A Brief Sexual Barrier Intervention for Women Living with AIDS: Acceptability, Use, and Ethnicity

Deborah L. Jones, Stephen M. Weiss, Robert Malow,
Mary Ishii, Jessy Devieux, Heidi Stanley, Andrea Cassells,
Jonathan N. Tobin, Elizabeth Brondolo, Arthur LaPerriere,
Jonell Efantis-Potter, Mary Jo O'Sullivan, and
Neil Schneiderman

ABSTRACT *Interventions aimed at reducing sexual transmission of human immunodeficiency virus/sexually transmitted diseases (HIV/STDs) have focused primarily on male condom use among seronegative men and women. However, female-controlled sexual barriers (female condoms and vaginal microbicides) offer women living with acquired immunodeficiency syndrome (AIDS) alternative methods to protect themselves and others from disease transmission. A pilot behavioral intervention was conducted to increase sexual barrier use and enhance and assess factors related to acceptability. Participants (N = 178) were drawn from the Stress Management and Relaxation Training with Expressive Supportive Therapy (SMART/EST) Women's Project, a multisite phase III clinical trial for women living with AIDS (Miami, FL; New York City, NY; Newark, NJ). Intervention participants (n = 89) were matched for age and ethnicity with control condition participants (n = 89). Women were African American (52%), Haitian (15%), Hispanic (19%), Caucasian (10%), and other ethnicities (4%). The intervention condition received barrier products (male and female condoms and spermicides based on nonoxynol-9 in the form of vaginal gel, film, and suppositories) during three sessions held over 3 months. Data on barrier use and acceptability were analyzed at baseline and 3 and 9 months postintervention. Use of N-9 spermicides on a trial basis increased significantly by 3 months in the intervention conditions (22%–51%, $P < .05$). Cultural differences in acceptability were greatest between Haitian women and women in other ethnic groups. Exposure to this pilot behavioral intervention was associated with increased acceptability and use of chemical barriers without decreased use of male condoms.*

KEYWORDS *Acceptability, Ethnicity, HIV/AIDS, Sexual barriers, Women.*

Drs. Jones, Weiss, Ishii, Devieux, Stanley, O'Sullivan, and Schneiderman and Ms. Efantis-Potter are from the University of Miami School of Medicine, Miami, Florida; Drs. Malow and LaPerriere are with the University of Miami, Miami, Florida; Ms. Cassells and Drs. Tobin and Brondolo are with the Clinical Director's Network, New York, New York; Dr. Tobin is with the Department of Epidemiology and Social Medicine, Albert Einstein College of Medicine, New York, New York; Dr. Brondolo is with the Department of Psychology, St. John's University, New York, New York; and Dr. Jones is with Barry University, Miami Shores, Florida.

Correspondence and reprints: Deborah Jones, SMART/EST Women's Project, Department of Psychiatry and Behavioral Sciences, University of Miami School of Medicine, Dominion Tower, 1400 NW 10th Avenue, Suite 404 (D-21), Miami, FL 33136. (E-mail: dljones@mail.barry.edu)

INTRODUCTION

Reduction of unprotected sexual activity prevents the transmission of human immunodeficiency virus (HIV) to the uninfected, as well as HIV reinfection among HIV-positive individuals. As a group, women have sustained the largest increases in rates of new HIV infections and diagnoses of acquired immunodeficiency syndrome (AIDS) of all at-risk populations in the US, and minority women are disproportionately represented among HIV/AIDS cases.¹ The rapid increase in heterosexual transmission, since 1995 the primary mode of infection among women,^{1,2} highlights the importance of effective interventions that reduce sexual risk behavior, particularly among minority women who are HIV positive. Most minority women living with HIV/AIDS are poor, between the ages of 18 and 40 years, and at significant risk of exposure to other treatable sexually transmitted diseases (STDs).^{2,3} STDs are associated with increased risk for HIV infection or reinfection,^{4,5} increased HIV viral load,^{2,3} pelvic inflammatory disease, ectopic pregnancy, or chronic pelvic pain.^{2,6,7} In addition, for women living with HIV, bacterial vaginosis infection increases the risk of STD infection and the transmission of HIV from pregnant women to infants.²

