

# Cluster-Randomized Controlled Trial of an HIV/Sexually Transmitted Infection Risk-Reduction Intervention for South African Men

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South Africa has more HIV cases than any other country, and like other sub-Saharan countries, has a predominantly heterosexual epidemic.<sup>1</sup> In such an epidemic, men have an especially critical role to play: they are the ones who don male condoms, a particularly effective and available means of prevention, and thus control their use. They have, it has been argued, more power than women in relationships<sup>2-4</sup> and are responsible for infecting women in many contexts, including forced intercourse and violence.<sup>3</sup> Although calls for male responsibility in sexual behavior related to HIV and other sexually transmitted infections (STIs) have been made repeatedly,<sup>5-7</sup> to our knowledge, only 1 study has evaluated an intervention created specifically for heterosexual men in South Africa.<sup>8</sup> Men who received the gender-based-violence-and-HIV-risk-reduction intervention were more likely to report talking with a partner about condoms and using condoms consistently 1-month postintervention compared with men in an alcohol-and-HIV-risk-reduction control intervention.

The present study evaluated an HIV/sexually transmitted infection (STI) risk-reduction intervention for South African men who have intercourse with women. We used a cluster-randomized design to reduce the potential for contamination between treatment arms that would be present if we were to randomize individuals. We randomized randomly selected neighborhoods (i.e., clusters) to a 3-session intervention based on social cognitive theory<sup>9</sup> and extensive formative research<sup>10</sup> and designed to reduce HIV/STI risk behavior or to a 3-session attention-control intervention designed to promote health by improving diet and physical activity. We hypothesized that the HIV/STI risk-reduction intervention would increase self-reported consistent condom use during vaginal intercourse in the postintervention period,

**Objectives.** We tested the efficacy of a sexual risk-reduction intervention for men in South Africa, where heterosexual exposure is the main mode of HIV transmission.

**Methods.** Matched-pairs of neighborhoods in Eastern Cape Province, South Africa, were randomly selected and within pairs randomized to 1 of 2 interventions based on social cognitive theory and qualitative research: HIV/sexually transmitted infection (STI) risk-reduction, targeting condom use, or attention-matched control, targeting health issues unrelated to sexual risks. Sexually active men aged 18 to 45 years were eligible. The primary outcome was consistent condom use in the past 3 months.

**Results.** Of 1181 participants, 1106 (93.6%) completed the 12-month follow-up. HIV and STI risk-reduction participants had higher odds of reporting consistent condom use (odds ratio [OR] = 1.32; 95% confidence interval [CI] = 1.03, 1.71) and condom use at last vaginal intercourse (OR = 1.40; 95% CI = 1.08, 1.82) than did attention-control participants, adjusting for baseline prevalence. No differences were observed on unprotected intercourse or multiple partnerships. Findings did not differ for sex with steady as opposed to casual partners.

**Conclusions.** Behavioral interventions specifically targeting men can contribute to efforts to reduce sexual risk behaviors in South Africa. (*Am J Public Health.* 2014;104:467-473. doi:10.2105/AJPH.2013.301578)

the primary outcome, compared with the attention-control intervention, controlling for baseline condom use.

## METHODS

The participants were residents of townships near East London in Eastern Cape Province, South Africa. More than 98% of the residents of these areas are Black Africans whose first language is isiXhosa.

We identified 206 neighborhoods defined as geographical clusters tied to census data in the catchment area, allowing us to create matched pairs of neighborhoods similar on the percentage isiXhosa-speaking, percentage married, percentage male, percentage unemployed, percentage living in informal dwellings, and population size.<sup>11</sup> From the 103 matched pairs, we randomly selected 22 pairs.

In a cluster-randomized controlled trial, we used computer-generated random number sequences to randomize 1 neighborhood within each pair to the HIV/STI risk-reduction intervention and the other to the control intervention using concealment of allocation techniques designed to minimize bias in assignment. The biostatistician conducted the computer-generated random assignments, and the project director implemented the assignments. We enrolled the neighborhoods during a 25-month period beginning in November 2007, with all data collection completed by December 2010.

