sup>1</sup> with minority female adolescents disproportionately affected.<sup>2</sup> Adolescent girls who have had an STD are at particularly high risk for recurrent STD.<sup>3-5</sup> As many as 54% of girls younger than 15 years develop a second infection with *Chlamydia trachomatis* 1 to 6 years after initial chlamydial infection.<sup>3</sup>

A safer sex intervention for adolescents must capture their attention, impart information, and promote attitudinal and behavior changes in one brief, intensive session. Booster sessions may be important in sustaining behavior change.<sup>6</sup> Effective STD

interventions recognize gender-specific issues,<sup>7-13</sup> address developmental factors, are pilot tested, and are based on behavior change theory.<sup>12</sup>

Social Cognitive Theory postulates that a person's behavior is uniquely determined by reciprocal interactions among environmental influences, behavior, and personal factors, including self-efficacy (the confidence in one's ability to perform the behavior).<sup>13</sup> Interventions that apply Social Cognitive Theory include (1) information to increase awareness and knowledge of the consequences of behavior, (2) social and self-regulative skills development to translate the knowledge into preventive action, (3) opportunities for guided practice and corrective feedback in applying the skills, and (4) suggested changes in social norms and supports for desired behavior change.<sup>14</sup>

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## PARTICIPANTS AND METHODS

### PARTICIPANTS

Study participants were younger than 24 years and presented to a hospital-based adolescent clinic for treatment of cervicitis (by positive endocervical test results for gonorrhea or chlamydia) or were admitted to the affiliated pediatric hospital for management of pelvic inflammatory disease (PID). The opportunistic study intervention was designed to be administered at the time of STD treatment, when the participant was most likely to be considering her diagnosis and associated risk behaviors. Patients who were treated for an STD before laboratory confirmation were excluded from study participation. Patients who were pregnant at the treatment visit were also excluded. Finally, patients who had been exposed to the intervention through their participation in the pilot study<sup>23</sup> were excluded. Between July 6, 1996, and July 7, 1998, 330 patients had cervicitis or PID, 239 of whom met the eligibility criteria. Of 91 patients excluded from the study, 39 had received treatment for cervicitis before laboratory diagnosis, 18 were pregnant, and 34 had participated in the pilot study (**Figure 1**). Of 239 eligible patients, 123 consented and were randomized to receive the intervention or standard education; 64 participants had PID and 59 had cervicitis. For 82 patients, a research assistant was not available to approach them for study participation at the time of treatment. Thirty-one patients refused study participation because of time constraints, concerns about confidentiality, or disinterest, and for 3 patients, the medical provider did not think that study participation was appropriate because of complicating medical or psychological issues.

Participants were randomized to receive safer sex education according to either the study intervention (n=60) or standard care (n=63), stratified by presenting diagnosis (cervicitis or PID) using 2 separate random numbers lists. Three participants with cervicitis who were enrolled and randomized did not receive the intervention or return for any follow-up visits. There were no differences between the intervention and standard care groups in presenting diagnosis, demographic characteristics, or baseline scale scores or behaviors. Of 123 participants, 81 (66%) returned for the 1-month follow-up visit, 72 (59%) for the 3-month visit, 90 (73%) for the 6-month visit, and 64 (52%)

for the 12-month visit. Only 14 patients (11%) did not return for any follow-up visits; 40 (33%) attended all 4 follow-up visits. There were no differences in follow-up rates between the intervention and control groups. There were no differences in demographic variables or baseline condom use between participants who followed up and those who did not. The study was approved by the Committee on Clinical Investigation (institutional review board) of Children's Hospital, Boston, Mass.