At the onset of the HIV/AIDS pandemic, safer sex interventions designed to restrict transmission of HIV and other STDs primarily relied on promoting abstinence or increasing condom use by the uninfected. Later approaches included hierarchical interventions (e.g., New York State Department of Health AIDS Institute's Hierarchical Method of Prevention),⁸⁻¹¹ which presented a ranking of sexual protection methods from the safest, male and female condoms, to the most risky, spermicides based on nonoxynol-9. Most evaluations of hierarchical approaches have found that male condom use continues, and the overall proportional rates of protected sex acts was significantly increased following intervention.¹⁰⁻¹² However, most hierarchical interventions have not evaluated these findings beyond 6 months.

Many women living with HIV continue to practice HIV-risky sexual behavior,^{12,13} often associated with relationship status, poverty, emotional status, substance abuse, and personality factors.¹³⁻¹⁶ Among HIV-positive people, risk behavior may also be influenced by the perception of lessened infectivity due to medication and reduced viral load.¹⁴ Results from prevention studies have emphasized the importance of tailoring interventions to address the needs, beliefs, and values of specific target populations,^{17,18} such as HIV-positive women.² HIV-positive women have generally been neglected in social science intervention research in comparison to other populations. Yet, interventions targeting HIV-positive women contribute to both primary and secondary prevention by providing strategies for reduction of transmission and prevention of HIV reinfection and other STD infections, respectively.

Acceptability studies have assessed women's preferences regarding specific characteristics of female-controlled chemical barrier products (microbicides)^{19,20} in anticipation of the eventual availability of a safe and effective vaginally applied method of protection against HIV/STD transmission. Research suggests that use of chemical barriers is better predicted by knowledge of appropriate use, rather than fear of HIV/AIDS transmission risk, and that exposure to such products is essential to effecting behavior change.¹⁵ Despite the ready availability of N-9-based spermicides (marketed as a spermicidal contraceptive), little information exists on the acceptability of such products among seropositive women. This may be due, in part, to the circumstances of use of some forms of N-9, which has been associated with

vaginal irritation²² and lesion-based HIV shedding,²³ either of which may increase risk of STD/HIV transmission.

This pilot study tested a culturally sensitive physical and chemical sexual barrier intervention designed to assess the acceptability following use of potential adjuncts or, for some women, alternatives to male and female condoms in the form of N-9 spermicidal barriers. We hoped to identify what prevented, as well as promoted, future willingness to use sexual barriers among HIV-positive women and the role of cultural considerations as impediments to use.

METHODS

Recruitment and Eligibility

Participants in the pilot sexual behavioral intervention were drawn from the SMART/EST Women's Project, a multisite phase III clinical trial; internal review board approval was obtained prior to the onset of the study. From 1997 to 1999, the SMART/EST Women's Project recruited from three major epicenters in the US for women living with HIV/AIDS: Miami-Dade County, Florida; New York City; and the New Jersey metropolitan area. Study candidates were drawn primarily from hospitals and community health centers/agencies and via participant referrals. SMART/EST Women participants ($n = 465$) were 18 years of age or older and met the Centers for Disease Control and Prevention (CDC) guidelines for case-defined AIDS (i.e., CD4 cell count below $200/\text{mm}^3$ and/or one opportunistic infection).¹ The pilot sexual barrier intervention was introduced in the SMART/EST Women's Project in mid-1998. Following its introduction, 89 of the women were enrolled in the pilot intervention, and these women were matched with 89 women previously enrolled in the control arm of the SMART/EST Project (intervention condition = 89, control condition = 89).

