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Reducing Sexual Risk Behaviors and Alcohol Use Among HIV-Positive Men Who Have Sex With Men: A Randomized Clinical Trial

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Abstract

This randomized clinical trial ($N = 253$) evaluated the efficacy of a theory-based intervention designed to reduce both alcohol use and incidence of unprotected sexual behaviors among HIV-positive men who have sex with men with alcohol use disorders. An integrated, manualized intervention, using both individual counseling and peer group education/support, was compared with a control condition in which participants received resource referrals. The intervention was based on the transtheoretical model's stages and processes of change, and motivational interviewing was used to enhance client readiness for change. Major findings include treatment effects for reduction in number of drinks per 30-day period, number of heavy drinking days per 30-day period, and number of days on which both heavy drinking and unprotected sex occurred. Practitioners employing this intervention may achieve enhanced client outcomes in reduction of both alcohol use and risky sexual behavior.

Keywords

HIV; transtheoretical model; motivational interviewing

Men who have sex with men (MSM) remain disproportionately affected by HIV, composing 65% of men living with AIDS in 2002 and 67% of men diagnosed with HIV (Centers for

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Disease Control and Prevention, 2002). Recent studies from the United States and abroad have documented a rise in reported rates of unprotected anal sex (Mercer et al., 2004; Osmond, Pollack, Paul, & Catania, 2007; Prabhu, Owen, Folger, & McFarland, 2004; Truong et al., 2006), outbreaks of sexually transmitted infections (Centers for Disease Control and Prevention, 2005; Fox et al., 2001; Hopkins, 2004), and increases in HIV incidence among MSM (Calzavara, 2002; Kellogg, McFarland, & Katz, 1999; Marcus, Voss, Kollan, & Hamouda, 2006). Survey data have shown that 15%–30% of HIV-positive MSM engage in sexual practices that place seronegative partners at risk of HIV infection (Parsons, Halkitis, Wolitski, & Gomez, 2003; Weinhardt et al., 2004), suggesting that interventions should target particular subgroups of HIV-positive MSM who may be accounting for increased numbers of seroconversions.

Alcohol and other drug use have frequently been identified as predictive factors for sexual risk-taking among both HIV-negative MSM (Colfax et al., 2004; Stueve, O'Donnell, Duran, San Doval, & Geier, 2002; Vanable et al., 2004) and HIV-positive MSM (Parsons & Halkitis, 2002; Purcell, Parsons, Halkitis, Mizuno, & Woods, 2001; Semple, Patterson, & Grant, 2003; Wolitski, Parsons, & Gomez, 2004). Although the specific nature of the relationship between drinking and risky sex remains largely unexplained, both global and event-level studies have found strong positive correlations between alcohol use and unprotected sex (Colfax et al., 2004; Irwin, Morgenstern, Parsons, Wainberg, & Labouvie, 2006; Leigh & Stall, 1993; Stall & Purcell, 2000; Vanable et al., 2004). The evidence for event-level associations is found in studies that utilized samples of HIV-negative MSM. It is less clear to what degree event-level associations between alcohol use and unprotected sex exist among HIV-positive MSM.

In addition to the concerns about the role that alcohol use may play in the sexual risk practices of HIV-positive MSM, alcohol consumption by HIV-positive persons is an important issue with significant implications for overall health and immune functioning (Bing et al., 2001; Kresina et al., 2002; Lucas, Gebo, Chaisson, & Moore, 2002; Meyerhoff, 2001; Nath et al., 2002). HIV-positive persons often report high levels of alcohol use and alcohol-use disorders (Beltrami, Fann, & Toomey, 2000; Galvan et al., 2002; Kresina et al., 2002; Lightfoot et al., 2005; Stein et al., 2000). Deleterious effects on virologic response have been identified, such that heavy alcohol users are less likely to respond positively to HIV medication regimens (Ena, Amador, Benito, Fenoll, & Pasquau, 2003; Miguez, Burbano, Morales, & Shor-Posner, 2001; Palepu, Horton, Tibbetts, Meli, & Samet, 2004). HIV medication adherence has been shown to be negatively affected by alcohol use and by heavy drinking in particular (Cook et al., 2001; Halkitis, Parsons, Wolitski, & Remien, 2003; Martini et al., 2004; Murphy, Marelich, Hoffman, & Steers, 2004; Parsons, Golub, Rosof, & Holder, 2007; Parsons, Rosof, & Mustanski, 2007; Samet, Horton, Meli, Freedberg, & Palepu, 2004; Tucker, Burnam, Sherbourne, Kung, & Gifford, 2003). As such, reductions in alcohol use among those living with HIV are critically important for individuals to maximally benefit from HIV treatment advances.

