

Human Immunodeficiency Virus Sexual Risk Reduction in Homeless Men With Mental Illness

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Background: The spread of human immunodeficiency virus infection to impaired groups has intensified the challenge for its prevention; control of the epidemic now requires behavioral change among persons with limited ability to sustain attention and learn. In this randomized clinical trial, we tested an intervention to reduce sexual risk behaviors among homeless men with severe mental illness.

Methods: Men were recruited from a psychiatric program in a homeless shelter. Of 116 eligible men, 97 (83.6%) participated. Most were African American and had a chronic psychotic disorder and a comorbid substance use disorder. Participants were assigned to a 15-session experimental group intervention or to a 2-session control intervention and observed for 18 months. The 59 participants sexually active before the trial were the main target of the intervention. Sexual risk behavior was the primary outcome.

Results: Among the 59 sexually active men, follow-up data were obtained on 59 (100%) for the initial 6-month follow-up and on 56 (95%) for the remainder of the 18-month follow-up. The mean score on a sexual risk index for the experimental group was 3 times lower than for the control group (1.0 vs 3.1; $P=.01$) during the initial 6-month follow-up and 2 times lower during the remainder of the 18-month follow-up.

Conclusions: This intervention successfully reduced sexual risk behaviors of homeless men with mental illness. The effect diminished over 18 months but did not disappear. Similar approaches may be effective in other impaired high-risk groups.

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IN THIS randomized clinical trial, we tested an intervention to reduce sexual risk behaviors in a group with a high prevalence of human immunodeficiency virus (HIV) infection: homeless men with mental illness. Despite important advances in the understanding and the treatment of HIV infection, behavioral change still holds the greatest promise of containing the epidemic.¹⁻³ Yet, sexual practices in particular have proved difficult to modify.^{4,5}

Preventive interventions have demonstrated promise among high-risk but normally functioning populations, such as African American women, adolescents, and homosexual men.⁶⁻¹⁴ These have most commonly been cognitive-behavioral interventions based on social learning theory.¹⁵⁻¹⁹ For the intervention in the present study, we adapted this approach for a high-risk group in which psychiatric disorders, cognitive deficits, and substance abuse often interfere with the learning of new behaviors.²⁰⁻²²

Our intervention was also adapted for the marginal setting of a men's shelter. In

previous studies of mentally ill men at this shelter, we documented an HIV seroprevalence of 19%.²⁰ The data suggested that unsafe sexual practices were likely to be the main route for future infection and transmission, and the outcome measures for this study were designed to indicate the risk of transmission in both directions.^{23,24}

To assess the effectiveness of the intervention—titled “Sex, Games, and Videotapes” (SexG)^{25,26}—we carried out a randomized clinical trial with an 18-month follow-up, comparing the treatment group with a control group. Sexual risk behavior was the primary outcome. This analysis aimed to (1) test whether the intervention successfully reduced sexual risk behaviors during the initial 6-month follow-up; (2) identify the specific behaviors that were affected; (3) describe the maintenance of behavioral change during the remainder of the 18-month follow-up; and (4) detect any adverse effects associated with the use of the intervention, such as the stimulation of sexual risk behavior among sexually nonactive men.

SUBJECTS AND METHODS

The men for this study were recruited from a psychiatric outreach program in a 200-bed municipal men's shelter in New York, NY.^{27,28} The men were enrolled into the clinical trial in groups of 10 to 20 over 7 successive recruitment periods. During the recruitment periods, 139 men attended the outreach program, but 23 were ineligible for the trial (ie, too disturbed to give informed consent). Among the 116 eligible men, 3 refused participation and 16 left the shelter before being assigned to an intervention group. The remaining 97 (83.6%) chose to participate. These study procedures were approved by the Institutional Review Board of the New York State Psychiatric Institute.

The men were randomly assigned to either the SexG or control intervention. Intervention group assignments were placed in sealed envelopes that were randomly ordered; an envelope was assigned to each man as he completed baseline assessments. (Randomization did not yield precisely equal numbers in the 2 groups.) We randomly assigned 52 eligible men to the SexG intervention and 45 to the control intervention. The HIV status of the men was unknown.