Interested candidates were initially screened by telephone to determine potential eligibility (see the Figure). Candidates who were deemed eligible (age ≥ 18 years and clinical AIDS diagnosis as described above) completed an informed consent form and were assessed with the Mini-Mental State Exam,²⁴ the HIV Dementia Scale,²⁵ the Structured Clinical Interview for DSM-III-R, Nonpatient Version for HIV Studies (SCID-NP-HIV),²⁶ and the Karnofsky ADL Scale²⁷ (score > 60 , able to provide self-care) to confirm eligibility for the SMART/EST Project. Participants then completed psychosocial questionnaires.

Participants completed a sexual barrier intervention baseline assessment. All control condition participants were enrolled prior to the onset of the sexual barrier intervention and completed three monthly control condition discussion sessions. All sexual barrier intervention participants completed three monthly intervention condition sessions over 3 months. Participants were followed over a 12-month period (baseline assessment, 3- and 9-month postintervention follow-up). All participants received monetary compensation for their time and travel expenses. Study assessors and investigators were blind to participant condition assignment and did not participate in provision of the intervention. Participants were asked not to reveal their condition assignment to assessors.

Due to the provision of vaginal products, all intervention participants were screened for STDs and vaginal abnormalities prior to receiving N-9 spermicides. If contraindications for N-9 use (discharge, burning, itching, or lesions) were identi-

FIGURE. Barrier acceptability among women living with HIV/AIDS.

fied, participants received product information, but were only provided with male and female condoms. Women referred for treatment and cleared for use were then provided with N-9 spermicides. Women were notified of their STD results, were advised as to appropriate treatment, and were referred for follow-up. Barrier intervention participants were matched with previously enrolled non-barrier intervention participants on age and/or ethnicity ($n = 89$, see the Figure; $N = 178$ participants in all).

Sexual Barrier Intervention

The sexual barrier intervention was manualized and developed with feedback from previous pilot participants. Facilitators were psychologists trained in the administration of the intervention. Each of the 120-minute sessions provided an opportunity for practice, feedback, and reinforcement in a supportive environment.^{12,28-30} Sessions addressed HIV/STD transmission, hierarchical counseling, and skill training to facilitate product use. Discussion focused on reactions to barriers, cognitive reframing, and sexual negotiation.

Information was presented through multiple modalities (i.e., written handouts, videos, hands-on experience). The intervention and accompanying videos were developed in English, Spanish, and Creole languages and culturally tailored to each audience (African American, Hispanic, Haitian); all sessions were held in English, Spanish, and Creole by linguistically matched facilitators. Videos were created specifically for HIV-positive women and illustrated the correct methods of barrier use and discussed answers to commonly asked questions.

After each session, participants were provided with large 1-month supplies of male and female condoms (sessions 1–3) and N-9 spermicidal products (sessions 2 and 3). Participants were strongly encouraged to use the N-9 products in conjunction with condoms.

Participants in the control condition participated in discussion sessions and/or viewed a brief stress management educational video, followed by an entertainment film. Intervention and control sessions were identical in length, 120 minutes, and were also held in English, Spanish, and Creole by linguistically matched facilitators.

Outcome Measures

All measures were administered at baseline, 3 months, and 9 months.

Sexual risk behavior was measured using a 60-item scale adapted from the Sexual Risk Behavior Assessment Schedule (SERBAS).^{31,32} The SERBAS-A structured interview measures frequency of sexual behavior and protection used in the past 3 months with primary (most frequent sexual relations) and nonprimary partners. Frequency was identified as all the time or 9 times out of 10, most times or 7 times out of 10, half the time or 5 times out of 10, sometimes or 3 times out of 10, or never. The measure identified the percentage of women sexually active, number of sexual partners, and percentage of women never using condoms (male and/or female combined).

