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Project Enhance: A Randomized Controlled Trial of an Individualized HIV Prevention Intervention for HIV-Infected Men Who Have Sex With Men Conducted in a Primary Care Setting

Steven A. Safren,
Department of Psychiatry, Massachusetts General Hospital, Harvard Medical School, and Fenway Health, Boston, Massachusetts

Conall M. O'Cleirigh,
Department of Psychiatry, Massachusetts General Hospital, Harvard Medical School, and Fenway Health, Boston, Massachusetts

Margie Skeer,
The Fenway Institute, Fenway Health, Boston, Massachusetts

Steven A. Elsesser, and
The Fenway Institute, Fenway Health, Boston, Massachusetts

Kenneth H. Mayer
The Fenway Institute, Fenway Health, Boston, Massachusetts, and Medicine and Community Health, Miriam Hospital, Brown University

Abstract

Objective—Men who have sex with men (MSM) are the largest group of individuals in the U.S. living with HIV and have the greatest number of new infections. This study was designed to test a brief, culturally relevant prevention intervention for HIV-infected MSM, which could be integrated into HIV care.

Method—HIV-infected MSM who received HIV care in a community health center (N = 201), and who reported HIV sexual transmission-risk behavior (TRB) in the prior 6 months, were randomized to receive the intervention or treatment as usual. The intervention, provided by a medical social worker, included proactive case management for psychosocial problems, counseling about living with HIV, and HIV TRB risk reduction. Participants were followed every 3 months for one year.

Results—Participants, regardless of study condition, reported reductions in HIV TRB, with no significant differential effect by condition in primary intent-to-treat analyses. When examining moderators, the intervention was differentially effective in reducing HIV TRB for those who screened in for baseline depression, but this was not the case for those who did not screen in for depression.

Conclusions—The similar level of reduction in HIV TRB in the intervention and control groups, consistent with other recent secondary prevention interventions, speaks to the need for new, creative designs, or more potent interventions in secondary HIV prevention trials, as the control group seemed to benefit from risk assessment, study contact, and referrals provided by

Correspondence concerning this article should be addressed to: Steven A. Safren, 1 Bowdoin Square, Boston, MA 02114. ssafren@partners.org.

study staff. The differential finding for those with depression may suggest that those without depression could reap benefits from limited interventions, but those with a comorbid psychiatric diagnosis may require additional interventions to modify their sexual risk behaviors.

Keywords

MSM; HIV prevention; AIDS/HIV; high-risk sexual behavior; depression

Men who have sex with men (MSM) constitute, by far, the largest group of individuals living with HIV in the U.S., as well as the group with the highest number of incident infections (CDC, 2010). Although antiretroviral therapy has extended the lives of people living with HIV, treatment does not invariably suppress HIV infectiousness, because of suboptimal adherence for some and/or intercurrent genital tract infections in others that can up-regulate HIV replication (Mayer & Venkatesh, 2010). Thus, individuals who have entered routine care can transmit HIV to others. In fact, individuals who are HIV infected and aware of their status are associated with almost half of the new HIV infections in the U.S (Marks, Crepaz, Senterfitt, & Janssen, 2005). Recently, anti-retroviral therapy has been demonstrated to decrease infectiousness and the efficiency of HIV transmission (Cohen et al., 2011). However, although MSM may be entering and benefitting from treatment, this has not yet been associated with a general decrease in new transmissions among MSM (Prejean et al., 2011). Accordingly, one important strategy to prevent the transmission of HIV is to promote sexual risk reduction for people living with HIV (CDC, 2006).

A meta-analysis of 12 studies that was published in 2006, and three notable intervention studies since, have revealed modest or mixed results of psychosocial interventions to decrease HIV transmission-risk behavior (TRB) for individuals living with HIV (Crepaz et al., 2006). Although the meta-analysis found statistically significant reductions in TRB when studies were aggregated, only five of the 12 individual studies examined showed significant effects. The meta-analysis concluded that successful prevention interventions are needed to address participants' mental health and medical adherence, provide skills for risk reduction, and integrate prevention with routine medical care. Of the other three studies published since the meta-analysis (Mausbach, Semple, Strathdee, Zians, & Patterson, 2007; Morin et al., 2008; Simon Rosser et al., 2010), all found reductions in both the intervention and control groups, with just one finding statistically significant differential improvements favoring the intervention under study (Morin et al., 2008). The one that did find differential improvements, "The Healthy Living Project," addressed a variety of psychosocial concerns as part of living with HIV, and was considerably more intense, consisting of fifteen 90-min long individual sessions with a counselor (Morin et al., 2008).