The purpose of this study was to evaluate the efficacy of a theory-based intervention designed to reduce both alcohol use and incidence of unprotected sexual behaviors among HIV-positive MSM with alcohol use disorders. Specifically, a randomized clinical trial was conducted in which an integrated, manualized intervention—using both individual counseling and peer group education/support—was compared with a control condition in which participants received resource referrals. We hypothesized that the eight-session integrated intervention, which was based on the transtheoretical model (TTM) and used motivational interviewing (MI), would result in greater reductions in alcohol use (i.e., number of drinking days, number of drinks, and number of heavy drinking days), risky sex

(any anal sex without a condom), and number of days in which drinking and risky sex occurred.

Method

Participants

Participants were recruited over a 3.5-year period beginning in April 1999. The recruitment efforts were based on a targeted sampling strategy to enhance the degree to which the sample includes participants who come from a variety of backgrounds; reside within different social circles; and participate, to varying degrees, in gay, bisexual, and/or HIV/AIDS communities. Two different recruitment strategies were used. In the first, *active recruitment*, recruiters went into AIDS service organizations and other mainstream venues (e.g., bars, cafes, and streets in predominantly gay neighborhoods), described the study, encouraged participation, and provided phone numbers to enroll. In the second, *passive recruitment*, “tear-off flyers,” study cards, and other materials about the study were left in stores, AIDS service agencies, and other venues. Also, advertisements were placed in gay and mainstream publications, and referrals to friends were encouraged. Substantial efforts were made to ensure that an ethnically diverse sample was obtained. These efforts included specific targeting of venues serving the needs of HIV-positive MSM of color.

Men responding to the recruitment efforts were screened by telephone to determine eligibility. Individuals were eligible if they (a) had anal or oral sex with another man in the past 3 months, (b) scored 8 or above on the Alcohol Use Disorders Identification Test (AUDIT; Babor, de la Fuente, Saunders, & Grant, 1992), (c) were able to provide adequate contact and locator information, (d) were not currently enrolled in an HIV-related behavioral intervention, (e) did not have current psychotic symptoms as assessed through the Psychotic Screening module of the Structured Clinical Interview (SCID-P; Spitzer, Williams, Gibbon, & First, 1992), and (f) were English speaking.

Individuals who were interested and eligible were then scheduled for a baseline interview. At the baseline interview, participants provided informed consent and then completed the self-administered baseline measures. Participants were paid \$30 for participating in the baseline assessment.

A total of 513 persons called the project line for initial screening, of which 487 identified as HIV-positive MSM age 18 years or older, and they were subsequently screened for eligibility (see Figure 1). A total of 117 (24.0%) men were not eligible because they failed to meet eligibility criteria at the time of phone screening. Of the 370 eligible participants, 22 (5.9%) were not interested in the study, and 69 (18.6%) failed to show up for their scheduled (or rescheduled) baseline interview. Of the 279 men presenting for baseline assessment, 17 (6.1%) were excluded because of comorbidity with Axis I disorders, and 9 (3.2%) were excluded for not currently meeting eligibility requirements (e.g., no longer sexually active, not enough problem drinking). This resulted in 253 confirmed eligible participants who completed the baseline assessment and who were randomized to the intervention condition ($n = 118$) or the control condition ($n = 135$). There were no significant differences in AUDIT scores between those eligible who did not show for their baseline assessments ($M = 22.28$; $n = 69$), those excluded prior to baseline ($M = 23.04$; $n = 26$), and those who completed the baseline assessment ($M = 21.93$; $n = 253$). Using power simulations of a repeated measures general linear model, assuming an effect size of 5% of the variance, we determined that a sample size of 200, after attrition, would provide an estimated power related to the treatment effect of .95.

