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A Behavioral Intervention Reduces HIV Transmission Risk by Promoting Sustained Serosorting Practices Among HIV-Infected Men Who Have Sex with Men

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Abstract

Objective—To examine factors that explain the effect of a cognitive-behavioral intervention on reductions in HIV transmission risk among HIV-infected men who have sex with men (MSM).

Method—Of the 1,910 HIV-infected MSM screened, 616 participants considered to be at risk of transmitting HIV were randomized to a 15-session, individually delivered cognitive-behavioral intervention (n = 301) or a wait-list control (n = 315).

Results—Consistent with previous intent-to-treat findings, there was an overall reduction in transmission risk acts among MSM in both intervention and control arms, with significant intervention effects observed at the 5, 10, 15, and 20 month assessments (Risk Ratios = .78, .62, .48, and .38, respectively). These intervention-related decreases in HIV transmission risk acts appeared to be partially due to sustained serosorting practices. MSM in the intervention condition reported a significantly greater proportion of sexual partners who were HIV-infected at the 5 and 10 month assessments (Risk Ratio = 1.14 and 1.18).

Conclusions—The Healthy Living Project, a cognitive-behavioral intervention, is efficacious in reducing transmission risk acts among MSM. This appears to have been due in large part to the fact that MSM in the intervention condition reported sustained serosorting practices.

Keywords

Men Who Have Sex with Men; Prevention with Positives; Randomized Controlled Trial; Prevention Case Management

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Introduction

Offering prevention services to HIV-infected individuals is now recommended as an important approach for reducing HIV incidence in the United States [1]. Both the Institute of Medicine (IOM) and the Centers for Disease Control and Prevention (CDC) have advocated for the inclusion of "Prevention with Positives" programs in a coordinated national prevention strategy [2, 3]. Furthermore, the CDC has launched an initiative focused on identifying and intervening with infected individuals [4, 5]. These new directions in HIV prevention work are a result of treatment success. Antiretroviral therapies are allowing HIV-infected individuals to live longer and more sexually active lives. Excluding them from ongoing prevention strategies would constitute a missed opportunity for intervention [2, 6].

To help develop effective HIV prevention counseling for people living with HIV, the National Institute of Mental Health (NIMH) sponsored the Healthy Living Project (HLP). Building on previous successes in reducing sexual transmission among people living with HIV (PLH) [7, 8], the intervention, based on social action theory [9], focused on helping people cope with the challenges of living with HIV [10], in particular not transmitting the virus. It involved fifteen 90-minute structured sessions, divided into three modules of five sessions each. Sessions were tailored to individuals within a structure that used problem-solving and goal-setting techniques. An overarching goal related to personal striving provided continuity throughout sessions. The intent-to-treat findings from the trial demonstrated that the HLP was successful in reducing the number of unprotected sexual risk acts that occurred with partners of serodiscordant status (i.e., those who are HIV-seronegative or serounknown) [11].

The present study examines the factors that explain the effects of the HLP on reductions in HIV transmission risk among men who have sex with men (MSM). Unprotected sex between HIV serodiscordant men continues to account for a substantial proportion of HIV infections each year in the United States (US) [12]. Studies of MSM in recent years have documented increases in transmission risk behaviors [13-20], sexually transmitted infections [13, 14, 21-23], and HIV incidence [19, 24]. For national prevention goals to be achieved [3], it is crucial to understand the specific facets of sexual behavior that are amenable to intervention. Such findings would inform the development of time-limited, efficacious interventions to reduce HIV transmission risk among MSM.

We have previously reported that a small but clinically meaningful portion of MSM who were screened for the HLP trial reported at least one transmission risk event in the previous three months. In that study, not disclosing one's HIV serostatus was identified as an independent correlate of reporting HIV transmission risk [25]. Informed by these data, we examined the extent to which the enhanced serosorting among MSM in the HLP paralleled intervention-related reductions in HIV transmission risk.