The 97 participants included 59 sexually active men, 33 in the SexG intervention group and 26 in the control group. The term "sexually active" was operationally defined as having had anal, vaginal, or oral sex during the 6 months before the trial. The exercises in the curriculum were designed specifically for these men, who could relate them directly to their recent or ongoing sexual experience and could rehearse safer behaviors outside the group sessions. Nonetheless, the 38 sexually nonactive men were retained in the trial, enabling us to examine whether the experimental intervention might unintentionally stimulate sexual risk behavior.

EXPERIMENTAL INTERVENTION

The SexG intervention, described in detail elsewhere,^{25,26} focuses mainly on reducing the frequency of unprotected penile-anal and penile-vaginal sexual intercourse with casual and occasional partners. Incorporating lessons from a decade of clinical experience, ethnographic research,^{29,30} and the suggestions of the men themselves,³¹ we designed an interactive and entertaining intervention based on familiar activities in which the men could excel: storytelling, competitive games, and acting scenes from their daily lives. We identified small but key changes in behavior that could enable the men to reduce the incidence of

unprotected sex, without attempting a more fundamental change in the men's sexual lives. The social, physical, and decision-making skills necessary for consistent condom use were modeled, practiced, videotaped, and practiced again after feedback was given. "True to life" scenarios were used: sexual encounters in parks, shelters, and movie theaters.

The SexG intervention comprised 15 sessions administered 2 days per week over an 8-week period (**Table 1**). Redundancy was built into the curriculum so that men who missed a session were likely to be exposed to similar material in subsequent sessions. The curriculum was standardized in a manual³² that specified the rationale, objectives, and procedures for each session. The cofacilitators—a mental health professional and a paraprofessional—followed the protocol in the manual, and adherence was monitored by a review of videotapes of each session.

Attendance was excellent. Among the 33 sexually active men assigned to receive the SexG intervention, only 6 men (18%) missed more than 3 consecutive sessions. Twenty men (61%) attended 12 or more of the 15 sessions. For the 19 sexually nonactive men assigned to the SexG intervention, attendance was similarly high, with 14 (74%) attending 12 or more sessions.

CONTROL INTERVENTION

The control group attended a 2-session intervention, also specified in a manual. In these sessions, the facilitators taught about HIV infection and other sexually transmitted diseases and gave basic instruction in condom use. All men participated in at least 1 of the 2 sessions; most (69%) participated in both.

DEFINITION OF PRIMARY OUTCOME: VEE SCORE

We used a previously described weighting scheme called the Vaginal Episode Equivalent (VEE) sexual risk index^{33,34} as the primary outcome. Based on extensive epidemiological data on transmission risk, this index assigned a greater weight to anal than vaginal sex and allowed for some contribution of oral sex.³⁵⁻⁴⁰ Two VEE points were assigned for each unprotected anal episode, 1 point for each unprotected vaginal episode, and 0.1 of 1 point for each unprotected oral episode.

To compute a man's VEE score, we simply added his VEE points for various types of unprotected sex, including anal, vaginal, and insertive oral sex with women and insertive and receptive anal and oral sex with men. The VEE scores for sex with casual and occasional partners are best computed separately from those for sex with regular partners.³³

Continued on next page

RESULTS

There were no significant differences in the background characteristics of the group receiving the SexG intervention and the control group (**Table 2**). The 2 groups were also similar with respect to the numbers and types of sexual partners in the 6 months before baseline (**Table 3**), having unprotected sex in the 6 months before baseline (SexG, 82%; control, 81%), and lifetime history of a diagnosed sexually transmitted disease (SexG, 39%; control, 33%). For the 59 sexually active men, follow-up data

were collected on all (100%) for the initial 6 months and on 56 (95%) for the entire 18-month follow-up.

6-MONTH FOLLOW-UP: DISTRIBUTION OF VEE SCORES

We used 4 categories to describe the distribution of the individual men's VEE scores with casual and occasional partners: 0, 1 to 5, 6 to 10, and more than 10 (**Table 4**). The distribution was markedly nonnormal, with most men having a score of 0. The median VEE score was 0.1 in

This analysis was restricted to sex with casual and occasional partners—the vast majority of partners for these men.