Before recruiting from a neighborhood, we met with community leaders to enlist their support. We then held a meeting to inform men about the study and advertised it using posters and other materials. We recruited men at different hours of the day and days of the week at a variety of venues (e.g., taxi ranks, shebeens,<sup>12</sup>

marketplaces) to reach a diversity of men. At the time of recruitment, community leaders, potential participants, and recruiters were blind to the condition to which we had randomized the neighborhood, and recruiters followed a common, standardized scripted recruitment protocol. Men aged 18 to 45 years who lived in a selected neighborhood, reported vaginal intercourse in the previous 3 months, did not report plans to relocate beyond a reasonable distance from the study site within the next 15 months, and had a photo ID or were willing to have their picture taken for identification purposes were eligible. We enrolled men who completed the baseline questionnaire and returned the subsequent week for intervention session 1. We conducted data-collection and intervention sessions at the University of Fort Hare in East London and provided transportation to the sessions.

### Interventions

We developed interventions based on social cognitive theory<sup>9</sup> and extensive formative research,<sup>10</sup> including 15 focus groups and 4 pilots of the intervention with the target population. Each intervention consisted of six 75-minute modules, with 2 modules delivered during each of 3 sessions in 3 consecutive weeks. Each intervention was highly structured and implemented in a small group of 9 to 15 men led by a male, isiXhosa- and English-speaking facilitator who used standardized intervention manuals. We translated the interventions into isiXhosa, back-translated them from isiXhosa to English, and delivered the interventions in isiXhosa. Each intervention included interactive exercises, games, brainstorming, role-playing, take-home assignments, group discussions, and videos, produced specifically for the interventions, filmed in authentic township settings, including a shebeen.

We designed the HIV/STI risk-reduction intervention to (1) strengthen behavioral beliefs that support condom use, (2) increase skill and self-efficacy to use condoms, and (3) increase HIV/STI risk-reduction knowledge. The name of the program and the theme that was infused throughout was “Men, Together Making a Difference!” Each session began with a “Circle of Men” activity, which gave men an opportunity to express their thoughts and feelings in a fellowship of amaXhosa men where age, education or profession did not matter but

a bond as brothers was important. A brainstorm activity explored how manhood is defined and how men together can make a difference in protecting themselves, their families, and communities against HIV. A powerful activity, “Acknowledging the Threat of HIV,” illustrated how HIV can ruin the foundation of the home and family. Participants used their creativity to construct the best house they could fashion from shoeboxes and contact paper. Then, to their surprise, the facilitator directed them to destroy it with a brick bearing the label “HIV.”

A video magazine, “The Subject Is: HIV,” addressed HIV’s devastating impact in South Africa, abstinence, fidelity, condom use, partners’ reactions to requests for condom use, and dangers of multiple partners. A video drama, “Eiyish!,” addressed dangers of multiple partners and failure to use condoms, alcohol and risk behavior, effects of condom use on sexual enjoyment, advantages of monogamy, and sexual networks. Sessions 1 and 2 included take-home assignments that the participants reviewed at the subsequent session. Other activities addressed the risk of different sexual behaviors, HIV’s spread through a social network, condom-use skills, making condoms fun and pleasurable, and responding to partners’ concerns about using condoms. Men practiced condom negotiation in role-play scenarios with performance feedback from other participants and facilitators. In “Reduce-Your-Risk Rugby Game,” men reviewed what they learned in a fun way.

The health-promotion intervention was designed to control for nonspecific features including group interaction and special attention.<sup>13</sup> It contained activities similar to the HIV/STI risk-reduction intervention but focused on behaviors linked to the risk of heart disease, hypertension, stroke, diabetes, and certain cancers—leading causes of morbidity and mortality among South Africans.<sup>14–17</sup> It was designed to increase fruit and vegetable consumption and physical activity and decrease excessive alcohol consumption.

The facilitators were 17 men aged 25 to 53 years (mean = 38.9 years) from the community who were fluent in English and isiXhosa. All had at least a high school diploma, including 7 who had at least a bachelor’s degree; all had previously implemented life skills or HIV curricula. We randomly assigned them to 6 days of training to implement 1 of the 2 interventions,

thus randomizing facilitators’ characteristics across interventions. During the training, trainers modeled the intervention activities and stressed the importance of implementation fidelity. Facilitators practiced implementing their assigned intervention, received feedback, and created common responses to potential issues that might arise during implementation.