Methods

Study Population

Between April 2000 and January 2002, HIV-infected individuals in the four study cities were recruited from community agencies and medical clinics for a baseline interview. The assessment was used to screen participants for eligibility in the randomized intervention trial. Potential participants were required to be at least 18 years of age, provide written informed consent and medical documentation of their HIV infection, be free of severe neuropsychological impairment or psychosis, and not be currently involved in another behavioral intervention study related to HIV. In addition, eligibility for randomization into the trial required participants to have engaged in at least one act of unprotected vaginal or anal intercourse in the previous three months with any partner of HIV-negative or unknown

serostatus or with any HIV+ partner other than a primary relationship (e.g., a one-time partner). Severe neuropsychological impairment and psychosis were assessed on a case-by-case basis by interviewers in consultation with senior project personnel, including the clinical supervisor at the involved institution[11].

Randomization and Follow-up

Participants were randomized within city and sub-group to participate in the intervention or a wait-list control condition. Participants were assigned to subgroups based on recent sex and drug use acts using the hierarchy established by the CDC[26]. MSM were defined as men who reported sexual contact with other males in the past three months, regardless of self-identification as gay or whether they also had female partners. Figure 1 includes a flow diagram of program participation among MSM in the Healthy Living Project. Follow-up rates were similar among participants in the intervention and wait-list control, ranging from 81 % to 89% at each follow-up assessment. Overall, 193 (64%) participants in the intervention and 232 (74%) in the wait-list control completed all follow-up assessments.

Intervention Condition

The Healthy Living Project experimental intervention was designed to adapt a cognitive-behavioral intervention based on feasibility and acceptability data from formative research[27]. The intervention was adapted based on a prevention case management model which includes ongoing individually tailored sessions to meet the unique needs of each participant. In total, participants received fifteen 90-minute individual counseling sessions grouped into three modules, each consisting of five sessions. Module 1 (Stress, Coping, and Adjustment) addressed quality of life, psychological coping, achieving positive affect and cultivating supportive social relationships. Module 2 (Safer Behaviors) addressed self-regulatory issues, such as avoiding sexual and drug-related risk of HIV transmission or acquisition of additional sexually transmitted diseases, as well as disclosure of HIV status to potential partners. Module 3 (Health Behaviors) addressed accessing health services, adherence, and active participation in medical care decision-making. Intervention sessions followed a standard structure and set of activities, but were individually tailored to participants' specific life contexts, stressors, and goals. Participants received $10, $15 and $20 for attending each session of Modules 1, 2, and 3, respectively. Facilitators were trained centrally in cognitive-behavioral intervention strategies and were “certified” if supervisors' observations and quality assurance ratings indicated skilled implementation. All intervention sessions were audiotaped and 10% were rated at a central site to ensure replication with fidelity. More detailed information regarding the methods, intervention program, and fidelity monitoring have been published elsewhere[27]. Participants in the control condition received no active psychosocial interventions from the study team during the 25-month trial. Intervention sessions and study assessments were also conducted in Spanish.

Assessments

Assessment interviews were scheduled at study entry and every 5 months for both the intervention and control groups. Participants received $30 for completing each assessment interview at study entry, month 5, month 10, month 15, and month 20, and $60 for the month 25 interview. Assessments were conducted in private settings in research offices, community-based organizations, and clinics using laptop computers [28, 29]. Procedures involved a combination of audio computer assisted self-interviewing (ACASI) and computer assisted personal interviewing (CAPI) using the Questionnaire Development System (Nova Research Company, Bethesda, MD, USA). ACASI has been shown to be an effective method of decreasing social desirability and thereby enhancing veracity of self-report of sensitive behaviors, including sexual and substance use risk acts [30, 31].

Demographic Characteristics and Health Status Indicators

Demographic characteristics and health status indicators were assessed using CAPI. Detailed background and demographic data included items such as participant age, race/ethnicity, gender, self-identified sexual orientation, relationship status, educational level, employment status, and income. In addition, health status indicators, including self-reported most recent CD4 count, HIV viral load, and current use of antiretroviral medication were assessed.

Sexual behavior: Partner-by-Partner and Global Assessment

A detailed ACASI interview was developed to assess sexual behavior. The interview had a three-month recall period, and included separate but equivalent versions of questions for sex with men and sex with women, each with language tailored to be consistent with the participant's gender and sexual orientation. The interview began with an introduction and definition of sexual terms to minimize ambiguity. All participants were then asked if they had engaged in any sexual activity during the previous three months with men, women, or both, and the number of partners of each gender. Based on responses to these items and the gender of the participant, the computer-based interview asked pertinent questions about sexual behavior.