Barrier acceptability was measured with an adaptation of the Barrier Questionnaire.³³ Participants rated current and previous use of, and willingness to use, sexual barriers using a Likert-type scale (with use identified as never used, like very much, like somewhat, neutral, dislike somewhat, strongly dislike; willingness to use identified as not at all willing to use, slightly willing, moderately willing, very willing). Stem prompts were adapted to willingness “to use” products. The measure identified the percentage of women (1) currently using barriers, (2) having previously used spermicides, (3) rating acceptability after use (combined “liked very much” + “liked somewhat,” combined “disliked somewhat” + “disliked very much”), and (4) willingness to use (combined “moderately willing” + “very willing to use,” combined “not at all willing” + “slightly willing to use”).

Gynecological/Sexually Transmitted Disease Assessment

The gynecological assessment was derived from the gynecological examination protocol for phase II microbicide testing recommended by the International Working Group on Vaginal Microbicides,³⁴ and included 10 domains of vaginal abnormality and previous STD history. The assessment identified the percentage of intervention participants with vaginal lesions, irritation or other contraindications (e.g., discharge, burning, itching) for the use of N-9 spermicides, and STDs. Participants were tested for STDs (chlamydia, gonorrhea, and trichomoniasis) using biological specimens.

Statistical Analyses

This study used a repeated-measures design with condition (sexual barrier intervention, control) as the between-subject factor and time (baseline and 3 and 9 months postintervention) as the within-subject factor. Participants were matched as to age and ethnicity. All comparisons ($N = 178$) used an α (two tailed) of .05.

RESULTS

Participant Characteristics

The mean age of sample participants ($N = 178$) was 36 years; most women (81%) were unemployed. The majority (52%) were African American; 18% were Hispanic, 15% were from the Caribbean, 10% were Caucasian, and 5% were of other ethnic backgrounds, including Native American and Pacific Islander. There were 68% who reported having completed the 12th grade, and 21% lived with their partner or spouse. Half had previous histories of drug (50%) and/or alcohol dependence (29%). There were no significant differences in education or employment status between intervention and control condition participants.

Baseline

Most women were sexually active and often practiced unprotected sex; there were no significant differences between conditions. Of all participants, 68% (121) had been sexually active in the last 3 months, 9% (16) with two or more sexual partners. Of those sexually active, 33% (59) reported never using condoms. Almost half of the intervention condition (43%) had a history of one or more STDs; the baseline frequency of STDs was 0%. Of those in the intervention condition, 28% (25) were identified as having abnormal vaginal presentations and were referred for treatment prior to N-9 use.

Previous Use and Willingness to Use at Baseline

One third of all participants (32%) had previously tried using chemical sexual barriers (Table 1). The greatest baseline differences between ethnic groups were found between Haitian women and other ethnic groups (Table 2).

Three Months Postintervention

At 3 months postintervention, both groups increased their percentage of protected sex acts using a male condom (intervention 40%, $P < .001$; control 34%, $P < .01$) when compounded with baseline. Use of N-9 spermicides was significantly higher among women in the intervention condition ($\chi^2 = 5.04$, $P < .05$; baseline 22%, 3 months postintervention 51%), while male condom use did not diminish. Trial basis use (percentage of women who tried product) of vaginal contraceptive film was significantly higher in the intervention condition (40%) than the control condition (11%; $\chi^2 = 7.47$, $P < .05$). Women in the control group did not increase trial basis use or willingness to use with regard to N-9 spermicides or female condoms.

Acceptability ratings did not change in either intervention or control conditions (Table 3). Willingness to use products with specific characteristics increased from baseline in the intervention condition (timing of product use, $c2 = 5.49$, $P < .05$; baseline = moderately to very willing to wait 20 minutes before having sex, 27%, 3 months, 40%, 9 months, 46%) (Table 4). Willingness to use wet products decreased in the intervention condition ($\chi^2 = 12.78$, $P < .05$; baseline 35%, 3 months 31%). Willingness to use a product without a partner's knowledge increased in the intervention condition over time, while the control condition decreased (moderately to very willing, $\chi^2 = 16.17$, $P < .001$; baseline, intervention 44%, control 48%, $\chi^2 = 8.76$, $P < .01$; 3 months postintervention 54%, control 42%).