### Assessments

We employed audio computer-assisted self-interviewing (ACASI), which provided both audio and video presentation of the questions and response options on a laptop computer, to collect data before, immediately following, and 6 and 12 months following intervention. The measures, which had been pilot tested with more than 250 men, were available in isiXhosa (following translation and back translation from English), English, and a combination of isiXhosa (audio) and English (visual).

The primary outcome was report of consistent condom use during vaginal intercourse in the past 3 months. Separate binary variables reflected consistent condom use with steady partners and casual partners. Men who reported at least 1 vaginal intercourse act in the past 3 months and whose number of reported condom-protected vaginal intercourse acts equaled their number of vaginal intercourse acts were coded as practicing consistent condom use. Men who reported at least 1 vaginal intercourse act and whose reported number of condom-protected vaginal intercourse acts was less than their reported number of vaginal intercourse acts were coded as not practicing consistent condom use.

We also assessed secondary condom-use outcomes separately for steady partners and casual partners: the proportion of condom-protected acts of vaginal intercourse, condom use at last vaginal intercourse, and the frequency of condom use rated on a 5-point scale from 1 “never” to 5 “always.” The condom use measures were selected because they are widely used in HIV/STI risk-reduction intervention trials.<sup>18–21</sup> Studies with biological outcomes support their validity.<sup>22–25</sup> In addition, we assessed unprotected vaginal intercourse (0 = did not have vaginal intercourse or always used condoms, 1 = did have vaginal intercourse without using a condom), heterosexual anal intercourse, and communication about condom

**TABLE 1—Sociodemographic Characteristics of Neighborhoods and Participating Men by Intervention Condition at Baseline: Eastern Cape Province, South Africa, 2007–2009**

Characteristic	HIV and STI Intervention No., No. (%), or Mean ±SD	Health Control Intervention No., No. (%), or Mean ±SD	Total No., No. (%), or Mean ±SD
<b>Neighborhoods<sup>a</sup></b>			
No.	22	22	44
isiXhosa home language, %	99.0 ±2.9	99.0 ±3.2	99.0 ±3.0
Married, %	19.1 ±3.1	19.2 ±3.2	19.1 ±3.1
Male, %	48.1 ±2.1	48.1 ±2.1	48.1 ±2.2
Unemployed, %	60.6 ±9.3	60.6 ±9.5	60.6 ±9.3
Urban-Informal <sup>b</sup>	6/22 (27.3)	6/22 (27.3)	12/44 (27.3)
Population size group			
727–1113	9/22 (40.9)	10/22 (45.4)	19/44 (43.2)
1114–1299	4/22 (18.2)	3/22 (13.6)	7/44 (15.9)
1300–1881	9/22 (40.9)	9/22 (40.9)	18/44 (40.9)
<b>Men</b>			
No.	609	572	1181
isiXhosa home language	607/609 (99.7)	571/572 (99.8)	1178/1181 (99.8)
Married	27/609 (4.4)	41/572 (7.2)	68/1181 (5.8)
Steady partner in past 3 mo	494/609 (81.1)	451/572 (78.8)	945/1181 (80.0)
Casual partner in past 3 mo	328/609 (53.9)	274/572 (47.9)	602/1181 (51.0)
Unemployed	425/609 (69.8)	368/572 (64.3)	793/1181 (67.1)
Completed high school	279/609 (45.8)	239/572 (41.8)	518/1181 (43.9)
Alcohol dependent <sup>c</sup>	377/609 (61.9)	330/572 (57.7)	707/1181 (59.9)
Age, y			
18–24	282/609 (46.3)	273/572 (47.7)	555/1181 (47.0)
25–29	158/609 (25.9)	126/572 (22.0)	284/1181 (24.0)
30–45	169/609 (27.8)	173/572 (30.2)	342/1181 (29.0)
Housing circumstances			
Own house or flat	115/609 (18.8)	107/572 (18.7)	222/1181 (18.8)
Family's house	369/609 (60.6)	361/572 (63.1)	730/1181 (61.8)
Partner's house	19/609 (3.1)	13/572 (2.3)	32/1181 (2.7)
Rented room	15/609 (2.5)	12/572 (2.1)	27/1181 (2.3)
Shack in someone else's yard	91/609 (14.9)	79/572 (13.8)	170/1181 (14.4)

Note. STI = sexually transmitted infection.