Beginning with the most recent sex partner and working backward, the participants provided initials or nicknames to identify up to five sexual partners of each gender in the previous three months. For each partner, the participant was asked to describe the person's HIV serostatus, to indicate whether they disclosed their own HIV infection to the individual or if the individual had uncovered this information independently (e.g., met participant at an HIV-seropositive support group), and to define the nature of their relationship with the person. For the latter question, a participant was permitted to describe a person as a steady, main partner; as someone with whom they had sex for love or fun but not as a main partner, a casual partner; as someone with whom they had sex once but not again, a one time partner; as someone with whom they had sex for drugs, money, or a place to stay, sex for exchange; or as someone who forced them to have sex, rape. For analyses, these categories were collapsed into main partner, casual or one-time partner, and other types of partners.

To assess sexual behavior with these partners, the participants were asked a sequence of questions about the number of times vaginal, anal, and oral sex took place and, if appropriate, whether anal sex was insertive or receptive. For anal and vaginal sex, participants were asked about the number of times they had used condoms from the beginning to the end of penetration (using separate questions for male and female condoms, when appropriate), about the number of times that condoms were used but had slipped or broken, and about the number of times internal ejaculation occurred with no protection.

Finally, a set of global measures was used to assess sexual behavior with any additional partners not already captured in the assessment. For both male and female partners, participants were queried about the number of times they engaged in protected and unprotected sexual activities with all partners beyond the five most recent.

Transmission risk acts with all sexual partners—Our primary endpoint was change from baseline in the number of transmission risk acts for each MSM in the study. A transmission risk act was defined as unprotected sex acts with a sexual partner whose HIV serostatus was negative or unknown to the participant. An unprotected sex act was defined as any act of insertive or receptive anal or vaginal intercourse in which a participant did not use a condom, a definition that excludes risk acts resulting from accidental condom slippage or breakage.

The number of transmission risk acts could be determined directly for 69% of MSM who reported five or fewer sexual partners of each gender at all time points. The remaining MSM (31%) reported engaging in unprotected sex with more than five partners of both HIV positive and negative/unknown serostatus at one or more time points, and thus the transmission risk for some of their sex acts (with respect to the HIV status of an individual's sexual partners) could not be determined. This uncertainty occurred for 345 (11%) out of 3112 observations across all time points. For these observations, the number of unprotected sex acts with partners of each HIV serostatus was imputed using multiple imputation as described in the overall trial manuscript[11, 32].

Transmission risk acts with five most recent sexual partners—In order to establish the efficacy of the intervention based on HIV status of an individual's sexual partner or the relationship with the partner (i.e. primary, casual, one time partner, etc.), we also aggregated data collected as part of the partner-by-partner risk assessment with an individual's five most recent sex partners of each gender to derive the number of times participants had anal and vaginal sex with their five most recent sex partners of each gender and the number of times that participants had sex that put these partners at risk for HIV (anal or vaginal sex without a condom with HIV-uninfected or unknown HIV status partners). This information was aggregated over an individual's most recent sexual partners and specifically among an individual's most recent primary and casual sexual partners. It was also used to identify the proportion of an individual's recent sexual partners who were HIV-infected.

Statistical Analysis

We compared participant characteristics at study entry among those randomized to the intervention and control groups using chi-square tests of homogeneity for categorical variables and non-parametric Wilcoxon tests for continuous variables. We modeled sexual behavior during over the 25-month investigation period among those randomized to the intervention and control groups using generalized estimating equations (GEE) with separate indicator variables at each time point for those in the intervention and control groups (these models assumed a Gaussian distribution of the data except where noted below). The predicted values from these models were then graphed to assess the effect of the intervention over time. Based on the shape of these relationships, the effect of the intervention on sexual behavior was then modeled using linear and quadratic terms as appropriate to conserve statistical power.