A more complex weighting scheme might differentiate the risk of transmission from the risk of contracting HIV infection. This would entail, for instance, assigning a different weight to receptive than insertive anal sex.^{35,39} This was not appropriate for our intervention, however, because it was designed to prevent both transmission and contraction among participants of unknown HIV status.

ASSESSMENTS

Before randomization, the men were administered a baseline assessment that included the Personal History Interview for demographic characteristics and history of sexually transmitted diseases, the Structured Clinical Interview for the DSM-III-R [*Diagnostic and Statistical Manual of Mental Disorders, Third Edition, Revised*] (SCID)⁴¹ for psychiatric and substance use diagnoses, and the Sexual Risk Behavior Assessment Schedule (SERBAS)—Adult Armory Version for an overview of sexual behavior during the 6 months before the study.⁴² The SCID and the SERBAS were previously tested for reliability in this population (N.S.; Paul Colson, PhD; E.S.; unpublished data, 1997).^{23,43,44}

The SCID interviewers were clinically experienced mental health professionals formally trained in psychiatric diagnosis by the authors of the SCID. The SERBAS interviewers were trained and supervised using the protocol of the authors of the SERBAS. This training included didactic sessions, supervisory feedback on audiotaped practice interviews, and ongoing supervisory feedback on audiotaped study interviews (Heino F. L. Meyer-Bahlburg, DrRerNat; Rhonda S. Gruen, MA; unpublished data, 1992).

Outcome assessments were administered every 6 weeks for about 18 months (12 follow-up assessments over 72 weeks). Using the Vaginal Episode Equivalent—Assessment for Men,⁴⁵ a semistructured interview adapted from the SERBAS, the interviewers elicited a description of each sexual episode during the follow-up as required to compute the VEE score. These interviewers were unaware of the group assignment of the men.

DATA ANALYSIS

We adopted an orthodox approach to the analysis of clinical trial data. Thus, an intention-to-treat analysis⁴⁶ was used; the 3 men unavailable for follow-up (all after 6 months) were assigned the average outcome for the sample after they dropped out of the study. The main effects were demonstrated in bivariate comparisons, that is, without

adjustment for covariates. In further analyses, adjustment did not change these findings (results available from E.S.).

First, the SexG intervention group and the control group were compared with respect to their mean score on the sexual risk index (VEE score) during the initial 6 months of follow-up. Because the distribution of VEE scores was markedly nonnormal, a parametric and a nonparametric approach were used. In the parametric analysis, a *t* test was used. In the nonparametric analysis, the bootstrap method was used to construct a 95% confidence interval for the difference between the mean scores of the 2 groups.⁴⁷ The bootstrap method was preferred to other nonparametric procedures because it yields confidence intervals and remains informative when a large proportion of scores are 0.

Second, we sought to determine whether risk was reduced through decreasing the number of sexual episodes or by increasing the proportion of sexual episodes that were protected by the use of a condom. To test for differences between the group receiving the SexG intervention and the control group in the proportion of episodes protected by the use of a condom, a weighted *t* test was used.⁴⁸ This was done in a linear regression analysis using the weighted least squares method; the weight for each man was his total number of sexual episodes (the denominator used in calculating proportion).

Third, we compared the group receiving the SexG intervention and the control group on an outcome that could be measured at baseline and at follow-up (the baseline sexual assessment was a 6-month retrospective and not sufficiently detailed for computing the VEE scores). For this purpose, we defined high-risk behavior as having multiple partners and unprotected anal or vaginal sex. To examine statistical significance, the χ^2 statistic was used.

Fourth, we examined the maintenance of sexual risk reduction after the 6-month follow-up. The remaining 12 months of the 18-month follow-up were divided into two 6-month intervals. The mean VEE scores of the group having the SexG intervention and the control group were compared for each of these intervals, using the same methods described above for the initial 6-month follow-up. In addition, a repeated-measures analysis of variance was conducted with VEE scores during each 6-month interval (ie, 3 time points) as dependent variables and with the group (SexG vs control) as an independent variable.⁴⁸

Finally, we described the sexual experience of the men who were sexually nonactive before the trial. We compared the number of these men in the SexG intervention group and the control group who were sexually active at any time during the 18-month follow-up.

the SexG group compared with 1.2 in the control group; the 75th percentile score was 2.0 in the SexG group compared with 6.4 in the control group. The proportion of men with high VEE scores (>5) was 3% in the SexG group compared with 31% in the control group.