<sup>a</sup>Neighborhood characteristics are based on the 2001 South African Census, the latest data available.

<sup>b</sup>Urban-informal refers to informal dwellings (shacks) in an urban area.

<sup>c</sup>Based on a score of ≥ 2 on the CAGE (Cutting down, Annoyance by criticism, Guilty feeling, and Eye-openers) questionnaire.

use with steady partners and casual partners separately and multiple partners (0 = reported having 0 or 1 partner, 1 = reported having 2 or more partners regardless of type of partner). Participants also completed measures of socio-demographic variables, problem alcohol consumption,<sup>26</sup> theoretical mediator variables, and health-promotion behaviors and mediators.

As compensation, participants received R100 (\$13) grocery-store vouchers at the postintervention, 6-month follow-up, and the 12-month follow-up assessments, a cap with study logo

at the postintervention assessment, a t-shirt with study logo at the 6-month assessment, and a jersey at the 12-month assessment.

### Sample Size and Statistical Analysis

The a priori unit of inference was the individual. Based on pilot data with 73 men in 4 neighborhoods, we estimated an intraclass correlation (ICC) of 0.01. Assuming  $\alpha = 0.05$ , a 2-tailed test, ICC = 0.01, 15% attrition at 12-month follow-up, and  $n = 1152$  men in the trial from 44 neighborhoods with an average of

26 men in each neighborhood, the trial was estimated to have 81% power to detect a 10% increase in consistent condom use from 32% in the control group to 42% in the HIV/STI intervention group, adjusting for the expected variance inflation because of clustering.<sup>27</sup>

Before analyzing intervention efficacy, we used generalized estimating equation (GEE) models, controlling for clustering of men within neighborhoods, to analyze attrition. We tested the efficacy of the HIV/STI intervention compared with the health-promotion control intervention over the 6- and 12-month follow-ups using a logistic, linear, or multinomial GEE model, depending on the type of outcome variable (binary, continuous, or ordinal), properly adjusting for longitudinal repeated measurements on men clustered within neighborhoods<sup>28,29</sup> and controlling for baseline measure of the criterion. We fit the models and specified contrast statements to obtain estimated odds ratios for binary outcomes, consistent condom use, and use of a condom at last vaginal intercourse; mean differences for continuous outcome proportion condom-protected vaginal intercourse; odds ratios for ordinal outcome frequency of condom use; and their corresponding 95% confidence intervals. We used robust standard errors and specified an independent working correlation matrix.

The models included time-independent covariates, baseline measure of the criterion, intervention condition, time (2 categories representing 6- and 12-month follow-up), and type of partner (2 categories representing steady and casual partners). The model that analyzed incidence of multiple partners did not include type of partner because as mentioned earlier we operationalized multiple partners irrespective of type of partner. We reported estimated average intervention effects over the 2 follow-ups constructed from appropriate estimate statements from fitted GEE models and *d* values,<sup>30</sup> which for odds ratios were calculated using Cox transformation.<sup>31</sup> Models assessing whether the efficacy of the intervention differed depending on type of partner (steady versus casual) included the baseline measure of the criterion, intervention condition, time, type of partner, and the intervention condition × type of partner interaction. Models assessing whether the efficacy of the intervention differed between the 2 follow-ups included the baseline measure

of the criterion, intervention condition, time, type of partner, and the intervention condition × time interaction.