All 253 participants were biological men; 1.6% ($n = 4$) reported being transgendered but had not undergone sexual reassignment surgery. The mean age was 38.6 years ($SD = 6.73$), and ages ranged from 19 to 61 years. The sample was ethnically diverse, with 79.0% ($n = 200$) identifying as men of color. The majority of participants (73.1%; $n = 185$) identified as gay or homosexual. Most of the participants (85.4%; $n = 216$) had at least a high school education or equivalent, and 59 (23.4%) had a college degree. Less than half (42.7%; $n = 108$) reported some form of employment, and 27.3% ($n = 69$) were on disability. One third of the sample (34.0%; $n = 86$) reported some previous incarceration (see Table 1 for detailed sociodemographics).

Participants had tested HIV-positive an average of 10 years ($SD = 4.73$) prior to the baseline assessment, and the mean for the most recent CD4 count was 419 ($SD = 264$). For self-reported viral load, 33.6% ($n = 85$) reported an undetectable viral load, and 9.9% ($n = 25$) reported that they did not know their viral load. Slightly over half of participants reported not having an AIDS diagnosis (54.9%; $n = 139$). The majority reported having some access to HIV medical care (97.2%; $n = 246$) and having some form of health insurance (85.8%; $n = 217$). Differential effects by race/ethnicity were found; White participants had tested positive for HIV for more years than African American or Latino men, $F(3, 244) = 3.18, p < .05$. This may be an artifact of more recent emphasis on testing and prevention for non-White groups, or it may represent a cultural difference in terms of reluctance of men of color to identify as gay or homosexual, resulting in delay in diagnosis. No differential effects by race/ethnicity were found for CD4 count, viral load, or AIDS diagnosis.

Design and Procedure

Participants were randomized to condition (either an eight-session integrated intervention or a resource referral condition) at the baseline assessment, using concealment of allocation procedures. Prior to enrollment, investigators off-site used a random-number table to generate the allocation sequence. Sealed, opaque envelopes were created by the off-site team, containing assignment, and sent to the field staff. Assessment interviewers were blind to condition until after the assessment. As participants completed baseline assessments, the sealed envelopes were opened and used to execute the assignments.

As participants were randomized to condition, cohorts of approximately 12–15 study participants were formed for the intervention condition. Forming intervention cohorts allowed for the group component of the intervention. The baseline assessment provided the reference point for the follow-up assessments, with follow-up assessments administered at 3, 6, 9, and 12 months postbaseline. Participants were paid \$30 for each follow-up assessment. If a participant missed a particular follow-up assessment interview, alcohol use and sexual activity for the missed outcome period were captured at a subsequent follow-up assessment using the Timeline Followback Interview (TLFB; Sobell & Sobell, 1992).

Study Conditions

Intervention condition—The goal of the intervention was to test the effectiveness of a TTM- and MI-based intervention to reduce the sexual transmission of HIV through promotion of two target behaviors: abstinence from or reduction in alcohol use and reduction of incidence of unprotected sexual practices. The intervention was based on two proven interventions employing the TTM's stages of change (SOC), processes of change (POC), and MI. These were the Hemophilia Behavioral Intervention Evaluation Project (HBIEP; Parsons, Huszti, Crudder, Rich, & Mendoza, 2000), an intervention developed to reduce the transmission of HIV from HIV-positive men with hemophilia to their HIV-negative sexual partners, and motivational enhancement therapy (MET), which was developed as one of the three treatments to address alcohol abuse in Project MATCH

(Miller, Zweben, DiClemente, & Rychtarik, 1992). The intervention in this study was a mixed-format intervention designed to integrate these two strong theory- and research-based approaches: (a) individual MI-based sessions designed to promote alcohol abstinence with alcohol-abusing clients and (b) group sessions using SOC- and POC-based activities designed to promote the consistent use of safer sex among HIV-positive MSM at risk for transmitting HIV to their sexual partners. By linking the two approaches, the integrated intervention maximizes the potential impact for both target behaviors. The intervention content and design were informed by a panel of investigators and advisors with significant expertise in the development of HIV prevention interventions, individual and group therapy, and HBIEP and MET. The manual development process involved a series of discussions in which the experts reviewed the materials from the HBIEP and MET manuals and adapted the components they considered to be the most relevant to the present population and study.