### METHODS

#### Measures

After a sociodemographic interview, participants completed a self-administered, 62-item questionnaire that used items from previously validated surveys. Questions about age of first sexual intercourse, number of sexual partners (lifetime and past 3 months), use of alcohol or other drugs before sexual intercourse (ever and the last time), and condom use with last sexual intercourse were adapted from the Youth Risk Behavior Survey.<sup>24</sup> Using a scale developed by Redding et al,<sup>25</sup> the adolescents were asked if they had a main partner currently and if they had another, non-main partner in the past 6 months; consistent condom use stage of change was measured with 5 items for each type of partner. This scale required skipping questions as directed and used a scoring algorithm to determine stage of change. As part of this scale, frequency of condom use (5-point response scale, from "every time" to "never") with a main partner and with another partner was assessed. Both condom use frequency variables were dichotomized to determine inconsistent condom use ("not every time" or "every time") for each type of partner. Participants were asked to report history of previous STDs or PID and types of sexual intercourse (vaginal, oral, and anal). A 15-item true-false sexual risk knowledge scale targeted facts emphasized in the intervention (scored 0-15). Attitudes about condoms were measured by summing agree-disagree responses to 10 statements.<sup>26</sup> A 6-item condom use negotiation self-efficacy scale measured how often the participant felt able to ask a partner to use a condom without fear of anger, rejection, or misunderstanding using a 5-point Likert-type response scale (scored 6-30). For each scale, if at least 80% of items had responses, the mean value of the obtained responses was substituted for the missing responses.

Drawing in part on Social Cognitive Theory, the Transtheoretical Model of Behavior Change provides a practical approach to individual-level interventions.<sup>15</sup> The Transtheoretical Model suggests personalized counseling and recognizes the dynamic nature of change, which is postulated to occur through the stages of precontemplation, contemplation, determination, action, and maintenance.<sup>16,17</sup> Studies<sup>17-20</sup> indicate that this model can be adapted for sexual risk behaviors, such as condom non-use. The technique of motivational interviewing uses the principles of individual responsibility, internal attribution, and cognitive dissonance to move an individual from one stage of behavior change to the next<sup>21</sup> and is applicable to counseling for young people.<sup>22</sup>

Social Cognitive Theory, the Transtheoretical Model of Behavior Change, and motivational interviewing pro-

vide the conceptual framework for the present randomized controlled trial of a safer sex intervention individualized for female adolescents who have had an STD, with a 12-month follow-up.

## RESULTS

There were no significant differences between the intervention and standard education groups in baseline sociodemographic characteristics or sexual history (**Table 1**). The median age of participants was 17.2 years, and the median last grade completed was 11th. Participants were of diverse race and ethnicity. Sexual risk behaviors were prevalent. Sixty-two percent of participants reported having only vaginal intercourse; 25% had vaginal and oral intercourse; 3% had vaginal, anal, and

## Standard Education

For participants randomized to the standard care condition, STD education was provided at the discretion of the treating clinician. This education included a discussion of STD transmission and the importance of consistent condom use. Participants were offered free condoms at the conclusion of the visit.

## Intervention

The intervention began with a 7-minute videotape adapted from *Time Out: The Truth About AIDS, HIV, and You*,<sup>27</sup> in which popular entertainers and sports figures discussed and dramatized condom names, buying condoms, and negotiating condom use and 2 female adolescents demonstrated condom use to their peers. Condom use was portrayed as normative behavior.

The female health educators were trained by the principal investigator (L.A.S.) in the theoretical underpinnings of the intervention and motivational interviewing techniques. The educators used a standardized intervention manual developed for this study that outlined key points to cover, activities to perform, and motivation strategies to employ.

The educational session began with a self-assessment exercise. Participants were asked to mark on the Wheel of Change (**Figure 2**) the phrase that best represented where they were in thinking about changing their sexual risk behavior.

While conveying the same basic information to each participant, the educator individualized the session based on assessment of the participant's stage of change. The intervention recognized that adolescents with an STD were most likely to be in an early stage for change of high-risk sexual behavior. For participants in the precontemplation stage, the emphasis was on imparting information and feedback about unsafe sex. For those in the contemplation or determination stage, the discussion included creating a list of pros and cons of condom use and role-playing condom use negotiation.