6-MONTH FOLLOW-UP: MEAN VEE SCORES

The mean score on the VEE sexual risk index was 1.0 in the SexG group and 3.1 in the control group ($t_{37}=2.63$, $P=.01$). The difference in the mean VEE scores was 2.1

(3.1–1.0); using the bootstrap method, the 95% confidence interval for this difference was 0.5 to 3.7.

6-MONTH FOLLOW-UP: SPECIFIC BEHAVIORS

The total number of episodes of all types of sex was similar for the SexG group ($n=261$) and the control group ($n=247$). The proportion of episodes protected by the use of a condom was higher in the SexG group (0.73) than in the control (0.52) group (weighted $t_{45}=2.11$, $P=.04$).

Table 1. Curriculum for Sex, Games, and Videotapes Intervention*

Sessions and Lesson	Theme
Sessions 1 and 2: Say the word	Create environment in which men feel comfortable talking about sex Establish group dictionary of commonly used words Discuss popular misconceptions about HIV Learn about STDs as cofactors for HIV Learn correct condom use
Sessions 3 to 6: A quick fix	Sex with female commercial and other casual partners Learn spontaneous condom use Eroticize condom use
Sessions 7 to 10: All you need is love	Sex with special partners Includes occasional sex with special or steady partner Address misconceptions about HIV transmission with this type of partner Develop skills to handle emotional responses to discussion of condom use
Sessions 11 to 14: Peanut butter	Anal sex with men and women Learn why anal sex is a high-risk behavior Discuss same-sex behavior, introduce alternatives to unprotected anal sex
Session 15: Graduation	Receive identification cards as HIV Prevention Specialists Reinforce learning from entire training Empower the men to act as helpers in the future

*HIV indicates human immunodeficiency virus; STDs, sexually transmitted diseases.

6-MONTH FOLLOW-UP: HIGH-RISK BEHAVIOR

With "high risk" defined as having multiple partners as well as unprotected anal or vaginal sex (see the "Data Analysis" section), at baseline the proportion at high risk was similar in both groups (36% vs 42%). At the 6-month follow-up, the proportion at high risk was significantly lower in the SexG group than in the control group (24% vs 58%; $\chi^2_1=6.84$, $P=.01$).

MAINTENANCE OF RISK REDUCTION

During months 7 to 12, the mean (\pm SD) VEE score was 1.5 (\pm 3.8) in the SexG group and 3.1 (\pm 6.3) in the control group (bootstrap 95% confidence interval for the difference in the mean scores, -1.0 to 4.6). During months 13 to 18, the mean (\pm SD) VEE score was 1.8 (\pm 4.8) in the group receiving the SexG intervention and 3.4 (\pm 7.0) in the control group (bootstrap 95% confidence interval for the difference in mean scores, -1.5 to 5.0). Thus, the difference between the mean VEE score of the SexG group and the control group diminished from 2.1 in the initial 6-month follow-up to 1.6 in the 7- to 12-month and 13- to 18-month follow-up intervals. In a repeated-measures analysis of variance, however, there was no sig-

Table 2. Demographic Characteristics and Diagnoses of SexG and Control Groups Recruited From a Psychiatric Program for Homeless Men*

Characteristics	SexG Group (n=33)	Control Group (n=26)	χ^2 (df)	P
Age, y				
<35	39	46	0.27 (1)	.60
≥ 35	61	54		
Ethnicity				
African American	52	65	1.52 (2)	.47
Latino	42	27		
Other	6	8		
Educational level				
<High school	52	62	0.59 (1)	.44
\geq High school	48	38		
Lifetime homelessness, y				
<1	36	27	0.59 (1)	.44
≥ 1	64	73		
Psychiatric diagnosis				
Schizophrenia or schizoaffective	58	65	4.63 (2)	.10
Major depression or bipolar	36	16		
Other	6	19		
Cocaine and alcohol lifetime abuse or dependence				
No alcohol and no cocaine	33	27	0.83 (3)	.84
Cocaine only	27	23		
Alcohol only	15	23		
Cocaine and alcohol	25	27		

*Data are given as percentages unless otherwise noted. SexG indicates the group receiving the intervention "Sex, Games, and Videotapes," described elsewhere.^{25,26}

nificant time or group by time effect ($P=.07$ for group, $P=.81$ for time, and $P=.92$ for group by time).