As a next step to the work referenced above, we sought to address both HIV TRB and other psychosocial concerns for MSM living with HIV, in the context of HIV care, attempting to do so with a relatively brief intervention. To do this, we utilized medical social workers as interventionists who would provide proactive case management and thereby address the psychosocial concerns of MSM living with HIV through referral. We hypothesized that integrating proactive HIV prevention case management to address psychosocial problems, with increasing behavioral skills for reducing HIV sexual TRB would be more effective than standard of HIV care, which included as-needed case management services.

Method

Sample and Procedures

Five hundred three HIV-infected MSM who received HIV primary care at Fenway Health in Boston, MA, the largest center in New England caring for sexual and gender minority

populations (Mayer et al., 2001), completed an audio, computer-assisted, self-administered assessment (ACASI). We had two different trials happening during the time of this study. For the present study, patients were offered participation if they had reported, on the ACASI, HIV TRB in the past 6 months. If they did not report HIV TRB in the past 6 months, or if they did not want to participate in the current study for another reason (e.g., if they did not want to change their current case manager to a study case manager), they were offered participation in a demonstration project, which used trained HIV-infected peer counselors as interventionists (Safren et al., 2011). The remaining 107 either did not meet eligibility criteria ($n = 73$) or did not want to participate in the intervention/longitudinal aspects of the study ($n = 24$), or participated in a pilot nonrandomized run-in phase ($n = 10$). Please see Figure 1 for study flow including during the screening/randomization phase.

Eligibility criteria for the current study included being: (a) A self-identified HIV-infected MSM 18 years of age or older, (b) a patient who received his primary care at Fenway Health for at least 3 months, (c) engaged in at least one instance of HIV TRB (TRB; self-reported unprotected sex with either HIV-negative and/or HIV-unknown status partners) in the 6 months prior to baseline, and (d) willing to be followed by a study case manager. Once enrolled, the men were randomized via computer-generated sequences into either the intervention condition ($n = 100$) or the control condition ($n = 101$), which entailed standard HIV care at Fenway Health. The computer-generated, randomization-allocation number list was prepared by a staff member with no participant contact in the trial, and details of the allocation group were contained onsite in sequentially numbered sealed envelopes. At enrollment, the responsible interventionist would assign randomization by opening the next sequentially numbered envelope. Postrandomization, study condition was not concealed, and hence was not blinded.

All study procedures were reviewed and approved by the IRB at Fenway Health, and all participants underwent a full informed-consent process, including a discussion of alternatives of participation, for the study. Participants were compensated $25 for their first assessment and $50 for each completed 3-month assessment thereafter for a total of $225 over the course of the study. Participants did not receive a financial incentive for the intervention visits.

Experimental Intervention

Rationale for experimental intervention—For many HIV-infected MSM, psychosocial concerns can include negotiating safer sex, substance use (e.g., Natale & Moxley, 2009), HIV status disclosure, distress associated with stigma and disclosure (e.g., Courtenay-Quirk, Wolitski, Parsons, & Gomez, 2006; Dowshen, Binns, & Garofalo, 2009; Klitzman, 1999), anxiety about living with a chronic illness (e.g., Berg, Mimiaga, & Safren, 2004), and negotiating consistent adherence to treatment (e.g., Halkitis, Kutnick, & Slater, 2005; Halkitis, Palamar, & Mukherjee, 2008). Because standard HIV primary care involves provider visits quarterly, we used this as an opportune time to provide an intervention (Mayer, Safren, & Gordon, 2004). Many state- and other-funded HIV care clinics have medical social workers as part of a treatment team, and hence, using them as interventionists was part of the design to increase the potential scale of the project if it were to be efficacious. Accordingly, because of the high rates of psychosocial and psychiatric comorbidity, such as depression and problematic substance use in HIV (Bing et al., 2001), these interventionists could provide both the TRB counseling for the project and could provide enhanced, proactive case-management services for any psychosocial needs that arose.