The educator offered the participant the following list of topics and asked her to guide the order and emphasis of the intervention: consequences of unprotected sex, risk perception, preventing pregnancy, preventing STDs, condoms, spermicide, obtaining condoms, secondary abstinence, and

talking about sex. The educator (1) reviewed the videotape; (2) discussed STD transmission using a pelvic model; (3) asked the participant to practice correct condom use on a penis model; (4) discussed secondary abstinence; (5) demonstrated use of the female condom; and (6) provided written materials about safer sex, condoms, and spermicide and a gift of a condom key chain. Approximately 30 minutes were required to cover the intervention topics.

All participants were asked to return for follow-up visits 1, 3, 6, and 12 months after enrollment to complete the questionnaire again. They were offered \$10 at each follow-up visit. Intervention participants had a booster session with an educator at 1, 3, and 6 months to indicate their current stage on the Wheel of Change, discuss interim sexual history, and review the content of the intervention. These participants were offered condoms, written materials, and the opportunity to view the videotape again.

## Data Analysis

Changes from baseline to each follow-up visit for the scale scores and condom use frequency variables were calculated and differences between treatment groups were determined using the Mann-Whitney *U* test. For the dichotomous risk variables—condom nonuse with last sexual intercourse, inconsistent condom use with main partner and with another partner, having a main partner, and having another partner—change in the risk behavior was categorized as follows:

- Risk (behavior present) at baseline, no risk (behavior not present) at follow-up
- No risk at baseline, no risk at follow-up
- Risk at baseline, risk at follow-up
- No risk at baseline, risk at follow-up

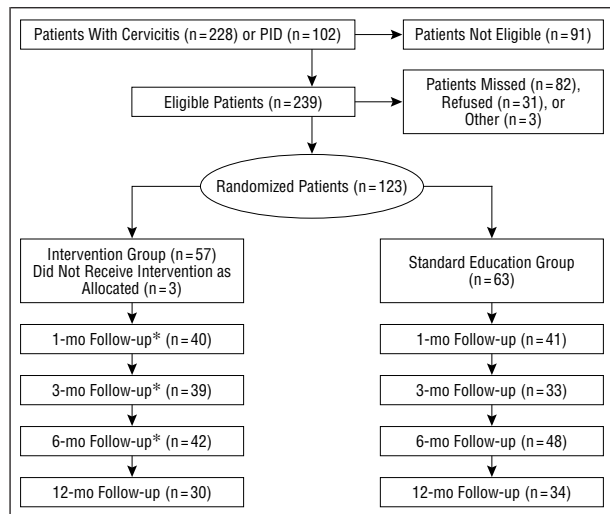
Differences between treatment groups in change in risk from baseline to each follow-up visit were analyzed using the  $\chi^2$  test. Difference between treatment groups in the proportion of participants reporting recurrent STD at the 12-month visit was determined using the  $\chi^2$  test. For the intervention group, differences in Wheel of Change stage between baseline and each follow-up visit were determined using the Wilcoxon signed rank test. All analyses were conducted using SPSS for Windows, version 10.0 (SPSS Inc, Chicago, Ill).

oral intercourse; and 2% had only oral intercourse (both of these participants had culture-positive cervicitis); 8% did not respond to the item (data not shown).

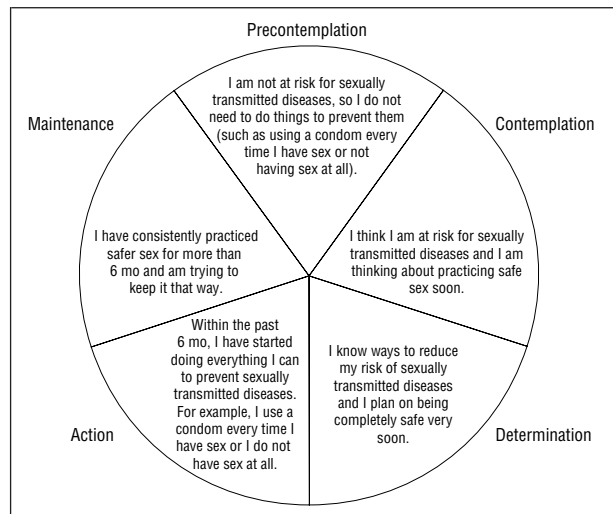
At baseline, less than half of the participants reported using a condom with last sexual intercourse (**Table 2**). Of 93 participants reporting a main partner in the past 6 months, only 26 (28%) used condoms consistently with this partner. Consistent condom use with another, nonmain partner was more frequently reported. Baseline median knowledge, attitudes, and negotiation scale scores were high. The cervicitis group had higher baseline knowledge ( $P=.03$ ) and negotiation ( $P=.008$ ) scores than the PID group. On the stage of change scale, 73% of respondents did not follow the instructions to skip questions and thus the scale could not be scored. On the Wheel of Change, 49 intervention par-

