

A RANDOMIZED, CONTROLLED TRIAL OF A BEHAVIORAL INTERVENTION TO PREVENT SEXUALLY TRANSMITTED DISEASE AMONG MINORITY WOMEN

ROCHELLE N. SHAIN, PH.D., JEANNA M. PIPER, M.D., EDWARD R. NEWTON, M.D., SONDR A. T. PERDUE, DR.P.H., REYES RAMOS, PH.D., JANE DIMMITT CHAMPION, PH.D., AND FERNANDO A. GUERRA, M.D., M.P.H.

ABSTRACT

Background African-American and Hispanic women are disproportionately affected by sexually transmitted diseases, including the acquired immunodeficiency syndrome (AIDS). In the effort to reduce infection rates, it is important to create and evaluate behavioral interventions that are specific to the target populations.

Methods We enrolled women with nonviral sexually transmitted diseases in a randomized trial of a sex- and culture-specific behavioral intervention. The intervention consisted of three small-group sessions of three to four hours each designed to help women recognize personal susceptibility, commit to changing their behavior, and acquire necessary skills. The control group received standard counseling about sexually transmitted diseases. The design of the intervention was based on the AIDS Risk Reduction Model and ethnographic data on the study populations. Participants in both groups underwent screening, counseling, and an interview before randomization and at the 6- and 12-month follow-up visits. The principal outcome variable was subsequent chlamydial or gonorrheal infection, which was evaluated on an intention-to-treat basis by logistic-regression analysis.

Results A total of 424 Mexican-American and 193 African-American women were enrolled; 313 were assigned to the intervention group and 304 to the control group. The rate of participation in the intervention was 90 percent. The rates of retention in the sample were 82 and 89 percent at the 6- and 12-month visits, respectively. Rates of subsequent infection were significantly lower in the intervention group than in the control group during the first 6 months (11.3 vs. 17.2 percent, $P=0.05$), during the second 6 months (9.1 vs. 17.7 percent, $P=0.008$), and over the entire 12-month study period (16.8 vs. 26.9 percent, $P=0.004$).

Conclusions A risk-reduction intervention consisting of three small-group sessions significantly decreased the rates of chlamydial and gonorrheal infection among Mexican-American and African-American women at high risk for sexually transmitted disease. (N Engl J Med 1999;340:93-100.)

©1999, Massachusetts Medical Society.

chancroid after a single exposure.⁵ The efficiency of male-to-female transmission of the human immunodeficiency virus (HIV) is about four times as high as that of female-to-male transmission.⁶ Rates of heterosexually acquired HIV infection among women have been increasing in the United States.^{7,8} In 1995, heterosexual contact emerged as the leading cause of AIDS among American girls and women 15 to 44 years old⁸; in 1996, 6 percent of men and 40 percent of women with AIDS had been infected by heterosexual transmission.⁹

The African-American and Hispanic populations are disproportionately affected by sexually transmitted disease. The incidence of gonorrhea is substantially higher among African-American and Hispanic persons than among whites¹; for AIDS the respective incidence rates are six and three times as high as among whites.¹⁰ The proportion of cases of AIDS that occur among minority groups has been increasing since 1992.¹¹ Differences in the incidence of AIDS according to race and ethnic group are especially dramatic for women. In 1996 these rates were more than 17 and 6 times as high for African-American and Hispanic women, respectively, as for white women (61.7 and 22.7 as compared with 3.5 per 100,000).^{7,9}

Changing sexual behavior is critical to controlling sexually transmitted infection. However, success in reducing high-risk sexual behavior has been limited, particularly among women.^{8,12,13} For women, change is impeded by inequalities between the sexes and dependence on male partners for emotional and economic well-being; minority women are at a further disadvantage because of discrimination and their disproportionate poverty.^{4,12-19} Of the few controlled trials that have used systematic screening for sexually transmitted diseases at base line and at follow-up to assess the efficacy of interventions,²⁰⁻²² only one²¹ found significant differences among study groups, and none focused on minority women. We sought to create culture- and sex-specific small-group interventions to prevent sexually transmitted diseases among African-American and Mexican-American women and

SEXUALLY transmitted diseases, including the acquired immunodeficiency syndrome (AIDS), are a global problem that causes immense suffering and costs billions of dollars annually.¹⁻³ Women and children have the most severe symptoms and sequelae.¹⁻⁴ Women are twice as likely as men to become infected with the pathogens causing gonorrhea, chlamydial disease, hepatitis B, and

From the Departments of Obstetrics and Gynecology (R.N.S., J.M.P.) and Microbiology (S.T.P.) and the School of Nursing (S.T.P., J.D.C.), University of Texas Health Science Center at San Antonio, San Antonio; the Department of Obstetrics and Gynecology, East Carolina University, Greenville, N.C. (E.R.N.); Research and Evaluation, Mujeres Project, San Antonio, Tex. (R.R.); and the San Antonio Metropolitan Health District, San Antonio, Tex. (F.A.G.). Address reprint requests to Dr. Shain at the Department of Obstetrics and Gynecology, University of Texas Health Science Center at San Antonio, 7703 Floyd Curl Dr., San Antonio, TX 78284-7836.

used clinical markers to assess their efficacy in a randomized, controlled trial. Behavioral changes that lead to prevention of the most common sexually acquired diseases may be considered a proxy for changes that prevent heterosexual transmission of HIV.²¹ HIV infection could not be used as an outcome variable in our study because of its low prevalence in our heterosexual community.