The TTM constructs provided a guiding framework for the intervention sessions, which were tailored to the clients' stage of change. The interventions used specific experiential and behavioral POC-based activities designed to promote movement through the SOC, depending on the client's level of readiness. The interventions also focused on the decisional balance, temptation, and confidence levels of the client. The MI counseling style guided the client to explore and resolve ambivalence about changing while highlighting and increasing perceived discrepancy between current behaviors and overall goals and values (Miller & Rollnick, 2001).

Therapists using MI express empathy, manage resistance without confrontation, and support the self-efficacy of the individual, using counseling techniques such as open questions, reflective listening, summarizing, and affirming (Miller & Rollnick, 2001). Studies have supported the efficacy of MI to reduce drinking and enhance treatment engagement among problem and dependent drinkers across diverse populations (Dench & Bennett, 2000; Handmaker, Miller, & Manicke, 1999; Hester, Squires, & Delaney, 2005; Hettema, Steele, & Miller, 2005; Irwin et al., 2006; Juarez, Walters, Daugherty, & Radi, 2006; Monti et al., 1999; Morgenstern et al., 2007; Project MATCH Research Group, 1998; Vasilaki, Hosier, & Cox, 2006). Thus, MI has been used successfully with several populations similar to the target population of the present study (i.e., not necessarily viewing their drinking as a problem). However, studies of the impact of MI- and TTM-based treatment on drinking and safer sex in HIV-positive individuals are lacking.

Training—A total of nine therapists and four peer counselors participated in delivering the intervention condition. The therapists providing the four individual sessions were master's- or doctoral-level clinical and counseling psychologists or trainees. Therapists received local training in MI by an experienced MI trainer (a member of the Motivational Interviewing Network of Trainers) and centralized training in the study protocol. Each therapist saw at least 2 "pilot" participants through all four sessions with extensive supervision before being qualified as a "Positive Choices" therapist. Additionally, they received ongoing weekly supervision, from the MI expert, that included review and rating of videotaped sessions. The peer counselors who conducted the group sessions were self-identified HIV-positive gay men. The peer counselors attended a 2-day workshop in conducting brief motivational interventions prior to conducting groups, but they did not receive intensive training in MI. Peer counselors received supervision immediately following each group session and participated in monthly supervision sessions.

Control condition—Participants in the control condition were provided with a detailed referral guide to community-based agencies and programs focused on alcohol issues, HIV, and safer sex. In addition, participants received a "fact sheet" outlining information regarding potential interactions between alcohol and HIV medications. The control group

was not matched with the experimental group as to time and attention but rather received educational materials about HIV and alcohol use, advice to stop drinking or to drink below risky levels, and comprehensive referral information for local programs and resources.

Intervention Protocol

The intervention was guided by a manual that was adapted in part from the MET and HBIEP manualized interventions. The manual, designed specifically for this study (“Positive Choices”), delineated both the style and techniques to be incorporated at each intervention session. Discussions in each session were tailored to each participant’s self-rated stage of change. Each session also focused on the TTM’s POC, which are defined as the coping activities that help a person move through the SOC. The mixed format intervention began with two individual modified MET (Miller et al., 1992) sessions that focused on alcohol and its relation to sexual behaviors and HIV. These sessions were followed by the four group, stage-based sessions from HBIEP (Parsons et al., 2000) that focused on HIV risk reduction and safer sexual behaviors. Finally, there were two individual modified-MET sessions that focused on integrating the effects of the prior individual and group sessions on both behaviors. The sessions were “sandwiched” to provide participants with (a) two sessions of individualized attention and focus on MI, followed by (b) opportunities to address skills building in a group setting, followed by (c) more individualized attention and relapse prevention during the final two sessions. The first two individual sessions were also designed to alleviate participant anxieties about group sessions and to prepare them for the group experience. The final two individual sessions permitted an opportunity to process individually lessons learned from the group.