ticipants (82%) marked their stage of change for safer sex behavior. As expected, most were in a pre-action stage: of those who completed the Wheel of Change, 11 (23%) indicated contemplation; 27 (56%), determination; 3 (4%), action; and 8 (17%), maintenance.

Results are presented for the 1-, 6-, and 12-month follow-up visits (Table 2). There were no differences between treatment groups in change in any of the study variables at the 3-month visit. At 1 month, compared with controls, intervention participants had greater increases in STD risk knowledge ( $P=.02$ ) and positive attitudes toward condoms ( $P=.007$ ) and were somewhat more likely to report more frequent ( $P=.08$ ) and more consistent ( $P=.09$ ) condom use with a nonmain partner. For the change in knowledge score, the group  $\times$  diagnosis interaction was not significant. At 6 months, compared with



**Figure 1.** Study enrollment. Asterisk indicates inclusion of a booster session; PID, pelvic inflammatory disease.



**Figure 2.** The Wheel of Change was used by participants to self-assess stage of change regarding their sexual risk behavior.<sup>18</sup>

**Table 1. Baseline Characteristics of Female Adolescents With STDs\***

Characteristic	Total (N = 123)	Standard Education Group (n = 63)	Intervention Group (n = 60)
Age, median (range), y	17.2 (13.9-22.0)	17.5 (13.9-21.9)	17.0 (14.1-22.0)
Last grade completed, median (range)	11 (7-15)	11 (7-14)	10 (8-15)
Race/ethnicity, No. (%)			
Non-Hispanic black	60 (49)	31 (49)	29 (48)
Hispanic	22 (18)	10 (16)	12 (20)
Non-Hispanic white	17 (14)	7 (11)	10 (17)
Other	21 (17)	13 (21)	8 (13)
Presenting diagnosis, No. (%)			
Cervicitis	59 (48)	28 (44)	31 (52)
PID	64 (52)	35 (56)	29 (48)
Years sexually active, median (range), No.	2.5 (<1-9.7)	3.0 (<1-9.7)	2.4 (<1-9)
Sexual partners in lifetime, median (range), No.	4 (1-41)	4 (1-25)	3 (1-41)
Ever had STD/PID before enrollment visit, No. (%)	54 (44)	29 (46)	25 (42)
Ever pregnant, No. (%)	44 (36)	20 (32)	24 (40)
A mother, No. (%)	22 (18)	8 (13)	14 (23)
Ever used alcohol or other drugs before sex, No. (%)	55 (45)	26 (41)	29 (48)

\*STDs indicates sexually transmitted diseases; PID, pelvic inflammatory disease. There were no significant differences between treatment groups at baseline. Percentages may not add to 100 because of missing values.

controls, fewer intervention participants reported increasing their risk of having sex with a nonmain sexual partner in the previous 6 months ( $P = .01$ ), and there was a tendency for fewer intervention participants to report increased risk of condom nonuse with last sexual intercourse ( $P = .09$ ). As at 1 month, at 6 months, intervention participants had greater increases in positive attitudes toward condoms than did controls ( $P = .007$ ). At 12 months, intervention participants tended to have decreased risk of having a main sexual partner ( $P = .07$ ) compared with controls. At the 12-month follow-up visit, 17% of intervention participants reported having an STD since enrolling in the study compared with 32% of participants receiving standard education ( $P = .17$ ) (data not shown).