METHODS

Study Procedures

This study was approved by the institutional review boards at the University of Texas Health Science Center and the San Antonio Metropolitan Health District. The efficacy of the intervention was evaluated in a randomized, controlled trial. The chief outcome variable was subsequent infection with *Chlamydia trachomatis* or *Neisseria gonorrhoeae*. In order to ensure the high-risk status of the participants, eligibility was limited to women who currently had a nonviral, sexually transmitted disease (chlamydial infection, gonorrhea, syphilis, or infection with trichomonas); eligibility was also limited to speakers of English (8 percent of otherwise eligible Hispanic women were therefore excluded) in order to maximize homogeneity across the racial and ethnic groups.

All 947 eligible women whom we could contact were recruited from public health clinics in San Antonio and were offered the opportunity to participate in this study at our research clinic. After giving their written informed consent, subjects were examined, screened for infection, treated (if necessary), counseled, and interviewed at base line and at their 6- and 12-month visits. Participants were told to return for repeated screening and additional treatment whenever they noticed gynecologic symptoms or were concerned about possible reinfection ("problem" visits). Information was also obtained about infections that had been diagnosed elsewhere. As an incentive to participate, the women received \$25 for the initial and 6-month visits and \$50 for the 12-month visit.

At each visit a targeted physical examination was performed and genital tract specimens were collected for microbiologic testing; specimens were tested for the presence of *N. gonorrhoeae*, *C. trachomatis*, and other pathogens of the lower genital tract. The primary method of screening for gonorrheal and chlamydial infections (at both scheduled follow-up and on- and off-site problem visits) was testing of endocervical samples with DNA probes (Gen-Probe PACE 2 assay, Gen-Probe, San Diego, Calif.). Limited quality-assurance testing was performed for *N. gonorrhoeae* (cultured in Thayer–Martin medium and detected with Phadebact monoclonal antibody [Boule Diagnostics, Huddinge, Sweden]) and for chlamydia (by culture with McCoy cells, by enzyme immunoassay [Kodak Sure Cell, Eastman Kodak, Rochester, N.Y.], or with fluorescent antibody [Syva Microtrak, Syva, San Jose, Calif.]). Any test that was positive for gonorrheal organisms or chlamydia was considered diagnostic. Testing for the presence of HIV was offered to all participants at each visit.

Standard individual counseling (in a session lasting 15 minutes) was provided by nurse clinicians according to guidelines issued by the Centers for Disease Control and Prevention; counseling was individualized according to the patient's sexual history and her responses to a test of knowledge. Because these clinicians had more time for patient care and education than staff at typical clinics, all participants may have benefited from involvement in the study.

Design of the Intervention

We adapted the AIDS Risk Reduction Model^{23,24} to guide the collection of qualitative data, the design of the intervention, the structure of the questionnaire, and the overall research strategy. The model builds on and integrates elements of several social and psychological theories, including the Health Belief Model,²⁵ self-efficacy theory,²⁶ decision-making models,²⁷ and diffusion theory.²⁸

Its three stages are recognition of one's risk, commitment to reducing that risk, and following through with that commitment by seeking solutions. Passing from one stage to the next requires knowledge of disease transmission; recognition of personal susceptibility; perception of the costs and benefits of behavioral change, including ways to increase enjoyment from low-risk activities; self-efficacy; and attainment of skills. Social support is helpful at each stage.

Ethnographic data were collected for approximately 18 months from both men and women on conditions of life and lifestyles, values and beliefs, sexual behavior, knowledge and concern about sexually transmitted diseases (including AIDS), perception of risk, male–female relationships, drug and alcohol use, condom use, strategies to motivate behavioral change, and the logistics of intervention. We conducted 25 focus-group interviews and 102 in-depth interviews and made extensive observations in low-income, inner-city communities.²⁹ Ethnograph (Qualis Research Associates, Amherst, Mass.), a computer software package for qualitative data, was used to analyze content.²⁹ Ethnographic data provided insight into how to encourage recognition of risk and motivate change and also identified barriers to change. For example, our data revealed cultural strengths such as strong racial and ethnic identification and pride; a need, particularly among Mexican Americans, to protect one's family from harm or shame; and among African Americans, emphasis on cleanliness and disease prevention, including a proscription against sharing utensils (not "eating behind"), a prohibition that was already extended to needle sharing (not "fixing behind"). Strategies for risk reduction consequently emphasized the disproportionate prevalence of disease among minority groups; possible effects of HIV infection on family members; and, like the importance of not "eating or drinking behind someone," the importance of not having unprotected sex (having sex "behind someone"). Barriers to change, such as fatalism, poor understanding of the transmission of sexually transmitted diseases, and belief that a potential sex partner's risk status can be assessed accurately, were also uncovered. Findings were integrated with the AIDS Risk Reduction Model to create the intervention, with advice from a multiracial and multiethnic team.

Successive iterations of the three-session intervention were pretested with 13 groups (a total of 85 women). The content and objectives of each session (roughly corresponding to the stages in the AIDS Risk Reduction Model) are shown in Table 1. The content of the interventions for African-American and Mexican-American women was largely the same, although emphases and cultural cues varied.