We performed the analyses using an intent-to-treat mode with participants analyzed based on their intervention assignment, regardless of the number of intervention or data-collection sessions attended. Analyses were completed using SAS version 9.<sup>32</sup>

RESULTS

The 22 neighborhoods in the 2 arms were similar on the characteristics we sought to match (Table 1) and on baseline measures of outcomes (Table 2). Of 1317 eligible men, 1181 (89.7%) were enrolled: 609 in the HIV/STI-risk-reduction-intervention neighborhoods and 572 in the control-intervention neighborhoods (Figure 1). Participants' mean age was 26.7 years (SD = 6.6 years). Only 5.8% were married, but 80.0% had a steady partner, a woman with whom they had a romantic relationship for at least 6 months. Two thirds were unemployed, and only 43.9% had completed high school.

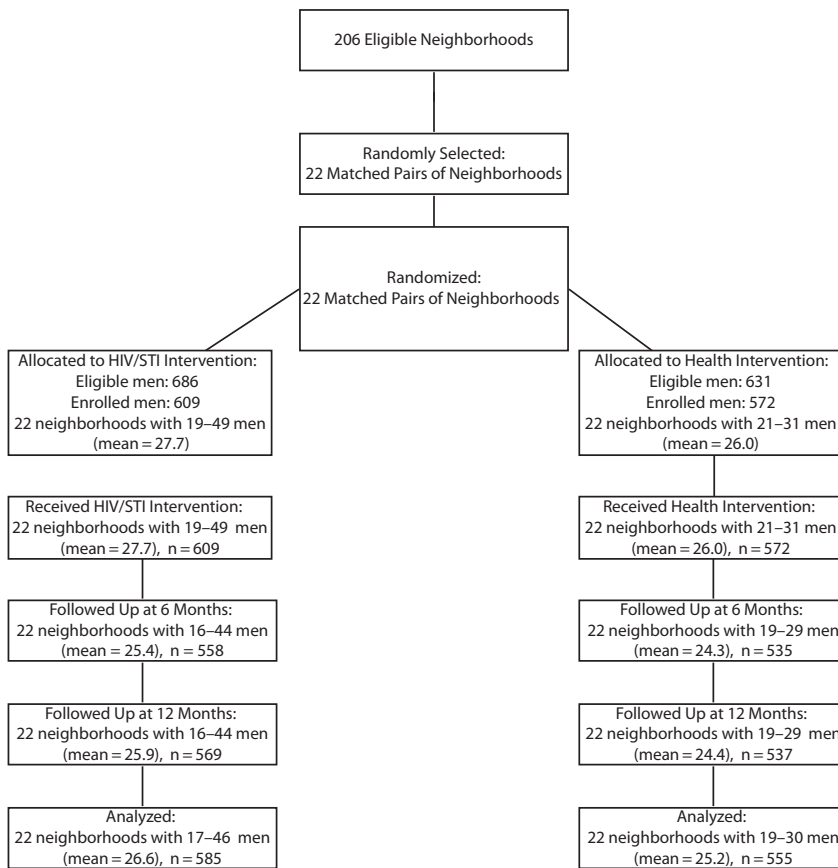
All 44 neighborhoods remained in the trial to its completion (Figure 1). All participants attended intervention session 1, 1171 (99.2%) attended intervention session 2, and 1165 (98.6%) attended intervention session 3. A total of 1140 or 96.5% attended at least 1 of the 2 follow-up assessments, 1093 (92.5%) attended the 6-month follow-up, and 1106 (93.6%) attended the 12-month follow-up. The percentage that attended a follow-up session did not differ in the HIV/STI risk-reduction intervention (585 of 609 or 96.1%) compared with the health-promotion control intervention (555 of 572 or 97.0%). Attending a follow-up did not differ by age group, high school education, unemployment, marital status, steady or casual partners, alcohol problems, condom use, or communication with partners about condoms.