Because it was part of the intervention, the Wheel of Change was administered to intervention participants only. Compared with their baseline self-assessment, intervention participants had positive move-

ment in self-stage on the Wheel of Change at each follow-up visit. By the 12-month visit, most participants who completed the Wheel of Change indicated that they were in the action (38%) or maintenance (25%) stage (Wilcoxon signed rank test comparing 12-month visit with baseline,  $P = .04$ ).

#### COMMENT

In this randomized controlled trial, we sought to determine whether a theory-based safer sex intervention individualized to participants' stage of change would reduce sexual risk behaviors and recurrent STD in a high-risk sample of adolescent girls diagnosed as having an STD. The opportunistic intervention was designed to be conducted at the time of STD treatment. Three booster sessions were included at intervals typical for clinical return visits and consistent with movement in stage of change. A 1-year follow-up visit provided a long-term as-

**Table 2. Condom Use, Partnering, and Scale Scores at Baseline and Follow-up Visits\***

Characteristic	Follow-up, mo								
	Baseline			1		6		12	
	Total (N = 123)	Standard Education (n = 63)	Intervention (n = 60)	Standard Education (n = 41)	Intervention (n = 40)	Standard Education (n = 48)	Intervention (n = 42)	Standard Education (n = 34)	Intervention (n = 30)
Condom use with last sexual encounter	53 (43)	24 (38)	29 (47)	24 (59)	22 (55)	26 (54)	25 (60)§	18 (53)	18 (60)
Main partner now	93 (76)	47 (75)	46 (77)	31 (76)	30 (75)	38 (79)	34 (81)	31 (91)	23 (77)§
Condom use with main partner									
Mean frequency (of 5)	3.2	3.3	3.2	3.5	3.7	3.4	3.7	3.5	3.6
Consistent ("every time")†	26 (28)	14 (30)	12 (26)	9 (29)	12 (40)	12 (32)	17 (50)	11 (36)	12 (52)
Another partner in the past 6 mo	43 (35)	19 (30)	24 (40)	12 (29)	16 (40)	25 (52)	10 (24)	12 (35)	7 (23)
Condom use with another partner									
Mean frequency (of 5)	4.1	4.1	4.3	4.2	4.7§	4.5	4.2	4.1	4.5
Consistent ("every time")‡	22 (51)	10 (53)	12 (50)	4 (33)	11 (69)§	17 (68)	6 (60)	5 (42)	5 (71)
Scale scores, mean									
Sexual risk knowledge	13.1	13.1	13.1	12.6	13.6	13.1	13.7	13.2	13.4
Condom attitudes	8.0	8.1	8.0	8.1	8.4¶	7.9	8.3¶	7.9	8.2
Condom use negotiation	27.0	26.7	27.2	28.0	27.7	27.7	27.8	28.2	27.9

\*Data are given as number (percentage), except where indicated otherwise.

†Values are for participants reporting a main partner currently.

‡Values are for participants reporting another partner in the past 6 months.

§P < .10 for significant difference between treatment groups in change in the variable from baseline.

||P < .05.

¶P < .01.

assessment period not frequently reported in intervention trials in adolescents.<sup>28</sup>

The small sample size and modest follow-up rate require that we consider the data with caution. However, the results suggest that the intervention was related to improvement in cognitive and behavioral factors. We found that at 1 month the intervention was associated with higher sexual risk knowledge and better condom use attitudes. The data also suggest an increase in the frequency of condom use with a nonmain partner among intervention participants, but the difference from controls did not reach statistical significance. Because only 28 adolescents (35%) who followed up at 1 month reported a nonmain partner in the previous 6 months, the study had limited power (35%) to detect a significant difference in condom use between groups. Baseline condom use frequency was higher with a nonmain partner than a main partner, which might indicate further progression along the stages of change and explain the tendency toward improvement in condom use seen for a nonmain partner only. Other studies<sup>20,29</sup> have found differences in condom use frequency with main vs other sexual partners. Recognition of the nature of the partner relationship and its impact on safer sex behaviors is an aspect of intervention development that requires further investigation.<sup>30</sup> In their efforts to encourage condom use and other safer sex behaviors in adolescents, health care providers need to inquire about main vs other sexual partners and determine with their patients factors that might enhance or hinder condom use with specific partners.