The four individual sessions were organized as follows:

1. The goal of Session 1 was to present factual information on the impact of alcohol on sexual behaviors. Session 1 consisted of (a) rapport-building; (b) assessment of readiness to change and confidence in changing; (c) review of a fact sheet on risky sexual behavior and the spread of sexually transmitted diseases and HIV, the health risks of drinking alcohol for HIV-positive individuals, and the interaction of alcohol and HIV medications; and (d) a decisional balance exercise examining the pros and cons of changing drinking and adopting safe sex practices.
2. In Session 2, the client was provided with norms-based, but personalized, feedback derived from the participant’s baseline assessment measures. The feedback report included personal risk factors for drinking based on AUDIT score and the number of standard drinks consumed per week. The report also included information on how the participant’s drinking compared with norms from the adult male population, as well as to gay men in New York City. In addition, the report included a graph depicting the participant’s temptation and confidence profiles for both alcohol and risky sex. Therapists discussed each aspect of the report and used MI, in particular, to elicit intention to change the target behaviors. Participants were also encouraged to articulate goals and develop change plans for the two behaviors in Session 2.
3. The goals in Session 3 (provided after completion of the four peer-led group sessions) were to motivate the client to change the target behaviors and to decrease his temptation to engage in risk behavior and increase his confidence to avoid it. Session 3 consisted of the therapist’s reassessment of the client’s stage of change for alcohol and safer sex. The client’s decisional balance exercises from Session 1 were reviewed and revised as necessary. The TTM experiential or behavioral POC were particularly emphasized in Session 3, with the therapist concentrating on any processes that the client seemed to be underutilizing. Therapists chose processes to

focus on that were most relevant to the client's stage of change for each target behavior.

4. Session 4 continued the goals of session three with a specific focus on goal setting and the development and revision of change plans first approached in Session 2. Session 4 consisted of the therapist's review—and revision, as appropriate—of the client's change plan. Barriers were discussed, and therapists focused on increasing the client's self-efficacy for overcoming barriers and achieving his goals. Each client was presented with a laminated business card that listed the client's most highly endorsed pro for each of two target behaviors (on the basis of the decisional balance exercise from the previous session).

The four peer-led group sessions were also based on the TTM stages and POC and were delivered using MI strategies. Peer counselors focused on HIV risk reduction and the adoption and maintenance of safer sexual behaviors (consistent condom use or abstinence). At the onset of each group, the clients completed an algorithm to identify their current SOC for consistent use of condoms or abstinence. On the basis of the SOC of the majority of the clients, peer counselors then selected a POC-based activity from the 24 different POC-based activities outlined in the intervention manual. Because the TTM recognizes the potential for relapse, even among those in the action and maintenance stages, several POC-based activities emphasized relapse prevention techniques. The four weekly group sessions each followed the same structure: SOC assessment/scoring, selection of a POC-based activity, activity implementation, discussion, and feedback. This approach fostered group discussion and enabled clients to share their ideas and experiences with strategies for practicing safer sex. These interactive dialogues were aimed at promoting group norms and peer support for safer sexual behaviors. The peer counselors concluded the activity by providing feedback and, when appropriate, by assigning homework.

Primary Outcome Measures

A comprehensive battery of assessments was collected at 3-month intervals, from intake to 12 months postintake. The assessments were self-report and included a combination of paper and pencil instruments, completed by the participant, and interviewer-administered instruments completed with the assistance of the study interviewer. Assessments took approximately 90–120 min to complete and included the following: (a) demographics; (b) physical and mental health status; (c) gay community involvement and social support; (d) sexual relationships and activities, including prevalence and frequency of sexual behaviors by partner type (primary vs. casual) and partner serostatus (known HIV-positive, known HIV-negative, or HIV serostatus unknown) over the last 3 months; (e) HIV medication regimen and adherence; (f) prevalence and frequency of alcohol and other drug use; and (g) the TTM constructs—SOC and POC, decisional balance, and self-efficacy—for safer sexual behavior and alcohol use. Detailed information about alcohol use and unprotected sex was collected through the use of the TLFB. This semistructured interviewer-administered assessment begins by working with the participant to personalize a calendar of the past 90 days (30 days at baseline) to help prompt memory recall for drinking and sexual activities. The TLFB allowed for the collection of primary outcome data for previous follow-up periods that may have been missed for a particular participant (see Figure 1). TLFB measures have demonstrated good test–retest reliability, convergent validity, and agreement with collateral reports for daily drinking (Sobell, Brown, Leo, & Sobell, 1996) and for sexual behavior (Carey, Carey, Maisto, Gordon, & Weinhardt, 2001; Weinhardt et al., 1998). Specific quantities of alcohol consumed and sexual activity were collected for each day of the 30-day period prior to the intake assessment and for each 30-day period from the intake assessment up to the 12-month follow-up assessment. The 3-month assessment covered treatment phase alcohol consumption and sexual activity, whereas the 6-, 9-, and