EFFECTS ON SEXUALLY NONACTIVE MEN

Among the 38 men who were sexually nonactive before the trial (19 each in both groups), 36 were observed for 18 months. Eleven men in the SexG group were sexually active during the 18-month follow-up compared with 9 in the control group. Five in the SexG group had unprotected sex compared with 6 in the control group. One man in the SexG group, who was a virgin before the study, did initiate high-risk behavior during the follow-up; this man paid for sex with a woman, occasionally sold sex to men, and finally found a regular male partner, using condoms sometimes but not always.

COMMENT

This randomized clinical trial demonstrated that HIV sexual risk reduction is feasible among homeless men with mental illness. The trial produced compelling evidence of behavioral change, initially large in magnitude and then diminishing during the 18-month follow-up. Because the follow-up rate was close to 100% and the follow-up interviewers were unaware of the group assignment, this result is unlikely to be due to bias. There were 4 main findings:

First, during the 6 months after the intervention, the men in the experimental group reported significantly fewer sexual risk behaviors than those in the control group. The

Table 3. History at Baseline of Sexual Partners of the SexG and Control Groups During the 6 Months Before the Trial*

Sexual Partners	SexG Group (n=33)	Control Group (n=26)	χ^2 (df)	P
Number of Partners				
Women partners				
0	9	12	2.52 (2)	.28
1	21	38		
>1	70	50		
Men partners				
0	85	84	0.09 (2)	.96
1	6	8		
>1	9	8		
Types of Partners				
Women partners				
Any casual partners	76	76	0.23 (2)	.89
Exclusive main partner only†	15	12		
None	9	12		
Men partners				
Any casual partners	15	8	3.22 (2)	.20
Exclusive main partner only†	0	8		
None	85	84		

*Data are given as percentages unless otherwise noted. SexG indicates the group receiving the intervention "Sex, Games, and Videotapes," described elsewhere.^{25,26}

†Partner identified as lover, wife, or steady.

SexG group scored 3 times lower than the control group (mean, 1.0 vs 3.1; $P=.01$) on the sexual risk index, indicating that they had less unprotected sex with casual and occasional partners.

Second, the risk reduction was related to an increased use of condoms rather than decreased sexual activity. During sex with women, in particular, the men in the SexG group were more likely to use condoms than those in the control group. The total number of sexual episodes, however, was similar for the 2 groups.

Third, after the 6-month follow-up, there was a persisting difference between the groups. The trend was for this difference to diminish, suggesting a need to refine the intervention to enhance the maintenance of behavioral change. Nonetheless, up to the end of the 18-month follow-up, the SexG group still scored about 2 times lower than the control group on the sexual risk index. Thus, for many of the men, the trial produced more than a transient alteration in behavior.

Fourth, the SexG intervention generally did not stimulate renewed sexual activity among men who were sexually nonactive before the trial. This finding may reassure health professionals who hesitate to initiate HIV prevention among impaired persons for fear of provoking an increase in sexual risk behaviors among nonactive persons.^{49,50} Caution is still required, however, as illustrated by the case of a sexually inexperienced man assigned to the SexG group who reported having unprotected sex during the follow-up.