Timing and logistics of experimental intervention—The intervention included five 50–90 min visits with a medical social worker over the course of approximately 3 months, which included one "intake" visit to assess case management needs, and four "intervention" visits that would include the modules described below. These were followed by four follow-up "booster" visits at 3, 6, 9, and 12 months postintervention which occurred during study assessment visits. In these visits, participants would first complete the ACASI and then have the opportunity for the booster session. The intervention was delivered in the clinic setting, and the timing of the assessments and follow-up visits were quarterly to complement the standard of care for HIV clinic visits (Aberg et al., 2009). Interventionists were trained via didactic instruction, listening to audio recordings of sessions of senior interventionists during a pilot phase, and through standardized role-plays. They used a modular workbook to facilitate the counseling sessions. The core module and booster sessions were specifically focused on issues related to HIV, yet delivered in a flexible and individualized manner. Each of the seven module or booster sessions were generally conducted in the same format—information on the topic, motivational interviewing techniques to discuss barriers to change, and behavior change via use of new skills (IMB model; Fisher, Amico, Fisher, & Harman, 2008). In addition to the IMB model, the modules were influenced by Project EXPLORE (Koblin, Chesney, Coates, & EXPLORE Study Team, 2004), adapting this for HIV-infected MSM, input from our community advisory board, from HIV-infected peers, and from the investigator team (see Knauz et al., 2007). The various modules are described below.

Intake—Each participant had an "intake" meeting with his new medical social worker. This was an open-ended session, and involved rapport building and enabled the participants to describe their histories, similar to an intake session with a medical social worker. This, therefore, also included an overall assessment of case-management needs, which were then addressed over the course of the remaining sessions. Although the main focus was on HIV-related concerns, the session was open-ended to allow for a good working relationship between the counselor and the participant.

"Having sex" (mandatory module)—This session was a core module that all participants would receive. It involved education about HIV transmission. Accordingly, the counselor and the participant identified the participants' sexual risk limits, discussed how and why participants might be tempted to, or have gone outside of these risk limits, and provided education about HIV transmission (e.g., HIV risk, viral load, HIV medications and transmission, and HIV superinfection/reinfection). For the remaining sessions, participants selected three (out of six additional) topics that they deemed most relevant to their needs.

Party drugs—This module reviewed various substances that MSM commonly use and their effects on physical functioning and HIV medications. Participants discussed their individual factors that may lead to use of drugs, and/or combining (unsafe) sex with substance use. Participants would describe a more recent example of using drugs that may have lead to negative consequences or HIV risky behavior that they would have liked to avoid; and then the counselor and participant would end with a discussion of barriers and ways to overcome barriers, to reduce use and/or combining use with unsafe sex. This module also had role-play and skill-building exercises.

Managing stress—This module involved learning stress reduction techniques, and discussing a potential relationship between stress and sex, and how negative coping may lead to increased sexual risk taking. Mindfulness and relaxation training techniques were introduced.

Triggers—This module specifically focused on situations or other factors related to temptations to go outside of one's prespecified sexual risk limits. Accordingly, the counselor and participant would identify a recent trigger, discuss the situation, his emotional response, his physiological response, and the end result. As a skill-building exercise, each participant completed a trigger worksheet that examined goals, choices, and action plans to reduce the influence of triggers on engaging in sexual HIV TRB.

Cultures, communities, and you—This module addressed cultural concerns that a participant may have had and how they might have related to sexual decision making. In conjunction with the counselor, the participant would discuss if he felt he had to compromise sexually due to his racial or ethnic identity. Counselors would try to help participants increase their connectedness to their own communities, build social support, and improve self-efficacy and resiliency in order to make informed choices about sexual experiences.

Disclosure—This module focused on HIV status disclosure to partners and others in one's life. Participants would discuss personal rules about disclosure, and situations that would make them more or less likely to disclose their HIV status to others. They would discuss the pros and cons of disclosure in sexual situations, and, accordingly, identify barriers to disclosure. Skill-building and role-play techniques were also employed.

Getting the relationships you want—This module focused on differentiating sexual and/or romantic longer term relationships and articulating what kinds of relationships the participants may desire. As needed, participants would discuss efforts to improve their social networks and review steps and skills building to expand these networks, and try to meet/get the type of relationships they desire. Barriers and facilitators to longer term versus shorter term sexual partnerships were discussed when desires for longer term relationships were expressed.

Comparison Condition

The comparison condition received standard treatment as it would normally occur at Fenway Health. This involved having a medical social worker as part of one's treatment team, should needs arise, and having the expectation of at least quarterly HIV-care visits with appropriate blood monitoring. As part of the present study, the comparison condition completed the same five assessments (i.e., at baseline, 3 months, 6 months, 9 months, and 12 months), but did not receive the experimental HIV TRB intervention as described above.