12-month assessments represented posttreatment phase alcohol consumption and sexual activity. Daily alcohol consumption was recorded as number of standard drinks. The unit, known as a *standard drink*, is 0.6 ounces absolute ethanol by volume. In general, 12 ounces of beer, 4 ounces of wine, and 1.5 ounces of liquor are each equal to 1 standard drink. For sexual activity, participants reported any anal sex, whether a condom was used, partner type (primary or casual), and serostatus of the partner.

Outcome variables were calculated for each 30-day period from 30 days prior to intake to 12 months postintake. The primary outcome variables included the following for each 30-day period: (a) number of standard drinks (mean number of drinks), (b) number of drinking days (mean number of drinking days), (c) number of days of unprotected sex (mean number of days in which any anal sex occurred and a condom was not used), (d) number of heavy drinking days (mean number of days in which participant reported ≥ 5 drinks in one day), and (e) the number of days in which both drinking and unsafe sex occurred (mean number of days in which both drinking and any anal sex occurred without the use of a condom). In addition, in an exploratory analysis, we examined the number of days when both heavy drinking and unprotected sex occurred (mean number of days in which participant consumed ≥ 5 drinks and had any anal sex without the use of a condom). The cutoff for heavy drinking days was established in accordance with National Institute on Alcohol Abuse and Alcoholism (2007) guidelines.

Results

The effects of the intervention on risk drinking and unprotected sex variables were assessed to determine whether the treatment decreased the target behaviors, both independently and jointly. We determined estimates of treatment effects on the at-risk behaviors using generalized estimating equations with repeated measures count data. Outcome variables in this category were the number of days on which the behaviors, as defined above, occurred over each 30-day period.

To capture nonlinearities in temporal change over each of the 30-day periods for which the postintake outcome variables were calculated, we modeled time as a categorical variable with 12 levels. The time effect can best be seen through a graphical representation (see Figures 2, 3, 4, 5, and 6).

Alcohol consumption and unprotected sex outcomes were calculated for each 30-day period for participants in the treatment group ($n = 95$) compared with those in the control group ($n = 121$) over the 12 months of the study (see Table 2 for each outcome variable).

A main effect for treatment was found on number of drinks per 30-day period. Participants in the control group drank 1.38 times the number of drinks per 30-day period, on average, than participants in the treatment group (odds ratio [OR] = 1.38; 95% confidence interval [CI] = 1.02–1.86) consumed. A main treatment effect was also found for heavy drinking days per 30-day period. Participants in the control group had a higher number of heavy drinking days per 30-day period by a factor of 1.5 (OR = 1.5; 95% CI = 1.08–2.10).

In the evaluation of the alcohol consumption outcomes across time, an overall decline in the number of drinks, the number of drinking days, and the number of heavy drinking days per 30-day period was found for both groups (see Figures 2–6). Examination of unprotected sex per 30-day period also showed a time effect indicated by an overall reduction of the number of unprotected sex days over time for both the intervention and control groups.

Further analyses revealed that at baseline, 44% of the participants had not had any days of both heavy drinking and unprotected sex in the prior 30 days. In consideration of the clients

who at baseline had zero at-risk behavior days of heavy drinking and unprotected sex, through exploratory analyses, we split the sample into four groups. These groups represented the two treatment conditions and the presence or absence of any days of both heavy drinking and unprotected sex: (a) treatment/baseline heavy drinking and unprotected sex days ($n = 62$), (b) control group/baseline heavy drinking and unprotected sex days ($n = 58$), (c) treatment/no baseline heavy drinking and unprotected sex days ($n = 56$), and (d) control group/no baseline heavy drinking and unprotected sex days ($n = 77$). We used a repeated measures Poisson regression that incorporated the generalized estimating equations methodology to examine the number of at-risk behavior days per 30-day period on which both heavy drinking and unprotected sex occurred for the four groups.