TABLE 1. Percentage of women having previously used sexual barrier products by ethnic group at baseline, intervention and control conditions combined

Previous product use	Percentage of entire sample (N = 178)	Percentage of African Americans (N = 92)	Percentage of Hispanics (N = 33)	Percentage of Haitians (N = 27)	Percentage of Caucasians (N = 17)
Any vaginal chemical products	32	37	42	0	50
Male condoms	99	100	100	94	100
Rating of male condoms		Liked = 90	Liked = 62	Liked = 65	Liked = 75
Female condoms	29	29	40	6	50
Rating of female condoms		Liked = 14	Liked = 40	Liked = 5	Liked = 25
Gels	25	32	30	0	25
Rating of gels		Liked = 26	Liked = 20	No previous use	Liked = 13
Suppositories	14	10	40	0	20
Rating of suppositories		Liked = 4	Liked = 20	No previous use	Liked = 0
Films	8	6	30	0	0
Rating of Films		Liked = 4	Liked = 10	No previous use	Liked = 13

Trial Use, Nine Months Postintervention, Intervention Versus Control

At 9 months postintervention, trial basis use of N-9 spermicides (presented in Table 3) was significantly higher by participants in the intervention group than by those in the control group (suppositories, $\chi^2 = 11.73$, $P < .05$; intervention 83%, control 9%; film, $\chi^2 = 8.25$, $P < .05$; intervention 55%, control 0%), with no change in male condom use. Willingness to use products without partner knowledge increased in the intervention condition (moderately to very willing to use, $\chi^2 = 7.64$, $P < .01$; baseline 44%, 9 months postintervention 62%). Participant ratings of products following exposure did not change across time in either intervention or control condition (Table 4).

DISCUSSION

Overall response to this intervention was favorable. We found trial basis use of N-9 spermicides increased for those participating in the sexual barrier intervention without resulting in a decrease in condom use. These results support existing behavioral intervention research involving sexual education, including sexual negotiation skills,³⁵ female-controlled methods,^{12,36,37} and hierarchical counseling.^{10,11,38} Anecdotal reports during the intervention indicated increased awareness of the importance of safer sex in their sexual relationships following the intervention, and additional condoms and N-9 spermicides were generally requested at the final session.

Although trial basis use of N-9 spermicides did not result in a more favorable evaluation of specific products, participants in the intervention increased their will-

TABLE 2. Percentage of women willing to use sexual barrier products by ethnic group at baseline, intervention and control conditions combined

	Entire sample (N = 178), %	African American (n = 92), %	Hispanic (n = 33), %	Haitian (n = 27), %	Caucasian (n = 17), %
Type of product					
Male condoms	86	92	83	74	88
Female condoms	49	56	58	39	25
Gel	39	39	50	44	13
Suppositories	27	21	42	35	25
Film	22	19	33	26	13
Product type					
No smell	63	69	75	61	63
No taste	57	62	58	44	63
A range of flavors	63	77*	58	35†	63
Requiring insertion just before sex	50	60	58	26	38
Inserted 4 hours prior to sex	49	62	58	30†	38
Requiring 20 minutes before sex	22	23	17	26	13
Products that					
Make sex wet	34	39	42	22	25
Make sex dry	16	8	17	35*	13
Are used without partner knowledge	46	46	42	52	38
Prevent HIV trans- mission	90	98	92	74†	88
Prevent HIV/STDs without a condom	88	89	92	83	100
Allow pregnancy but prevent HIV/STDs	34	65	42	70	75*

*Significantly higher, $P < .05$.†Significantly lower, $P < .05$.

ingness to use products with characteristics common to N-9 spermicides. The increasing trend noted in the evaluations of trial basis use suggests that results may be limited by the number of women using specific products. As in previous research, participants increased their use of chemical barrier products.^{39,40} These results suggest expressed willingness to use specific barrier products may not be associated with participants' product ratings.