Measures

Demographic and HIV-related factors—Participants completed a basic questionnaire on the ACASI that assessed age, race/ethnicity, personal income, education level, and relationship status. Participants also indicated whether they had taken antiretroviral therapy, and treatment duration if they had. Relevant CD4 + T-cell counts (cells/mm^3) and plasma HIV RNA concentrations (copies per milliliter) were collected from participants' electronic medical records.

Transmission-risk behavior—Participants were asked, separately, about the number of times they had anal intercourse with their sexual partners (HIV-infected, HIV-negative, and HIV-unknown status), and the number of times when condoms were used/not used. These were asked separately for insertive and receptive sex. The primary outcome, TRB, was operationalized as insertive or receptive anal intercourse acts with HIV-uninfected partners or partners of unknown status within the past three months, measured at baseline, and at 3-, 6-, 9-, and 12-month follow-ups. Two measures of TRB were utilized for this study: (a) the

number of TRB acts, and (b) a binary measure, which was dichotomized as no TRB or at least one TRB act.

Depression—The nine-item depression subscale of the Patient Health Questionnaire (PHQ) (Spitzer, Korenke, & Williams, 1999) was used as the screener for major depressive syndrome (MDS). The PHQ is a self-report instrument designed to detect common mental-health problems in primary care settings through symptom severity and diagnostic assessments. This scale has shown excellent test–retest ($r = 0.84$) and internal consistency reliability (Cronbach's alpha: 0.89), as well as established construct and criterion validity (Kroenke, Spitzer, & Williams, 2001). In the current study, men who screened in for MDS (based on the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders,* 4th ed.; *DSM–IV;* Spitzer et al., 1994) assessed by this measure were considered to be depressed and those who did not were not considered to be depressed (dichotomous variable).

Heavy alcohol use—Heavy alcohol use was a dichotomous variable assessing whether or not participants reported drinking five or more drinks in a single day at least once per week over the past 3 months.

Drug-use impairment—Participants were queried about smoking, sniffing, snorting, swallowing, or injecting any drugs in the past 3 months, including marijuana, crack, cocaine, heroin, methamphetamines, ketamine, opiates (e.g., Vicodin, Oxycontin, Percocet), tranquilizers or barbiturates, hallucinogens, or inhalants. Participants were then asked five yes/no questions as part of the PHQ (Spitzer et al., 1999) to assess impairment related to drug use, and those who answered affirmatively to at least one of these diagnostic criteria within the past 6 months were identified as having drug-use impairment.

Data Analysis

All participants were included in the analyses and were analyzed according to the condition that they were originally assigned (i.e., intent to treat). To check the comparability of the intervention and control conditions after randomization, we first examined differences in demographic, HIV-disease stage, mental health, and sexual risk between the conditions at baseline. Chi-square tests of independence and Fisher's exact tests were conducted for categorical variables and *t* tests were performed for continuous variables.

To assess changes in TRB, we used a generalized linear model. Because the measure of TRB was a count variable with positive skew, we specified a negative binomial distribution and logit-link function to determine the risk of engaging in TRB. For the dichotomous outcome, we conducted a longitudinal logistic regression analysis to determine if there were significant changes in the odds of engaging in TRB. Longitudinal differences in TRB between the intervention and control conditions were assessed by including interaction terms between intervention status and time in the corresponding models.

Our power analysis indicated a sample size of 100 per condition for .80 power. This was based on the standard deviation of the outcome variable approximating that found in previous studies conducted at Fenway Community Health ($M = .50$; $SD = .43$), $\alpha = .05$; $\beta = .20$, and a medium effect size ($\eta = .20$; Cohen et al., 2002).

Because the intervention sought to proactively address psychosocial/case-management needs, to assess whether there were differences in TRB over time between the intervention and control conditions (i.e., effect moderation) by depression status, heavy alcohol use, or drug-use impairment, we fit three-way interaction terms between intervention status, time, and the potential moderators separately in the final model. For interaction terms that were

significant ($p < .05$), we stratified the analyses by the potential moderators to determine if there were differences between the intervention and control conditions among the subgroups.

All longitudinal regression analyses used direct likelihood-estimation procedures with PROC GLIMMIX in SAS version 9.2 (SAS Institute, Cary, NC). In the presence of incomplete data, these procedures impute estimates to replace the missing values (Molenberghs & Verbeke, 2005; Molenberghs & Kenward, 2007). Statistical significance was determined by $p < .05$ for all analyses.