Table 2 presents descriptive statistics for outcomes by intervention condition and assessment period. Table 3 presents estimated intervention effects during the follow-up period, corresponding significance tests (both unadjusted and adjusted for baseline outcome), and ICCs. Men in the HIV/STI risk-reduction intervention had higher odds of reporting consistently using condoms during vaginal intercourse averaged over the follow-up period than did their

TABLE 2.—Self-Reported Behaviors by Intervention Condition, Assessment Period, and Type of Partner: Eastern Cape Province, South Africa, 2007–2010

Outcomes	Baseline, No. (%) or Mean ± SE		6 Months, No. (%) or Mean ± SE		12 Months, No. (%) or Mean ± SE	
	HIV/STI Intervention (n = 609)	Health Intervention (n = 572)	HIV/STI Intervention (n = 558)	Health Intervention (n = 535)	HIV/STI Intervention (n = 569)	Health Intervention (n = 537)
Consistent condom use						
Steady partners	147/436 (33.7)	127/396 (32.1)	151/382 (39.5)	114/334 (34.1)	146/378 (38.6)	110/340 (32.4)
Casual partners	141/257 (54.9)	111/221 (50.2)	95/177 (53.7)	91/175 (52.0)	87/171 (50.9)	91/174 (52.3)
Proportion condom-protected vaginal intercourse						
Steady partners	0.524 ± 0.021	0.516 ± 0.022	0.585 ± 0.022	0.549 ± 0.023	0.613 ± 0.021	0.555 ± 0.022
Casual partners	0.713 ± 0.024	0.665 ± 0.028	0.712 ± 0.029	0.685 ± 0.029	0.678 ± 0.031	0.684 ± 0.030
Used condom at last vaginal intercourse						
Steady partners	232/436 (53.2)	217/396 (54.8)	265/382 (69.4)	196/334 (58.7)	256/378 (67.7)	216/340 (63.5)
Casual partners	200/257 (77.8)	163/222 (73.4)	148/177 (83.6)	141/175 (80.6)	136/171 (79.5)	139/174 (79.9)
Frequency of condom use						
Steady partners	2.991 ± 0.078	3.041 ± 0.083	3.309 ± 0.079	2.931 ± 0.085	3.238 ± 0.077	3.029 ± 0.081
Casual partners	3.712 ± 0.093	3.603 ± 0.109	3.892 ± 0.101	3.594 ± 0.110	3.702 ± 0.109	3.649 ± 0.111
Talked to partner about condoms						
Steady partners	360/494 (72.9)	308/451 (68.3)	353/419 (84.2)	285/379 (75.2)	331/413 (80.1)	289/390 (74.1)
Casual partners	209/328 (63.7)	179/273 (65.6)	161/225 (71.6)	147/220 (66.8)	148/211 (70.1)	145/209 (69.4)
Unprotected vaginal intercourse						
Steady partners	289/609 (47.5)	269/572 (47.0)	231/558 (41.4)	220/535 (41.1)	231/566 (40.8)	230/537 (42.8)
Casual partners	116/609 (19.0)	110/571 (19.3)	82/558 (14.7)	84/535 (15.7)	84/567 (14.8)	83/536 (15.5)
Anal intercourse						
Steady partners	67/579 (11.6)	60/546 (11.0)	43/532 (8.1)	49/510 (9.6)	36/541 (6.7)	36/523 (6.9)
Casual partners	45/550 (8.2)	37/509 (7.3)	29/506 (5.7)	39/488 (8.0)	22/517 (4.13)	20/499 (4.0)
Multiple vaginal intercourse partners	268/609 (44.0)	224/571 (39.2)	199/558 (35.7)	192/535 (36.1)	199/567 (35.1)	200/537 (37.2)

Note. STI = sexually transmitted infection.



*Note.* STI = sexually transmitted infection. Eligible men not enrolled failed to return for intervention session 1 for unknown reasons. The enrollment rate did not differ between treatment (88.8%) and control (90.6%) arms ( $P = .264$ ). Men who did not complete the 6-mo follow-up were deceased ( $n = 9$ ) or in prison ( $n = 4$ ), had permanently moved from the area ( $n = 17$ ), or were absent from the scheduled follow-up sessions or make-up sessions for unknown reasons ( $n = 58$ ). Men not followed up at 12 months were deceased ( $n = 14$ ) or in prison ( $n = 2$ ), had permanently moved from the area ( $n = 34$ ), or were absent for unknown reasons ( $n = 25$ ).