The behavioral–cognitive intervention consisted of three small-group, multicomponent sessions, each lasting three to four hours. Five or 6 (range, 3 to 12) participants and a female facilitator, all of the same race or ethnic group, met once a week for three consecutive weeks. Highly trained facilitators provided information and actively involved participants in lively and open discussions, games, videotape watching, behavior modeling, and role play. Learning was personalized. Graphic materials designed by us for low-literacy populations communicated difficult concepts such as the distribution in the distribution of sexually acquired diseases and the role of a sex partner's other partners in disease transmission. Facilitators did not impose their values; they encouraged realistic risk-reduction strategies within the constraints of their clients' own lives and values. Preventive strategies discussed included abstinence, mutual monogamy, correct and consistent use of condoms, full compliance with treatment protocols, and reduction in the number of partners. Sessions were standardized with scripts and flip charts; random observations by one-way mirror were made to ensure uniformity (all the participants were informed that they could be observed at any time). Incentive payments were \$25 for session 1 and \$15 each for sessions 2 and 3. Inexpensive meals, which encouraged bonding, and gifts were provided.

Statistical Analysis

Randomization was accomplished at the end of the initial visit by asking participants to select starting times for the intervention

TABLE 1. CONTENT AND OBJECTIVES OF THE INTERVENTION.***Session 1. Recognition of risk**

1. Increase awareness that minorities are disproportionately affected by AIDS and other sexually transmitted diseases (diagrams). Discuss risk as a community problem related to poverty, not skin color.
2. Address myths. For African-American participants, address the belief that the human immunodeficiency virus was purposely planted in the African-American community.
3. Address the belief that disease is "dirty" and encourage acceptance of responsibility for infection. Begin building feelings of self-efficacy and power to control one's life.
4. Discuss the selection of sex partners, and show that there is no way to judge who is safe.
5. Provide information about sexually transmitted diseases: their transmission, behavior that increases the risk of acquisition, symptoms (color illustrations of signs and lesions), and consequences for women and fetuses.
6. Increase awareness of personal risk by associating the current sexually transmitted disease with future infection (including HIV). Emphasize the effect on families (videotapes of actual persons with AIDS).

Session 2. Commitment to change

1. Provide information about the prevention of sexually transmitted diseases and the importance of early treatment, full compliance with treatment protocols, and observation of symptoms in partners. Discuss the avoidance of douching.
2. Particularly for African-American participants, extend the proscription against sharing eating utensils (to prevent disease) to a proscription against having unprotected sex.
3. Teach what to ask partners about current behavior and history.
4. Teach the use and erotic application of condoms (practice on plastic models of the penis).
5. Discuss barriers to condom use and how to overcome them.
6. Discuss what women want from a relationship, what they derive, and why they may tolerate poor behavior from partners. Discuss unprotected sex that results from misplaced trust and low self-esteem or from the desire to avoid conflict, violence, or loss of a partner. For African-American participants, discuss the dearth of available men.
7. Teach decision-making skills and emphasize that everyone has the power to make decisions (videotapes).

Session 3. Acquisition of skills

1. Increase skills for communicating and negotiating about sex, particularly condom use, stressing ways to minimize threats to male self-esteem (videotapes, handouts, and discussion).
2. For Mexican-American participants, facilitate recognition that sexual enjoyment is appropriate for women. Discuss how to use the concept of "machismo" to convince men to be responsible lovers.
3. Teach basic skills to deal with sexual dysfunction resulting from condom use.
4. Raise feelings of self-efficacy in communication about condom use (videotapes and role play with a male facilitator).
5. Increase skills in erotic application of condoms through additional practice.
6. Identify and discuss triggers to unsafe sex.
7. Set goals.
8. Facilitate bonding and mutual support within the group.
9. Acknowledge problems of economic and physical survival (information on local resources).
10. Encourage the sharing of information with others to build a support network for risk reduction.

*Items shown in parentheses are examples of teaching materials or techniques.

from several dates within three weeks of enrollment, without their knowing whether the starting time they selected was a starting time for the intervention or a "dummy" (control) starting time. Starting times for both the intervention and control groups were preassigned to dates randomized and balanced during the enrollment period across times of day, days of the week, weeks of the month, and months of the year. After selecting starting times, participants were informed of their group assignments. This ap-

proach to randomization was used to maximize similarity between the groups in motivation (all the women had to agree to select a starting time) and to minimize resentment of group assignment (since the participants believed they had made the group selection). Women in the control group received only standard counseling but were invited to receive the intervention after completing the study. Although the study was not conducted in a blinded manner, group assignments did not appear on interview documents or clinic records. Participants were asked their group assignment only at the end of follow-up interviews, to ascertain the benefits of the intervention.

All laboratory tests that were positive for *N.gonorrhoeae* or chlamydia, including those performed at on-site and off-site problem visits, were counted in the interval in which they occurred (entry through the 6-month follow-up, or any time after the 6-month follow-up through the 12-month follow-up). The overall count (entry to 12 months) included all tests positive for either infectious agent. Chi-square analysis was used to assess the extent to which behavioral variables were associated with infection and assignment to the intervention group. Multiple logistic-regression analysis was also used to assess associations of behavior with the study group, as well as to determine the effects of intervention, while controlling for differences between the groups in base-line characteristics related to outcome. Analyses were conducted on the basis of the intention to treat.