IMPLICATIONS

This study is one of the first to demonstrate that a sexual behavior change can be achieved in a marginal-

Table 4. Scores on a Sexual Risk Index (VEE) and Its Component Risk Behaviors for the SexG Control Groups*

Index and Behaviors	SexG Group (n=33)	Control Group (n=26)
VEE Score, No. (% of Subjects)		
0	23 (70)	13 (50)
1-5	9 (27)	5 (19)
6-10	1 (3)	7 (27)
>10	0 (0)	1 (4)
Mean (\pm SD)†	1.0 (\pm 2.0)	3.1 (\pm 3.6)
Component Risk Behaviors, No. of Episodes		
Sex with women		
Anal		
Unprotected	0	5
Total	5	12
Vaginal		
Unprotected	30	51
Total	149	100
Oral		
Unprotected	37	49
Total	86	74
Sex with men		
Anal		
Unprotected	0	7
Total	2	38
Oral		
Unprotected	4	6
Total	19	23
Total		
Unprotected	71	118
Total	261	247

*VEE indicates Vaginal Episode Equivalent for unprotected sex with casual or occasional partners during the initial 6 months of follow-up; SexG, the group receiving the intervention "Sex, Games, and Videotapes" described elsewhere.^{25,26} The VEE scoring is as follows: anal episodes, 2 points; vaginal episodes, 1 point; oral episode, 0.1 point.

†Significant difference in mean values ($t_{37}=2.63$; $P=.01$).

ized group with serious impairments. Because such populations have become a major locus of HIV infection, with the potential to transmit and to contract HIV,^{2,51-53} the result has important implications for public health efforts to control the HIV epidemic. More specifically, in regard to patients with severe mental illness and comorbid substance abuse, the study suggests that it is feasible to extend psychiatric rehabilitation to their sexual lives.

The intervention was based on well-established principles of social learning theory and social skills training.^{15,16} The original features were represented in the careful tailoring of these principles to the ethnography of the locale and life circumstances of homeless men with severe mental illness and associated cognitive impairments. To be meaningful in this context, a novel format had to be created for the intervention without sacrificing the elements that confer efficacy. In groups that revolved around storytelling and competitive games, the men were able to feel comfortable. Sexual behaviors were discussed using a rich vernacular and a raw humor that was generated by the men themselves. Thus, the approach of the SexG intervention might best be described as "ethnographically based social skills training."

LIMITATIONS

The following limitations are noted:

- The follow-up period of 18 months in this trial represents a small part of a person's life span. The effects of short behavioral interventions tend to fade over time, and this study was no exception. Further work will be needed to develop and test methods to enhance the maintenance of behavior change.

- As in all other trials of HIV preventive interventions, we lacked a generally accepted summary indicator of sexual risk behavior that could be used as the primary outcome measure. Unlike in most other trials, however, the summary indicator used here was adopted a priori and has been previously described and partially validated.^{33,34} In weighting anal sex only twice as risky as vaginal sex, we adopted a conservative approach; a larger weight for anal sex would be more compatible with observational studies of seroconversion and would yield stronger results in this study (Table 4).

- The outcome measures were based on self-report. The sexual behavior assessments used in this study were developed over a long period, modified for this group,²³ and tested for reliability in 2 previous studies of mentally ill men^{42,43} before being adapted for this specific project. In addition, the potential for response bias was minimized by the use of interviewers who were unaware of the subjects' assigned treatment group. Response bias remains a serious consideration, however, and future studies should explore the use of other outcome measures, eg, the incidence of sexually transmitted diseases.⁵⁴⁻⁵⁶

- The experimental and control interventions differed in the number of sessions. The longer duration and the nature of the experimental intervention may have contributed to the observed differences in outcome.⁵⁵

- The men were not tested for HIV in this study. The baseline HIV status could have provided useful descriptive information; data on seroconversion during follow-up could have provided corollary evidence to support the main findings. The outcome of seroconversion alone, however, would not suffice for the aims of this study. We aimed not only to reduce the risk of seroconversion for HIV-negative men, but also to reduce the risk for HIV-positive men of transmitting the infection to others.

- The number of men in this study was modest. Therefore, although the results were robust, they were not entirely definitive. To verify the effectiveness of this type of intervention and to establish its generalizability, the findings now need replication in related populations.

CONCLUSIONS

This study has documented that sexual risk can be reduced in a population with multiple disabilities. These men were afflicted by severe mental illness and faced a multitude of environmental constraints, and yet they achieved significant behavior change. This result provides some ground for optimism that patients with severe mental illness can successfully modify their sexual

lives. It also suggests that effective HIV prevention may be feasible in high-risk groups often considered to be intractable to behavior change.

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