Results demonstrate that ethnic preferences and exposure must be considered in the marketing and dissemination of microbicides. The necessity for an effective and acceptable vaginal chemical barrier method has highlighted the relative lack of information on acceptability among diverse populations. Product acceptability differed among ethnicities along several dimensions, including delivery systems and product characteristics. These diverse preferences can inform the development of microbicides.

Finally, although participants were not supplied with additional products after

TABLE 3. Acceptability ratings and use during study on a trial basis: by time points, intervention and control conditions

	Intervention condition tried using product, %			Control condition tried using product, %		
	Baseline (N = 89)	3 months (n = 36)	9 months (n = 11)	Baseline (N = 89)	3 months (n = 35)	9 months (n = 13)
Male condom use	98	100	100	100	100	100
Rating of male condoms	Liked = 76	Liked = 86	Liked = 92	Liked = 82	Liked = 81	Liked = 82
Female condom use	19	57	55	35	53	55
Rating of female condoms	Liked = 9	Liked = 34	Liked = 46	Liked = 21	Liked = 36	Liked = 46
N-9 spermicide trial basis use	22	51*	69	40	34	36
Gel trial basis use	16	49	82*	33	31	36
Rating of gels	Liked = 9	Liked = 37	Liked = 46	Liked = 27	Liked = 17	Liked = 37
Suppository trial basis use	12	40	82†	17	17	9
Rating of Suppositories	Liked = 0	Liked = 26	Liked = 46	Liked = 8	Liked = 11	Liked = 9
Film trial basis use	5	40*	55*	10	11	0
Rating of films	Liked = 5	Liked = 29	Liked = 46	Liked = 4	Liked = 11	Liked = 0

*Significant increase from preceding time point, $P < .05$.†Significant increase from preceding time point, $P < .01$.

the completion of the intervention, results suggest that use of female-controlled products continued to increase through 9 months postintervention, as did the acceptability of products that can be used without partner knowledge. Increasing acceptability may have been due to ready access to N-9 spermicides in the community or continued, rather than trial basis, use of products previously supplied.

The primary limitation of this study was its small sample size, which was com-

TABLE 4. Future willingness to use products tried during study on trial basis, all time points, intervention and control conditions

	Percentage of intervention condition participants willing to use in future			Percentage of control condition participants willing to use in future		
	Baseline (N = 89)	3 months (n = 36)	9 months (n = 11)	Baseline (n = 89)	3 months (n = 35)	9 months (n = 13)
Male condoms	78	80	77	94	90	91
Female condoms	47	40	46	52	56	64
Gels	44	51	62	34	31	37
Suppositories	27	37	39	28	22	18
Films	27	43	54	18	25	27

pounded by several additional factors. Approximately one third of those in the study were not currently sexually active, and one fifth of intervention participants were temporarily restricted from N-9 use due to vaginal abnormalities, common in HIV-positive women.² Both factors served to reduce the number of women who used N-9 spermicidal products. In addition, the temporary exclusion of women dependent on substance use may limit the generalizability of the study results given the frequency of HIV-positive women with a history of substance abuse. The use of professional facilitators rather than peer counselors may also limit the generalizability of the study to other settings or populations. Finally, results suggest the expressed willingness to use products and the exposure to products influence actual use; however, sample size restricted predictive analyses relating willingness to use and actual use and exposure to and actual use of N-9 spermicides.

Prevention of HIV sexual transmission does not occur in a vacuum.^{41,42} For women whose partners refuse to use condoms, over-the-counter microbicidal sexual barriers are long overdue and clearly represent an acceptable alternative method of protection. Female-controlled methods of protection allow HIV-positive women to limit transmission to others while ensuring their own protection, an idea whose time has finally come.

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