RESULTS

A total of 424 Mexican-American and 193 African-American women were randomly assigned (after stratification according to race and ethnic group) to the study group (313 women) or the control group (304 women). Most were enrolled before treatment; approximately 10 percent were treated at a public health facility. Of 947 potentially eligible women, approximately 22 percent refused participation and 13 percent did not appear within the required time (30 days from testing, or 14 days from treatment). Rates of participation in the intervention were 90 percent for at least one session, 82 percent for at least two, and 75 percent for three. Enrollment began in January 1993 and ended in July 1994. The 6- and 12-month retention rates were 82 percent (study group, 84 percent, and control group, 80 percent, for a total of 508 women) and 89 percent (study group, 91 percent, and control group, 87 percent, for a total of 549 women), respectively; 26 women with 6-month visits were lost to follow-up at 12 months, and 67 women who missed their 6-month visit returned at 12 months. Repeated screening for chlamydial and gonorrheal organisms was also performed at a total of 260 problem visits (13 at an off-site facility).

Results for women who were lost to follow-up at 6 or 12 months but who had positive laboratory tests at a problem visit before the 6- or 12-month visit are included (five participants at 6 months, of whom three returned at 12 months). Women were excluded from the analysis if laboratory data were missing (because of relocation or a telephone interview), if results were indeterminate, or if any treatments were missed (this was the case for four participants at 6 months and five at 12 months, two of

whom previously tested positive and thus were included in the overall count). The analysis included 509 women at 6 months, 545 at 12 months, and 549 for the total study period. Behavioral analysis included results for 477 women who attended both follow-up visits (5 of the total of 482 had missing data). The rates of loss to follow-up did not differ significantly between groups for any subgroup analysis.

TABLE 2. BASE-LINE CHARACTERISTICS OF THE 549 WOMEN IN THE CUMULATIVE ANALYSIS.*

VARIABLE	INTERVENTION GROUP (N=285)	CONTROL GROUP (N=264)
Age (yr)	21.8±0.33	21.3±0.36
Age <19 yr (%)	32.6	39.0
Monthly income per capita (\$)	243±12	267±14
Education (yr)	10.8±0.11	10.8±0.12
Race or ethnic group (%)		
Mexican-American	69.8	68.2
African-American	30.2	31.8
Currently married (%)	18.9	16.7
No. of sex partners in 3 mo before entry	1.57±0.09	1.37±0.05
Pregnant (%)	27.7	33.3
Sexually transmitted disease (%)†		
Gonorrhea	21.4	20.8
Chlamydial infection	67.0	70.5
Trichomonal infection	26.3	20.8
Syphilis	6.0	6.1

*Plus-minus values are means ±SE.

†Total percentages exceed 100 because some participants had multiple infections.

TABLE 3. NUMBER OF EPISODES OF INFECTION DURING THE 12-MONTH STUDY PERIOD.*

No. of EPISODES†	INTERVENTION GROUP (N=285)	CONTROL GROUP (N=264)
	no. (%)	
Zero	237 (83.2)	193 (73.1)
One	32 (11.2)	51 (19.3)
Two or more	16 (5.6)	20 (7.6)

*P=0.01 by chi-square analysis for the association of group assignment with the number of episodes of infection.

†An occurrence of gonorrhea, chlamydial infection, or both was counted as an episode of infection.

Base-line characteristics of the women are provided in Table 2. Low levels of income and education characterized the population, whose ages ranged from 14 to 45 years; 71 percent were younger than 24. Age (<19 years vs. ≥19 years) and the number of partners in the three months preceding enrollment were controlled for in multiple logistic-regression analysis because differences between the groups at base line were potentially important and because these variables predicted infection. There were no significant differences between the groups in the type of disease present at base line.

Most of the women who were infected at any time during follow-up had only one such episode (15 percent of participants and 70 percent of those who had any episode of reinfection) (Table 3). Women in the control group had more episodes of infection than women in the study group; this was true for both single and multiple infections. Of the women who were reinfected, 17.6 percent had gonorrhea, 65.5 percent had chlamydia, and 16.8 percent had both (with no significant differences between groups in the distribution of disease types).

Multiple logistic-regression analyses of the effects of intervention on subsequent infection revealed that women in the study group were significantly less likely than those in the control group to have gonorrheal or chlamydial infections at 6 months (P=0.05), from 6 to 12 months (P=0.008), and from entry through 12 months (P=0.004) (Table 4). The effect of the intervention did not decrease over time. The infection rate in the intervention group was 34 percent less than that in the control group at 6 months, 49 percent less at 12 months, and 38 percent less overall. Women who attended all three sessions had infection rates of 9.6 percent at 6 months, 8.2 percent at 12 months, and 15.5 percent overall. None of the participants tested positive for HIV during follow-up.

Ongoing analysis of behavior that contributed to reduced cumulative rates of infection (Table 5) indicated that noncompliance with treatment protocols (defined as having sex with an untreated or incompletely treated partner after the base-line infection), multiple partners, and higher-risk sex (defined as five or more acts of unprotected intercourse during the three-month period preceding each follow-up visit) were significantly associated with infection. Significantly fewer women in the intervention group than in the control group were noncompliant with treatment protocols (P<0.001), had multiple partners (P=0.004), or engaged in higher-risk sex (P=0.03). The differences between the groups were significant whether or not we controlled for base-line values.