The number of sexual partners may be the most important risk factor for STD.<sup>31</sup> Six months after enrollment, we found that intervention participants were much less likely than controls to report having a nonmain sexual

partner in the previous 6 months. Twelve months after enrollment, intervention participants tended to be less likely than controls to report a current main partner. Because abstinence is the most effective safer sex behavior, an intervention effect of decreasing the likelihood of having a sexual partner is noteworthy.

There are several limitations to this study. The sample was drawn largely from an urban pediatric hospital's general adolescent clinic and might not be representative of other adolescent populations. However, the baseline sexual history and behaviors in this sample are consistent with frequencies reported by other studies with adolescent clinic,<sup>32</sup> urban youth,<sup>33,34</sup> and school-based<sup>35</sup> samples. The sample size was small, limiting the power to detect an intervention effect, and the low participation rate threatens the external validity of our results. It is possible that the adolescents who declined participation differed on the sexual risk cognitive and behavioral measures from those who enrolled in the study. The attrition rate was moderate, but it is unlikely that the results were biased by attrition because there were no differences in baseline characteristics between participants who followed up and those who did not. However, we cannot exclude the possibility that treatment group differences may have been smaller if more participants had completed the follow-up visits. The unavailability of a research assistant to approach 82 eligible adolescents might have introduced bias.

Improvements in the cognitive and behavioral outcomes were not seen consistently over the follow-up visits, which may be a function of the small numbers of participants returning at each visit. None of the analyses revealed significant improvements in the control group over the intervention group, suggesting that the reported findings are unlikely to result from chance. Self-

reported measures of STD risk behaviors were used, the validity of which is open to question.<sup>36,37</sup> The sexual risk knowledge, condom use attitudes, and condom use negotiation scale scores were skewed, likely resulting in a ceiling effect on score changes. The significant improvement in scores on the knowledge and attitudes scales for intervention participants is notable in light of the high baseline scores. Results of the condom use stage of change scale could not be evaluated in this study owing to the participants' inability to correctly follow the skip pattern. Since this study concluded, a version of this scale has been developed that does not include a skip pattern,<sup>20</sup> which might be easier for adolescents to complete. Results on the Wheel of Change support the assumption that at baseline most adolescents who received the study intervention were in a pre-action stage of change for safer sex. Adolescents who received the intervention showed forward movement in their stage of change as measured by this instrument. Further study of the progression through stages for adolescent girls with STDs receiving standard safer sex education is needed to determine whether this movement was due to intervention effect. Validation of the Wheel of Change will be important because it might prove to be a useful tool to measure stage of behavior change in research and clinical practice.

Despite progress toward meeting the *Healthy People 2000* objectives for the reduction of STDs, adolescents consistently show slower decline in STD rates than adults.<sup>38</sup> Rates of the behaviors targeted by the STD/HIV (human immunodeficiency virus) risk reduction objectives have been found to have increased in the general adolescent population<sup>38</sup> or declined only in subgroups of adolescents, such as male high school students.<sup>35</sup> To effectively reduce STD rates, theory-based educational interventions to promote healthy sexual behaviors must target groups of adolescents not being reached by current efforts. Individualized, theory-based safer sex education administered at the time of STD treatment can be an effective intervention with adolescent girls. The results of this randomized controlled trial suggest that sexual risk knowledge and condom use attitudes might be improved in the short term and that sexual risk behaviors might be reduced in the long term. More research with larger sample sizes is needed to further evaluate the effect of this targeted intervention on STD recurrence in this high-risk population.

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