Models for change in the number of transmission risk acts included a linear term for month of assessment (months 5 through 25) for both intervention and control groups, as well as separate terms to account for an interaction at month 25.

$$E[Y]=\text{intervention}+\text{month}+\text{month}*\text{intervention}+\text{month25}+\text{month25}*\text{intervention}$$

The model for the number of transmission risk acts overall was similar to those for change in transmission risk act and assumed a negative binomial distribution.

$$E[\log(Y)]=\text{intervention}+\text{month}+\text{month}*\text{intervention}+\text{month25}+\text{month25}*\text{intervention}$$

The model for the proportion of sexual partners who were HIV-infected included linear (month of assessment and squared terms (month^2) for both the intervention and control groups.

$$E[\log(Y)] = \text{intervention} + \text{month} + \text{month} * \text{intervention} + \text{month}^2 + \text{month}^2 * \text{intervention}$$

This model also assumed a negative binomial distribution. Similar analyses were conducted for sexual behavior with all sexual partners and for sexual behaviors with participants' steady sexual partners, their casual or one-time partners, among participants who reported five or more sexual partners at study entry and among participants who did or did not report use of stimulants in the three months prior to study entry. Chi-square and p-values are reported for the overall effect of the intervention. In addition, we report the estimated effect of the intervention (with p-values) at each assessment time-point. All analyses were conducted using SAS 9.0 for Windows.

Results

Sample

This sub-sample contained 616 individuals classified as MSM. Of these MSM, 301 were randomized to the intervention and 315 were randomized to the control arm. A majority (97%) identified as gay or bisexual. Caucasians were 41% of the sample, African Americans were 36%, and Hispanics were 15%. Informed by our previous study that examined baseline correlates of HIV transmission risk among MSM[25], we determined whether there were differences between the intervention and wait-list control conditions in demographic characteristics, health status variables, alcohol and drug use, and mean scores on selected psychosocial measures (see Table 1). Men in the intervention group reported more alcohol use at baseline compared to the wait-list control group ($p \leq 0.02$), but no other group differences were observed.

Baseline Sexual Behavior

All MSM in the randomized sample reported anal and/or vaginal sex as defined by study eligibility criteria. MSM participants reported a mean of eight sexual partners in the past three months. Of these, a mean of 42% were HIV-infected. Overall, 73% of MSM reported any transmission risk behavior, defined as unprotected anal or vaginal sex with an HIV-uninfected or unknown HIV-status partner. MSM participants reported a mean of 15 anal/vaginal sex acts with HIV-uninfected or unknown HIV-status partners in the past three months. Of these, a mean of nine (63%) were unprotected.

Table 2 includes information on sexual behavior reported at study entry among MSM participants in the intervention and control arms. MSM in the intervention arm reported a greater number of sex acts with HIV-uninfected or unknown HIV status in the three months prior to study entry ($p \leq 0.02$). We did not observe any other statistically significant differences in sexual behavior reported at study entry (either overall or within specified sub-groups) among participants randomized to the intervention and control arms.

Intervention Effects on HIV Transmission Risk and Serosorting

There was a significant reduction in the number of transmission risk acts among MSM in both the intervention and control arms overall. Among those in the control arm (overall $\chi^2 = 18.52$, df = 2, $p<0.001$), mean decline in transmission risk acts was 2.4 during months 5 through 20 and 3.4 during month 25 ($p<0.001$ for all). Individuals in the intervention group experienced significantly larger reductions in transmission risk acts compared to the control arm (overall $\chi^2 = 7.5$, df = 2, $p \leq 0.02$), with statistically significant differences at the 5, 10, 15, and 20 month assessments (difference = -1.1, -2.2, -3.3, -4.4, respectively; $p<0.02$ for all). There was no significant difference at 25 months (difference = -3.0; $p \leq 0.12$). These additional declines

among those in the intervention arm reflect a significant relative decrease in the number of reported transmission risk acts (Risk Ratio) of 0.78 at month 5, 0.62 at month 10, 0.48 at month 15, and 0.38 at month 20 ($\chi^2 = 13.5$, df = 2, $p<0.001$).