Results

Recruitment was from April 2004 to August, 2007, with the last follow-up assessment being July 2008. Figure 1 depicts participant flow through screening, enrollment, and follow-up and Table 1 presents the demographic and HIV-related disease profile of the sample at baseline. At baseline, there were no statistically significant differences between those in the intervention and control conditions on age, education, income, race/ethnicity, depression, heavy alcohol use, drug use, CD4 count, or HIV RNA (viral load). There were no study-related serious adverse events or social harms.

TRB

The means and standard deviations of TRB for each of the baseline and follow-up time points (at 3 months, 6 months, 9 months, and 12 months) for the intervention and control conditions are also presented in Table 1. Regression analyses showed, in assessing average differences in TRB among the whole sample (regardless of experimental condition) for the TRB-count outcome, for every three months there was an associated 14% reduced risk of TRB (incidence rate ratio; IRR: 0.86; 95% CI: 0.77–0.97) and for the dichotomous TRB outcome, for every three months, there was a 20% reduced chance of engaging in any TRB (odds ratio; OR: 0.80; 95% CI: 0.73–0.87) (Table 2, Model 1). However, there were no significant differences of TRB over time between the intervention and control conditions for either outcome (IRR: 1.06; CI: 0.85–1.333 and OR: 0.94; CI: 0.777–1.1616, respectively; Table 2, Model 2). Figure 2 illustrates the difference in incidence rate between the intervention and control conditions for the count TRB outcome.

Effect moderation

The first moderator tested for was depression, which was significant, as indicated by the three-way interaction terms for both the count outcome (IRR: 0.18; CI: 0.07–0.49; $p < .001$) and the dichotomous outcome (OR: 0.11; CI: 0.03–0.50; $p < .1$). This indicated that there were differences in TRB between or within the intervention and control conditions over time by depression status. Accordingly, we broke down the three-way interaction to a stratified two-by-two analysis to examine differences between the intervention and control conditions separately by depression status.

For those who screened in for depression, the interaction term was significant for TRB, (IRR: 0.22; 0.08–0.58; Table 2, Model 3). As illustrated in Figure 3, the reduction in the incidence rate of TRB was significantly steeper in the treatment condition than in the control condition. Among men in the sample not meeting screen-in criteria for depression, the interaction between condition and time was not significant (IRR: 1.10; 0.89–1.38), indicating that there were no significant decreases in TRB by study condition for these participants (Table 2, Model 4). The stratified analysis for the dichotomous outcome of TRB produced similar results. Specifically, for those meeting screen-in criteria for depression, the interaction between condition and time was significant (OR: 0.11; 0.02–0.45), indicating

that the reduction in odds of TRB was significantly greater in the treatment condition than in the control condition (Table 2, Model 3). Among men in the sample not screening for depression, there were no significant decreases in TRB between conditions (OR: 1.00; CI: 0.81–1.25; Table 2, Model 4).

Next we tested effect moderation for heavy alcohol use and drug-use impairment. The corresponding three-way interaction terms were not significant ($p = .19$ and $p = .39$, respectively), indicating that there were no differences in TRB between the intervention and control conditions over time by these substance-use indicators. Therefore, further stratified analyses for these indicators were not conducted.

Discussion

This was a randomized controlled trial of an intervention to reduce sexual TRB in HIV-infected MSM recruited at their primary care site, which included case management plus tailored counseling addressing their psychosocial concerns as well as HIV risk reduction. Both those assigned to the intervention condition and those in the control condition reduced their risk. Accordingly, in the planned intent-to-treat analysis, those who received the intervention did not show statistically significant differences with respect to reduced HIV TRB, compared with those who came in for assessments of sexual TRB alone and had counseling and case management as it normally would have occurred at the clinic. This finding is consistent with other recent interventions that have seen HIV TRB reductions attributed to risk assessment alone in individuals with HIV (Lightfoot, Rotheram-Borus, Comulada, Gundersen, & Reddy, 2007; Mausbach et al., 2007; Myers et al., 2010; Simon Rosser et al., 2010). The one recent intervention that produced significant decreases in TRB was the Healthy Living Project, which consisted of fifteen 90-min sessions, considerably more intense than the one currently being reported here. Hence, it is possible that the present intervention was not potent enough. Our goal, however, was to develop a briefer intervention that might, therefore, have had a higher likelihood of implementation in those HIV clinics that already have medical social workers, and this may have resulted in less than necessary intervention potency. Further, it is possible that many people who choose to enter a study and have a recent history of risk are individuals already motivated to make changes, and hence even minimal intervention (assessment only) might be helpful. It is also possible that such effects may be vulnerable to demand characteristics and regression to the mean, particularly when including only those who have reported recent risk.