**FIGURE 1—Progress of participating neighborhoods and men through the trial: Eastern Cape Province, South Africa, 2007–2010.**

counterparts in the health-promotion-control intervention, controlling for baseline consistent condom use. Similarly, men in the HIV/STI risk-reduction intervention reported a greater proportion of condom-protected vaginal intercourse and more frequent condom use and had higher odds of reporting condom use at last vaginal intercourse compared with those in the health-promotion control intervention, controlling for baseline prevalence. There were significant effects of type of partner in all the condom-use analyses, indicating men had lower odds of using condoms with steady partners than with casual partners.

Analyses also revealed that men in the HIV/STI risk-reduction intervention had higher odds of reporting discussing using condoms with their partners than did those in the health-promotion control intervention. By contrast, the HIV/STI intervention did not significantly affect the incidence of unprotected vaginal intercourse, heterosexual anal intercourse, or multiple vaginal-intercourse partners. Type-of-partner effects indicated that men had higher odds of discussing condoms with their steady as opposed to casual partners.

The intervention condition  $\times$  type of partner and the intervention condition  $\times$  time interactions were not significant on any outcome,

indicating that the efficacy of the intervention did not vary for behavior with steady partners compared with casual partners or at the 6-month follow-up compared with the 12-month follow-up.

## DISCUSSION

The results supported the hypothesis that an intervention specifically developed for men would result in increased condom use during vaginal intercourse compared with an attention-control group. The intervention increased self-reported consistent condom use, proportion condom-protected intercourse, condom use at last intercourse, and frequency of condom use. Moreover, the effects were not significantly weaker 12 months postintervention compared with 6 months postintervention.

Other studies have tested sexual risk reduction interventions for men in sub-Saharan Africa. A quasi-experiment with South African men, though not distinguishing between steady and casual partners, reported that consistent condom use increased 1 month following intervention.<sup>8</sup> A trial in Zimbabwe found that an intervention did not reduce HIV-risk related behavior among male beer hall patrons.<sup>33</sup> To our knowledge, this is the first trial to find increases in self-reported condom use in African men over a 12-month postintervention period.

As in other studies, we found that men reported using condoms more consistently with casual partners than with steady partners.<sup>34–36</sup> However, the intervention's effect on condom use was not weaker for vaginal intercourse with steady partners as compared with casual partners. Indeed, the trend was in the direction of stronger effects on condom use with steady partners. These effects of the intervention on condom use with steady partners are important. The probability of transmission to steady partners is higher because of the high number of potential exposures. Consistent with this, most HIV transmission occurs between steady partners.<sup>37</sup> By increasing men's use of condoms with their steady partners, then, it should be possible to reduce rates of HIV transmission within couples.

Moreover, the intervention also increased self-reports of discussing condom use with partners. Research reveals that women, owing to gender-based power relations and cultural

**TABLE 3—General Estimating Equation Empirical Significance Tests and Effect Size Estimates for the Overall Intervention Effect Unadjusted for Baseline Prevalence and Adjusted for Baseline Prevalence: Eastern Cape Province, South Africa, 2007–2010**

Outcome	ICC	Unadjusted for Baseline			Adjusted for Baseline		
		Estimate <sup>a</sup> (95% CI)	P	d	Estimate <sup>a</sup> (95% CI)	P	d
Consistent condom use	0.006	1.18 (0.96, 1.46)	.123	0.10	1.32 (1.03, 1.71)	.008	0.17
Proportion condom-protected vaginal intercourse	0.024	0.04 (-0.01, 0.08)	.1	0.12	0.06 (0.01, 0.10)	.014	0.20
Used a condom at last vaginal intercourse	0.028	1.31 (1.04, 1.64)	.02	0.16	1.40 (1.08, 1.82)	.011	0.20
Frequency of condom use	0.006	1.34 (1.11, 1.63)	.003	0.18	1.41 (1.13, 1.76)	.002	0.21
Talked to steady partner about condom use	0.017	1.37 (1.09, 1.73)	.006	0.19	1.50 (1.16, 1.93)	.002	0.24
Unprotected vaginal intercourse	0.001	0.95 (0.81, 1.13)	.592	0.02	0.95 (0.81, 1.13)	.578	0.03
Anal intercourse	-0.001	0.86 (0.60, 1.23)	.409	0.07	0.85 (0.59, 1.23)	.385	0.10
Multiple vaginal intercourse partners	0.016	0.95 (0.78, 1.16)	.618	0.03	0.89 (0.73, 1.10)	.297	0.07

Note. CI = confidence interval; ICC = intraclass correlation coefficient. *d* is the effect size estimate in standard deviation units based on the mean difference or Cox transformation of the odds ratio.<sup>31</sup> Intervention effect is average over the 6- and 12-month follow-up assessments.