DISCUSSION

This intervention significantly decreased the rates of chlamydial infection and gonorrhea among high-

TABLE 4. ASSOCIATION BETWEEN STUDY-GROUP ASSIGNMENT AND INFECTION DURING THE FOLLOW-UP PERIODS.

STUDY PERIOD	TOTAL NO. OF PARTICIPANTS	PARTICIPANTS INFECTED*		ODDS RATIO (95% CI)†	P VALUE‡
		INTERVENTION GROUP	CONTROL GROUP		
		no. (% of group)			
Entry through 6-mo visit	509	30 (11.3)	42 (17.2)	0.58 (0.34–0.99)	0.05
6 through 12 mo	545	26 (9.1)	46 (17.7)	0.49 (0.29–0.83)	0.008
Entry through 12 mo	549	48 (16.8)	71 (26.9)	0.52 (0.34–0.81)	0.004

*Sample sizes for the study and control groups were 265 and 244, respectively, from entry through the 6-month visit, 285 and 260 from 6 to 12 months, and 285 and 264 for the entire period from entry through 12 months. Separate analyses were conducted for each interval.

†The values listed are the adjusted odds ratios estimated from multiple logistic-regression analysis with covariates, with control for age (<19 years vs. ≥19 years) and the number of sex partners in the three months preceding enrollment. The number of sex partners was transformed from a continuous measure into categories of 0 or 1, 2 through 4, and 5 or more to meet the distribution assumption of logistic regression — that is, to fit a logit function for reinfection. CI denotes confidence interval. Confidence intervals were derived from estimates of multiple logistic-regression variables.

‡P values were obtained from tests of the significance of the coefficient for an effect of the intervention in the multiple logistic-regression analysis.

TABLE 5. BEHAVIORAL VARIABLES AFFECTED BY THE INTERVENTION AND RELATED TO THE RISK OF INFECTION.*

VARIABLE	NO. OF PARTICIPANTS	PERCENT OF INTERVENTION GROUP (N=249)	PERCENT OF CONTROL GROUP (N=228)	P VALUE FOR COMPARISON OF GROUPS†	INFECTION RATE	P VALUE FOR COMPARISON OF INFECTION RATES‡
					%	
Compliance				<0.001		<0.001
Compliant	373	84.3	71.5		16.9	
Noncompliant	104	15.7	28.5		38.5	
No. of sexual partners				0.004		<0.001
None or one	296	67.5	56.1		14.9	
More than one	181	32.5	43.9		32.6	
No. of unprotected sexual acts				0.03		0.002
Fewer than five	120	29.7	20.2		11.7	
Five or more	357	70.3	79.8		24.9	

*Data are for the 477 women who attended both follow-up visits (at 6 and 12 months). The rate of infection, number of sex partners, and number of unprotected sex acts listed pertain to the cumulative study period (entry through 12 months). Compliance was defined as avoidance of sex with a partner who was untreated or incompletely treated (or whose treatment status was unknown) after treatment of the base-line infection. The number of unprotected sexual acts is a cumulative count of episodes of vaginal or anal intercourse, adjusted for the percentage of episodes with condom use, summed across all partners during the three months preceding each follow-up visit.

†There were no significant differences between groups for comparable variables at base line: more than one partner in the previous 12 months and more than two unprotected sexual acts in the previous 3 months. P values were obtained by logistic-regression analysis, with control for base-line values. Because there was no comparable base-line variable for compliance, chi-square tests were used to determine differences between the groups in this variable.

‡P values were obtained by chi-square tests of the association between infection status and behavior.

risk African-American and English-speaking Mexican-American women. Prevention of sexually transmitted disease was our goal, but insight into reducing the risk of gonorrhea or chlamydial infection may help reduce the risk of sexually transmitted HIV infection. Because of the very low prevalence of HIV in our population, we did not include HIV seroconversion as an additional outcome measure.

High rates of attendance at intervention sessions and high rates of retention in the study, particularly for a population that may be difficult to follow, strengthen the generalizability of our results. However, generalization to other women at high risk, outside of the groups we studied, should be done cautiously. We attribute the efficacy of our intervention to the integration of behavior-change theory with extensive qualitative data collected in target communities. This approach allowed us to create culturally meaningful strategies to promote the recognition of risk and to stimulate motivation to effect personal change. Other critical elements included a focus on male-female relationships and health-seeking behavior.

Knowledge alone does not necessarily lead to changes in behavior; preventive strategies that focus on providing information have had minimal success.^{13,24,30-32} More successful interventions, tested in randomized, controlled trials, have had a theoretical basis and have promoted self-efficacy and communication skills, as well as skills in the use of condoms, through modeling and role play. These techniques have produced some changes in self-reported behavior, such as increases in the use of condoms.^{20-22,30,32-42} The number of sex partners appears to be more resistant to change.^{36,40} However, because most studies have not used clinical disease as an outcome variable, evaluation of preventive strategies has been difficult.