In the secondary analysis of potential moderators, individuals who screened in for depression seemed to need the study intervention versus just study participation and assessments to reduce their risk. Specifically, among those who screened in for depression, those in the intervention condition showed significantly greater reductions in TRB compared with those in the comparison condition. But, among those who did not screen in for depression, the reduction in TRB was not different between conditions. If, as discussed above, the act of assessing sexual TRB itself or being in an intervention study for TRB may result in self-reported reductions in TRB, perhaps by encouraging HIV-infected MSM to reflect on their risk taking, or due to demand characteristics of studies like this, this may not be the case for those with depression. This pattern of results is consistent with findings from an analysis of our baseline data, which found that a social–cognitive (self-efficacy) model of HIV TRB fit the data well for the sample as a whole; however, a moderated effect occurred with depression, negating the model for those who screened in for depression (Safren et al., 2010). In addition, the current sample had substantial mental-health and substance-use concerns (Skeer et al., 2012; O'Cleirigh, Skeer, Mayer, Ripton, & Safren, 2011) and it is therefore plausible that more intense interventions are needed for those with a comorbid

disorder such as depression, while those not depressed might benefit from less intensive interventions.

There are several limitations to the current study. First, like many studies of sexual TRB, data are limited by self-report on an anonymous computerized survey. Because the intervention occurred in the HIV-care setting, those who engaged in risk may have felt it necessary to report that they had changed their behavior for the better. Hence, demand characteristics may be an issue in terms of interpreting the results. Another limitation is that selecting for individuals who reported recent risk may have increased the chances of regression to the mean. Finally, although 93% of the sample returned for at least one follow-up and 85.6% for the 12-month follow-up, overall retention could have been better than it was. Baseline data (O'Cleirigh et al., 2011) revealed high rates of mental-health and substance-abuse comorbidities in the sample, and hence retention may be due to the complexity of psychosocial issues involved with living with HIV as an MSM.

Despite these limitations, the differential effects (found among the subset who screened in for depression) between those who received the intervention and those who did not is worthy of future study. Because depression is quite common among individuals living with HIV (e.g., Bing et al., 2001), refinement of the current intervention for depressed MSM could have a substantial public-health impact on reducing new HIV transmissions by HIV-infected MSM in care. Additionally, future investigations of alternative ways to include comparison conditions and/or avoid demand characteristics for self-report of HIV TRB would be important in terms of further teasing out potential effects of study participation, versus whether the experimental intervention is in fact more effective than local standards of care.

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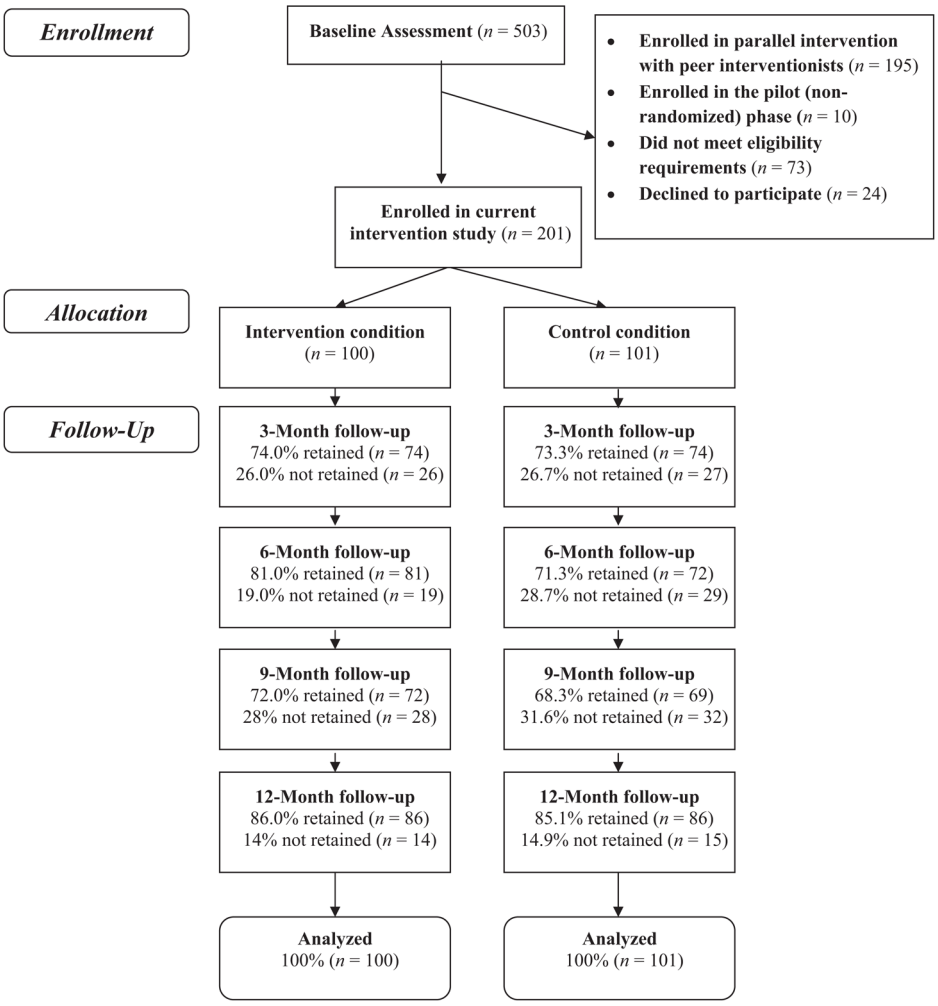