<sup>a</sup>Estimates are odds ratios (intervention vs health control) for all outcomes except proportion condom-protected vaginal intercourse where it is the mean difference (intervention–control).

considerations, are not expected to speak about using condoms with their husbands or other male partners.<sup>38</sup> Thus, increasing the number of men who talk to their partners about using condoms may help surmount barriers to communication about condoms and ultimately condom use within couples.

### Strengths and Limitations

This study has a number of important strengths. We enrolled a community-based sample of men who have intercourse with women in the context of a generalized heterosexual HIV epidemic. We developed the intervention using behavior-change theory and extensive formative research. Well-trained facilitators who used manualized content delivered it. Only a high school diploma was required for facilitators, which should facilitate scaling-up the intervention. Participants were blind to intervention condition before enrollment, thus avoiding differential self-selection bias. Matched pairs of neighborhoods were randomized to conditions, an attention-control intervention was employed, and intervention-attendance and follow-up retention rates were excellent, strengthening internal validity. Neighborhoods were randomly selected, strengthening generalizability to other neighborhoods in the area.

Although the use of ACASI may increase participants' motivation to respond accurately,<sup>39–42</sup> a limitation of the study is the reliance on self-reports of behavior. The use of

a biological outcome such as HIV or other STIs would have improved the study.<sup>43</sup> Another limitation is that the results may not generalize to all South African men. Some might reason that, because we applied Western theories to behavioral change in sub-Saharan Africa, intervention effects would be diminished. However, the effect sizes for the condom use outcomes were about 0.20 in this trial. These effect sizes compare favorably with those reported in meta-analyses of intervention effects on adults' condom use in the United States.<sup>44,45</sup>

### Conclusions

That HIV affects women most severely in regions such as sub-Saharan Africa where heterosexual exposure is a dominant mode of HIV transmission is well established. Yet, few interventions to change the heterosexual behavior of men in sub-Saharan Africa have been developed and rigorously evaluated. This is the first large-scale randomized controlled intervention trial exclusively focusing on South African men to obtain significant effects on an HIV sexual-risk behavior. South African men were willing to attend multiple intervention sessions, participate in role-play condom-negotiation scenarios with other men, and return for repeated efficacy assessments. Additional research might strengthen the impact of the intervention on multiple partnerships and address the generalizability of the present findings to biological outcomes. ■

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### Contributors

J. B. Jemmott III contributed substantially to the analysis and interpretation of the data, supervised all aspects of the trial's implementation, and drafted the article. L. S. Jemmott oversaw intervention development and facilitator training. A. O'Leary oversaw the application of social cognitive theory in the research and contributed to the drafting of the article. Z. Ngwane helped train the facilitators and oversaw the cultural and linguistic appropriateness of the procedures. L. D. Icard contributed to the drafting of the article. G. A. Heeren contributed to the conduct of preliminary studies and the drafting of the article. X. Mtsoe contributed to the conduct of preliminary studies and helped to ensure the cultural and linguistic appropriateness of the procedures. C. Carty supervised project staff. All authors contributed substantially to the conceptualization and design of the research, revised the content, and approved the final article.

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**Note.** The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institutes of Health or the Centers for Disease Control and Prevention. The funder had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript. The corresponding author, J. B. Jemmott III, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

### Human Participant Protection

Institutional review board 8 at the University of Pennsylvania, which was the designated institutional review board under the federalwide assurance of the University of Pennsylvania and the University of Fort Hare, reviewed and approved this research. Participants' informed consent was required for the participation. The treatment of research participants was in accordance with the ethical standards of the American Psychological Association and the Principles of the Ethical Practice of Public Health.

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