Infection is related to both behavior and exposure. Limited changes in behavior may fail to decrease the risk of infection, and the same behavior may yield different results in populations with low and high prevalence of the disease. Moreover, self-reported information about behavior may be biased. Consequently, it is possible to achieve changes in reported behavior without corresponding decreases in rates of infection.⁴³ A prospective cohort study of clients at a clinic for the treatment of sexually transmitted disease found that participants who reported that they always used condoms were as likely to become infected as those who said they never used them.⁴⁴ The National Institute of Mental Health Multisite Prevention Trial found significantly greater increases in condom use among men and women assigned to an intervention than among control subjects; however, chart review showed a reduction in the incidence of gonorrhea only for men.⁴² Boyer and colleagues²⁰ showed that the frequency of condom use increased among men who received the inter-

vention; their infection rates, however, were equivalent to those of control subjects.

In our study, sex with multiple partners, sex with an untreated or incompletely treated partner, and five or more acts of unprotected sex in two three-month periods contributed to infection and were affected by the intervention. These factors may affect the rates of infection more directly than increases in the frequency of condom use or decreases in the number of unprotected sexual acts. Changes in condom use may not be sufficient to affect infection rates because the effect probably depends on the context of exposure and may be offset by other factors. For example, persons choosing mutual monogamy as their primary risk-reduction strategy may not derive additional benefit from decreases in the number of unprotected acts because their exposure is already low; persons at higher risk may not derive benefit unless the absolute number of acts is minimal. Moreover, possible benefit may be offset by the pursuit of other high-risk behavior.⁴³ To gauge the usefulness of behavioral measures and the effect of various strategies for change, observation of clinical outcomes is critical.

The well-designed, randomized, controlled trial by Boyer et al.²⁰ of an intervention that was similar in content to ours and based on the same theoretical model found neither behavioral nor clinical differences between women who received the intervention and those who did not. An important difference in their design was the format of the intervention sessions, which were individual, not conducted in small groups. In addition, although their facilitators were sensitive to cultural differences and engaged participants in sex-specific skill-building scenarios, their intervention lacked culturally based preventive strategies derived from a knowledge of the target population, and it did not emphasize relationship issues.

Several studies have demonstrated effects of an intervention for men but not for women.^{20,45,46} Although both men and women face common barriers to behavioral change, such as misperceptions about risk and concern about poverty,²⁹ women must also confront power imbalances, unrealistic romantic ideals, and a need to minimize disruptions in their relationships.^{12-16,18,19,47} Interventions are more likely to be successful if they are culturally relevant and specifically address culturally defined aspects of the relationships between the sexes.^{12,14,29,47-51} Moreover, it has been suggested that women gain strength from interactions with others⁵²; discussing problematic relationships with other women may be particularly beneficial in increasing personal awareness and reinforcing resolve.^{12,14,52} Incarcerated women who did not receive training in communication skills but who participated in open discussions of issues related to sex roles and power spontaneously shared experienc-

es and personal approaches to communication, and in so doing they improved their communication skills as much as those who had explicit training.⁵³ We believe that the open discussions of relationship issues in our intervention contributed to bonding among the women, helped them confront their own situations, and encouraged empowerment and action.

Timeliness in treating sexually transmitted diseases and full compliance with treatment are also important. A population-based study in rural Tanzania indicated that improved management of cases of sexually transmitted diseases significantly reduced the incidence of HIV infection during a two-year follow-up.^{54,55} Although we focused on changing sexual behavior, our intervention also addressed health-seeking behavior, early recognition of symptoms, and prompt, complete treatment of both the patient and her partner (or partners). One type of behavior that contributed to reduced rates of infection was avoidance of sex with a partner who was untreated or treated incompletely.

Most studies of interventions have follow-up intervals of one to six months, and the effects of the intervention typically diminish substantially after several months.³⁵ However, in our study, reductions in the incidence of gonorrhea or chlamydial infection were larger at 12 months (49 percent) than at 6 months (34 percent). For some of the women, the effects of intervention may have been delayed. The interviews and examinations at six months could have "boosted" the effects of intervention, and it may have taken some women more time to disengage from high-risk partners and to discontinue high-risk behavior.

Interventions that reduce the risk of contracting a sexually transmitted disease such as gonorrhea or chlamydia may also prevent HIV infection. Heterosexual contact is the leading cause of AIDS in women,⁸ and persons with other sexually transmitted diseases have a risk of contracting HIV if exposed that is 3 to 50 times that of an uninfected person.^{2,55,56} This study shows that a culturally relevant behavioral intervention grounded in theory can reduce the frequency of gonorrhea and chlamydial infections for at least 12 months in minority women at high risk.

Supported by a grant (U01 AI31498) from the National Institute of Allergy and Infectious Diseases.

We are indebted to Alan E.C. Holden for assistance with the analysis of infection rates and behavioral outcomes, data editing, and overall statistical analysis; to Barbara Elizondo for assistance with data editing and statistical analysis; to Brooke Goodfriend for coordination of the behavioral project; to Carroll Brooks for past and continuing assistance with clinical issues related to this project; to the members of the Mexican-American and African-American communities who assisted with collection of ethnographic data and the design of the intervention; and to all the staff members at our research clinic and the clinic for sexually transmitted diseases of the San Antonio Metropolitan Health District who made this project possible.