Figure 1.
Participant flow through screening, enrollment, and follow-up.

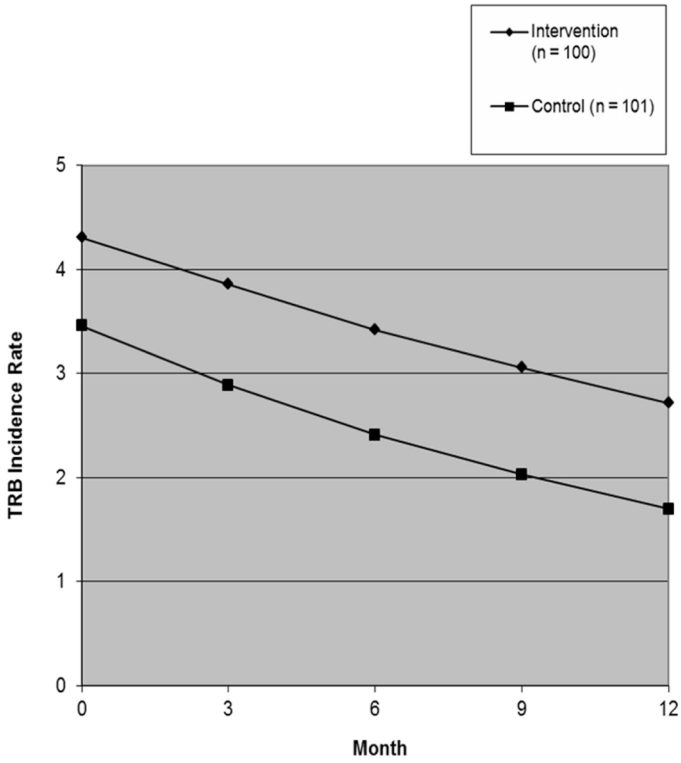

Figure 2.
Changes in the incidence rate of TRB by experimental condition.

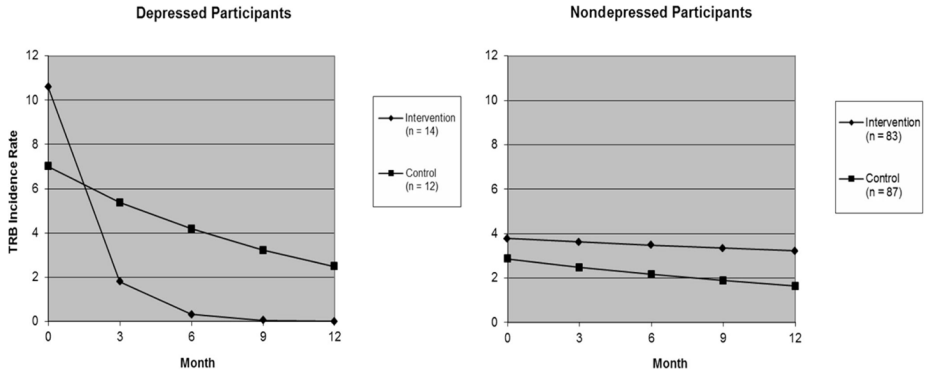

Figure 3.