To assess intervention effects on serosorting, we examined the proportion of HIV-infected sexual partners over time. As shown in Figure 2, results indicated a significantly greater proportion of HIV-infected partners in the intervention group compared to the wait-list control group (overall $\chi^2 = 8.86$, df = 2; $p\leq0.01$), with statistically significant differences at the 5 and 10 month assessments (Risk Ratio = 1.14 and 1.18; $p\leq0.04$ and $p\leq0.05$, respectively). This was a buffering effect such that men in the HLP intervention reported sustained levels of serosorting while men in the control wait-list condition reported decrements in serosorting over time. All findings were unchanged when baseline alcohol use was included as a covariate.

Discussion

Consistent with previous intent-to-treat findings[11], the Healthy Living Project was efficacious in reducing transmission risk acts among HIV-infected MSM. Compared to a wait-list control, we observed a significant relative reduction in risk acts: 22% at 5 months, 38% at 10 months; 52% at 15 months, and 62% at 20 months. At 25 months, MSM in the intervention reported a 30% reduction in transmission risk acts, but this effect was not statistically significant. This suggests that a cognitive-behavioral intervention as part of prevention case management may be efficacious in reducing risk of HIV transmission in this population. Prior behavioral intervention trials have observed decay of intervention effects over time [33, 34]. Similarly, the Healthy Living Project's failure to maintain an effect at the 25 month assessment (ten months after the conclusion of the intervention) suggests the need for prevention to be part of ongoing care or case management.

The Healthy Living Project intervention effects on serosorting lend further support to the observed reductions in HIV transmission risk acts among MSM. Serosorting among men in the intervention at the 5 and 10 month assessments was relatively stable while wait-list control participants reported decrements in the proportion of sex partners who were HIV-infected. Although enhanced serosorting among men in the intervention may explain reductions in HIV transmission risk, it is noteworthy that serosorting may also increase the risk of acquiring other sexually transmitted infections and possibly re-infection (or superinfection) with HIV[35, 36]. Thus, additional intervention efforts may be necessary if one's primary goal is to enhance condom use or promote other forms of risk reduction among HIV-infected MSM. It is unclear, however, whether intervention effects on HIV transmission risk and serosorting in this trial are due to the influence of non-specific change processes associated with any psychological treatment, specific HLP intervention elements, or both. Despite the fact that the first module (delivered between baseline and 5 months) focused on improving psychosocial adjustment, intent-to-treat analyses did not provide support for the efficacy of the HLP intervention with respect to any measure of psychosocial adjustment[37]. It may be that HLP intervention effects on HIV transmission risk and serosorting from baseline to 5 months were due in large part to non-specific change processes. It is noteworthy, however, that the second module of the HLP intervention (delivered between 5 months and 10 months) focused explicitly on building communication skills for negotiating safer sex and navigating HIV serostatus disclosure decisions. As a result, it is plausible that subsequent reductions in HIV transmission risk and enhanced serosorting among MSM in the intervention are due to the influence of specific skills provided during this module. As is the case with other psychological interventions designed for HIV-positive persons[38, 39], the multi-modal nature of the Healthy Living Project makes it difficult to definitively determine active intervention element(s). Dismantling trials are needed to inform the development of interventions that incorporate only the most efficacious approaches for reducing HIV transmission risk.

This study had several potential limitations. There were substantial reductions in risk behavior among men in both the intervention and control arms, suggesting that there may be an effect of repeat assessments of sexual risk. Having participants reflect on the numbers and HIV-serostatus of their partners may, in and of itself, constitute a prevention intervention. This should be explored in future randomized controlled trials. If brief, repeated assessments are proven to be efficacious for reducing HIV transmission risk, this would suggest the possibility of integrating short sexual risk assessments into clinical care settings. Another limitation is the self-reported nature of the outcome data for this trial. Although a biological outcome in this study was not feasible, this should be explored in future trials. The most logical biological outcome would have been to track sexual partners and assess the number of new infections attributable to trial participants. This would obviously be impractical. Given substantial attention to quality assurance and previous reports on the validity of self-report measures [29, 40], the findings appear substantial. The final limitation is the data had to be imputed for participants who had five or more sexual partners of either gender. We assumed that individuals' pattern of behavior for more than five partners was comparable to what was reported with the first five partners.