REFERENCES

1. Donovan P. Testing positive: sexually transmitted disease and the public health response. New York: Alan Guttmacher Institute, 1993.
2. Eng TR, Butler WT, eds. The hidden epidemic: confronting sexually transmitted diseases. Washington, D.C.: National Academy Press, 1997.
3. Wasserheit JN, Holmes KK. Reproductive tract infections: challenges for international health policy, programs, and research. In: Germain A, Holmes KK, Piot P, Wasserheit JN, eds. Reproductive tract infections: global impact and priorities for women's reproductive health. New York: Plenum Press, 1992:7-33.
4. Aral SO, Wasserheit JN. Interactions among HIV, other sexually transmitted diseases, socioeconomic status, and poverty in women. In: O'Leary A, Jemmott LS, eds. Women at risk: issues in the primary prevention of AIDS. New York: Plenum Press, 1995:13-41.
5. Harlap S, Kost K, Forrest JD. Preventing pregnancy, protecting health: a new look at birth control choices in the United States. New York: Alan Guttmacher Institute, 1991.
6. Aral SO. Heterosexual transmission of HIV: the role of other sexually transmitted infections and behavior in its epidemiology, prevention and control. *Annu Rev Public Health* 1993;14:451-67.
7. Focus on women and HIV. *HIV/AIDS Prev* 1997;July:1-2.
8. Wortley PM, Fleming PL. AIDS in women in the United States: recent trends. *JAMA* 1997;278:911-6.
9. Centers for Disease Control and Prevention. HIV/AIDS Surveillance Report. 1996;8(2).
10. *Idem*. HIV/AIDS Surveillance Report. 1994;6(2).
11. Update: trends in AIDS incidence, death, and prevalence — United States, 1996. *MMWR Morb Mortal Wkly Rep* 1997;46:165-73.
12. Amaro H. Love, sex, and power: considering women's realities in HIV prevention. *Am Psychol* 1995;50:437-47.
13. Auerbach JD, Wypijewska C, Brodie HKH, eds. AIDS and behavior: an integrated approach. Washington, D.C.: National Academy Press, 1994.
14. Fullilove MT, Fullilove RE III, Haynes K, Gross S. Black women and AIDS prevention: a view towards understanding the gender rules. *J Sex Res* 1990;27:47-64.
15. Mays VM, Cochran SD. Issues in the perception of AIDS risk and risk reduction activities by black and Hispanic/Latina women. *Am Psychol* 1988;43:949-57.
16. Miller JB, Stiver IP. The healing connection: how women form relationships in therapy and in life. Boston: Beacon Press, 1997.
17. O'Leary A, Jemmott LS. General issues in the prevention of AIDS in women. In: O'Leary A, Jemmott LS, eds. Women at risk: issues in the primary prevention of AIDS. New York: Plenum Press, 1995:1-12.
18. Sobo EJ. Finance, romance, social support, and condom use among impoverished inner-city women. *Hum Organ* 1995;54:115-28.
19. Worth D. Sexual decision-making and AIDS: why condom promotion among vulnerable women is likely to fail. *Stud Fam Plann* 1989;20:297-307.
20. Boyer CB, Barrett DC, Peterman TA, Bolan G. Sexually transmitted disease (STD) and HIV risk in heterosexual adults attending a public STD clinic: evaluation of a randomized controlled behavioral risk-reduction intervention trial. *AIDS* 1997;11:359-67.
21. Kamb ML, Fishbein M, Douglas JM Jr, et al. Efficacy of risk-reduction counseling to prevent human immunodeficiency virus and sexually transmitted diseases: a randomized controlled trial. *JAMA* 1998;280:1161-7.
22. Orr DP, Langefeld CD, Katz BP, Caine VA. Behavioral intervention to increase condom use among high-risk female adolescents. *J Pediatr* 1996;128:288-95.
23. Catania JA, Coates TJ, Kegeles SM, Ekstrand M, Guydish JR, Bye LL. Implications of the AIDS risk-reduction model for the gay community: the importance of perceived sexual enjoyment and help-seeking behaviors. In: Mays VM, Albee GW, Schneider SE, eds. Primary prevention of AIDS: psychological approaches. Vol. 13 of Primary prevention of psychopathology. Newbury Park, Calif.: Sage, 1989:242-61.
24. Catania JA, Kegeles SM, Coates TJ. Towards an understanding of risk behavior: an AIDS risk reduction model (ARRM). *Health Educ Q* 1990;17:53-72.
25. Becker MH, Joseph JG. AIDS and behavioral change to reduce risk: a review. *Am J Public Health* 1988;78:394-410.
26. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. *Psychol Rev* 1977;84:191-215.
27. Fishbein M, Ajzen I. Belief, attitude, intention and behavior: an introduction to theory and research. Reading, Mass.: Addison-Wesley, 1975.
28. Rogers EM. Diffusion of innovations. New York: Free Press, 1983.
29. Ramos R, Shain RN, Johnson L. "Men I mess with don't have anything to do with AIDS": using ethno-theory to understand sexual risk perception. *Sociol Q* 1995;36:483-504.
30. DiClemente RJ, Wingood GM. A randomized controlled trial of an