Changes in the incidence rate of TRB over time by experimental condition for depressed and nondepressed participants. *Note.* For participants who screened in for depression, beta coefficients for the comparison between intervention and treatment as usual are −1.546 (CI: −2.780, −0.313) and IRR is 0.21 (CI: 0.06, 0.73); $p = 0.015$. For participants who screened out for depression, beta coefficients for the comparison between intervention and treatment as usual are 0.521 (CI: −0.060, 1.101) and IRR is 1.68 (CI: 0.94, 3.01); $p = 0.079$.

Table 1

Descriptive Statistics of Baseline Demographic Characteristics and the Primary Study Outcome (Transmission Risk Behavior) for the Whole Sample and by Experimental Condition

	Mean (*SD*) or Percentage			*p* value (assessing differences by condition)
	Whole sample (*n* = 201)	**Intervention condition (*n* = 100)**	**Control condition (*n* = 101)**	
Age	40.7 (7.8)	40.3 (8.1)	41.1 (7.5)	0.503
Race/ethnicity				0.172
White	74.6%	70.0%	79.2%	
Black/African American	11.9%	13.0%	10.9%	
Latino/Hispanic	8.5%	13.0%	4.0%	
Other	5.0%	4.0%	5.9%	
Education				0.146
<High school	2.0%	4.0%	0.0%	
High school/GED	10.0%	10.0%	9.9%	
Some college	33.3%	39.0%	27.7%	
College degree	38.3%	34.0%	42.6%	
Graduate degree	16.4%	13.0%	19.8%	
Annual income				0.797
Less than $20,000	28.9%	29.0%	28.7%	
$20,001–$40,000	24.9%	23.0%	26.7%	
$40,001–$60,000	15.9%	17.0%	14.9%	
Greater than $60,000	30.3%	31.0%	29.7%	
Met PHQ-9 screening criteria for depression	13.9%	14.0%	11.9%	0.467
HIV disease and medication				
CD4 count (cells/mm^3)	538.5 (286.6)	520.2 (296.9)	556.6 (276.3)	0.369
Viral load (mean plasma HIV RNA: copies/ml)	18,332 (52,689)	19,073 (48,824)	17,569 (56,644)	0.842
Undetectable viral load	50.0%	55.0%	45.0%	0.157
Currently taking HIV medication	56.7%	61.0%	52.5%	0.223
Ever taken HIV medication	66.2%	70.0%	62.4%	0.253
Transmission risk behavior				
Baseline	4.39 (7.44)	5.12 (8.46)	3.67 (6.25)	0.169
3-Month follow-up	2.93 (7.11)	2.82 (5.35)	3.04 (8.56)	0.855
6-Month follow-up	2.32 (6.55)	2.56 (6.03)	2.04 (7.12)	0.624
9-Month follow-up	3.12 (16.98)	5.03 (23.81)	1.20 (2.58)	0.200
12-Month follow-up	2.48 (6.38)	2.72 (7.89)	2.22 (4.27)	0.641

Table 2

Results of the Negative Binomial and Logistic Regression Models Presenting the Main Effects of the Intervention on Sexual Transmission Risk Behavior and Stratified by Depression Status

	Model 1: Main effects	Model 2: Main effects over time	Model 3: Effects over time for depressed participants	Model 4: Effects over time for non-depressed participants
	IRR (CI)	IRR (CI)	IRR (CI)	IRR (CI)
Negative Binomial Regression Models				
Condition				
Control	1.00	1.00	1.00	1.00
Intervention	1.49 (0.88–2.50)	1.25 (0.68–2.29)	1.522 (0.68–682.29)	1.333 (0.69–2.54)
Time	0.866 (0.77–0.97) *	0.84 (0.71–0.98) *98	0.77 (0.47–1.26)	0.87 (0.74–1.02)~
Condition × Time	—	1.06 (0.85–1.33)	0.222 (0.08–0.58) **58	1.10 (0.89–1.38)
	OR(CI)	OR(CI)	OR(CI)	OR(CI)
Logistic Regression Models				
Condition				
Control	1.00	1.00	1.00	1.00
Intervention	1.39 (391.01–1.92) *	1.13 (0.66–1.93)	12.4545 (2.15–72.0) **	0980.55–1.77)
Time	0.800 (0.73–0.87) ***	0.76 (0.66–0.88) ***	0.822 (0.60–1.12)	0.7777 (0.66–0.90) ***
Condition × Time	—	0.944 (0.777–1.16)	0.1111 (0.02–0.45) **	1.000 (0.818–1.25)

~ $p < .10$.

* $p < .05$.

** $p < .01$.

*** $p < .001$.