The Healthy Living Project was delivered as 15 sessions for research purposes, but the same content was adapted to eight sessions and delivered to the wait-list control participants. Perhaps the most appropriate adaptation of the intervention would be a specialist-delivered model in HIV clinical care settings where sessions could be provided in the context of regular medical visits. Intervention sessions could follow the model of the Healthy Living Project intervention by focusing initially on managing stress and executing effective coping responses and subsequent sessions should address HIV transmission risk as well as other important health behaviors. Following the active intervention phase, occasional booster sessions may be necessary to assist participants with achieving sustained behavior change. This approach could help offset the relative lack of prevention counseling reported by MSM in other studies [41-42].

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Table 1

Participant characteristics by assignment

	Intervention		Control	
	n	%	n	%
Study Site				
Los Angeles	125	41.5	133	42.2
Milwaukee	20	6.6	25	7.9
New York	50	16.6	49	15.6
San Francisco	106	35.2	108	34.3
Race/Ethnicity				
White	121	40.2	130	41.3
Black/African American	117	38.9	106	33.7
Hispanic/Latino	38	12.6	52	16.5
Other	23	7.6	27	8.6
Unknown/No answer	2	0.1	0	0
Sexual Orientation				
Homosexual/Bisexual	288	95.7	310	98.4
Heterosexual	13	4.3	5	1.6
Age				
39 or less	147	48.8	159	50.5
40 or more	154	51.2	156	49.5
Education Completed				
High school or less	103	34.2	94	29.8
Some college or more	198	65.8	221	70.2
Employment				
Unemployed	175	58.1	190	60.3
Employed	126	41.9	125	39.7
Primary Relationship				
No	202	67.1	209	66.4
Yes	98	32.6	106	33.7
Unknown/No answer	1	0.0	0	0.0
CD4 Cell Count				
Below 200	50	16.6	43	13.7
200 or above	233	77.4	254	80.6
Unknown/No answer	18	6.0	18	5.7
Most Recent Viral Load				
Undetectable	109	36.2	109	34.6
Detectable	184	61.1	198	62.9
Unknown/No answer	8	2.7	8	2.5
Currently on ART				
No	52	17.3	48	15.2
Yes	209	69.4	230	73.0
Unknown/No answer	40	13.3	37	11.7
Alcohol Use				

	Intervention		Control	
	n	%	n	%
None	79	26.2	75	23.8
Some	194	64.5	226	71.7
Daily	27	9.0	12	3.8
Unknown/No answer	1	0.0	2	0.1
Stimulant Use				
No	213	70.8	230	73.0
Yes	88	29.2	85	27.0
Other Drug Use				
No	235	78.1	228	72.4
Yes	66	21.9	87	27.6
Continuous Predictors	**M**	**SD**	**M**	**SD**
Coping Self-Efficacy	6.4	1.7	6.3	1.8
Perceived Stress	19.0	7.2	19.2	7.0
Depression	12.7	8.8	13.6	9.0
Anxiety	36.9	10.8	37.6	11.7
Positive States of Mind	12.7	3.3	12.4	3.7
Social Provisions				
Guidance	10.8	2.8	11.0	2.6
Reassurance of Worth	10.2	2.3	10.3	2.3
Social Integration	10.2	1.6	10.2	1.6
Social Attachment	10.8	2.0	10.9	1.9
Social Nurturance	9.5	2.4	9.6	2.4
Reliable Alliance	11.0	2.7	11.1	2.8

Table 2

Sexual behavior reported at study entry by assignment

	Intervention		Control	
	% mean	**(95% CI)**	**% mean**	**(95% CI)**
Any anal/vaginal sex	100		100	
Any transmission risk behavior*	70.0	(64.7, 75.2)	68.9	(63.7, 74.1)
Number of anal/vaginal sex acts – mean	16.8	(10.7, 22.9)	9.1	(7.3, 11.0)
Number of transmission risk acts – mean	10.6	(5.7, 15.5)	5.7	(4.2, 7.2)
Percent transmission risk behavior	63.6	(58.5, 68.8)	66.0	(60.7, 71.7)
Number of sexual partners – mean	12.2	(9.0, 15.4)	8.8	(7.2, 10.5)
Number of HIV-infected sexual partners – mean	1.6	(1.4, 1.8)	1.6	(1.4, 1.7)
Percent of sexual partners HIV-infected	42.9	(38.6, 47.2)	40.9	(36.8, 45.0)