- HIV sexual risk-reduction intervention for young African-American women. *JAMA* 1995;274:1271-6.
31. Morrison DM, Baker S, Gillmore MR. Sexual risk behavior, knowledge, and condom use among adolescents in juvenile detention. *J Youth Adolesc* 1994;23:271-88.
 32. St Lawrence JS, Brasfield TL, Jefferson KW, Alleyne E, O'Bannon RE III, Shirley A. Cognitive-behavioral intervention to reduce African American adolescents' risk for HIV infection. *J Consult Clin Psychol* 1995;63:221-37.
 33. Hobfoll SE, Jackson AP, Lavin J, Britton PJ, Shepherd JB. Reducing inner-city women's AIDS risk activities: a study of single, pregnant women. *Health Psychol* 1994;13:397-403.
 34. Jemmott JB III, Jemmott LS, Fong GT. Reductions in HIV risk-associated sexual behaviors among black male adolescents: effects of an AIDS prevention intervention. *Am J Public Health* 1992;82:372-7.
 35. Kalichman SC, Carey MP, Johnson BT. Prevention of sexually transmitted HIV infection: a meta-analytic review of the behavioral outcome literature. *Ann Behav Med* 1996;18:6-15.
 36. Kelly JA, Murphy DA, Washington CD, et al. The effects of HIV/AIDS intervention groups for high-risk women in urban clinics. *Am J Public Health* 1994;84:1918-22.
 37. Kelly JA, Kalichman SC. Increased attention to human sexuality can improve HIV/AIDS prevention efforts: key research issues and directions. *J Consult Clin Psychol* 1995;63:907-18.
 38. Oakley A, Fullerton D, Holland J. Behavioural interventions for HIV/AIDS prevention. *AIDS* 1995;9:479-86.
 39. Rotheram-Borus MJ, Koopman C, Haignere C, Davies M. Reducing HIV sexual risk behaviors among runaway adolescents. *JAMA* 1991;266:1237-41.
 40. Schilling RF, el-Bassel N, Schinke SP, Gordon K, Nichols S. Building skills of recovering women drug users to reduce heterosexual AIDS transmission. *Public Health Rep* 1991;106:297-304.
 41. Valdiserri RO, Lyter DW, Leviton LC, Callahan CM, Kingsley LA, Rinaldo CR. AIDS prevention in homosexual and bisexual men: results of a randomized trial evaluating two risk reduction interventions. *AIDS* 1989;3:21-6.
 42. The National Institute of Mental Health (NIMH) Multisite HIV Prevention Trial Group. The NIMH Multisite HIV Prevention Trial: reducing HIV sexual risk behavior. *Science* 1998;280:1889-94.
 43. Aral SO, Peterman TA. Measuring outcomes of behavioural interventions for STD/HIV prevention. *Int J STD AIDS* 1996;7:Suppl 2:30-8.
 44. Zenilman JM, Weisman CS, Rompalo AM, et al. Condom use to prevent incident STDs: the validity of self-reported condom use. *Sex Transm Dis* 1995;22:15-21.
 45. Cohen DA, MacKinnon DP, Dent C, Mason HR, Sullivan E. Group counseling at STD clinics to promote use of condoms. *Public Health Rep* 1992;107:727-31.
 46. O'Leary A, Jemmott LS, Goodhart F, Gebelt J. Effects of an institutional AIDS prevention intervention: moderation by gender. *AIDS Educ Prev* 1996;8:516-28.
 47. Weeks MR, Schensul JJ, Williams SS, Singer M, Grier M. AIDS prevention for African-American and Latina women: building culturally and gender-appropriate intervention. *AIDS Educ Prev* 1995;7:251-64.
 48. Deren S, Shedlin M, Beardsley M. HIV-related concerns and behaviors among Hispanic women. *AIDS Educ Prev* 1996;8:335-42.
 49. Kline A, Kline E, Oken E. Minority women and sexual choice in the age of AIDS. *Soc Sci Med* 1992;34:447-57.
 50. Newman LF, Zierler S, Cheung D. Epidemiological and ethnographic methods for research in high-risk behavior: integrated approaches to acceptability and intervention. In: Wasserheit JN, Aral SO, Holmes KK, Hitchcock PJ, eds. *Research issues in human behavior and sexually transmitted diseases in the AIDS era*. Washington, D.C.: American Society for Microbiology, 1991:258-66.
 51. Nyamathi A, Shin DM. Designing a culturally sensitive AIDS education program for black and Hispanic women of childbearing age. *NAACOGS Clin Issues Perinat Womens Health Nurs* 1990;1:86-98.
 52. Surrey JL. Relationship and empowerment. In: Jordan JV, Kaplan AG, Miller JB, Stiver IP, Surrey JL, eds. *Women's growth in connection: writings from the Stone Center*. New York: Guilford Press, 1991:162-80.
 53. St Lawrence JS, Eldridge GD, Shelby MC, Little CE, Brasfield TL, O'Bannon RE III. HIV risk reduction for incarcerated women: a comparison of brief interventions based on two theoretical models. *J Consult Clin Psychol* 1997;65:504-9.
 54. Grosskurth H, Mosha F, Todd J, et al. Impact of improved treatment of sexually transmitted diseases on HIV infection in rural Tanzania: randomised controlled trial. *Lancet* 1995;346:530-6.
 55. St Louis ME, Wasserheit JN, Gayle HD. Janus considers the HIV pandemic — harnessing recent advances to enhance AIDS prevention. *Am J Public Health* 1997;87:10-2.
 56. Wasserheit JN. Epidemiology synergy: interrelationships between human immunodeficiency virus infection and other sexually transmitted diseases. *Sex Transm Dis* 1992;19:61-77.