An interaction between the four groups and time predicted subsequent occurrences of same-day heavy drinking and unprotected sex, $\chi^2(33, N = 216) = 67.5, p < .001$. Contrasts between groups revealed that for those participants who had baseline heavy-drinking and unprotected-sex days (at-risk behavior days), those in the control group had a higher number of at-risk behavior days at follow-up than those in the treatment condition by a factor of 2.19 (OR = 2.19; 95% CI = 1.17–4.11).

Discussion

It appears that the treatment is effective in reducing alcohol consumption among the target population. The treatment condition predicted reductions in both number of drinks consumed per 30-day period and number of heavy-drinking days per 30-day period. Given the problems—both in terms of virologic response to medication and medication adherence—that alcohol use or abuse posits for persons with HIV, a reduction in alcohol consumption has significant implications for this population.

A major finding was an effect of the manualized integrated TTM/MI intervention in reducing the number of days on which both heavy drinking and unprotected sex occurred (at-risk behavior days). Clients in the control condition were twice as likely to have at-risk behavior days as were clients in the treatment condition. It is worth noting that nearly half ($n = 70$; 44%) of the participants did not report any days in the baseline period in which both heavy drinking and unprotected sex occurred. Although event-level analysis was not the focus of the study, the prior literature surrounding the relationship between drinking and unprotected sex has been conducted with HIV-negative men, and the association has not been well established for the HIV-positive population. Additional research is needed to explore the association between alcohol use and unprotected sex in HIV-positive men.

The intervention did not show interaction or main effects for either number of drinking days per 30-day period or number of days of unprotected sex. However, as with number of drinks and number of heavy drinking days, both of these variables exhibited a time effect. For all of these outcomes, their frequency or quantity generally decreased over time across the two conditions. There are a number of plausible explanations for the lack of an intervention by time effect. It could be the result of small effect sizes or that the effect of the intervention tended to level off over time, reducing the overall difference between the treatment and the control groups. Another possible explanation is a measurement effect. Frequent and intensive research follow-up procedures that include detailed self-report data about the participant's drinking have been linked to a greater degree of research reactivity. The presence of reactivity effects suggests that a control group receiving frequent follow-ups is actually receiving an intervention, which could obscure differences between the treatment group and control groups (Clifford & Maisto, 2000). This appears to be particularly true when measures, such as the TLFB, are administered face-to-face as in the current study (Worden, McCrady & Epstein, 2007). Thus, it would appear that the mere fact of asking

clients repeatedly about their number of drinking days, or about unprotected sex, may have had the effect of reducing these unwanted and risky behaviors.

Additionally, the study was limited in geographic scope. Future studies may benefit from expanding the geographic catchment area. Because of other factors in the study, it was not feasible to restrict the inclusion criteria to include only those respondents who have engaged in unprotected insertive or receptive anal sex; furthermore, on the basis of the literature at that time, we did not foresee any need to do so. In any event, restricting the criteria in this way, given a limited geographic area, likely would have resulted in insufficient sample size. Expanding the catchment area in future studies would increase the probability of selecting a sufficiently large sample of respondents engaging in at-risk sexual behavior, enabling the investigators to restrict the inclusion criteria.

In spite of these limitations, the study provides promising evidence that an integrated treatment approach incorporating the TTM and MI may have significant desirable effects for the health of HIV-positive men, in terms of the association between heavy drinking and unprotected sex, as well as medication compliance and virologic response gains resulting from reduced consumption of alcohol. Further refinements of the intervention, along with dismantling studies to determine the most efficacious elements of the intervention, are warranted by these results.

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Figure 1.
Consolidated Standards of Reporting Trials (CONSORT) chart. mos. = months; TLFB = Timeline Followback Interview.

Figure 2.
Number of standard drinks.

Figure 3.
Number of days of drinking.

Figure 4.
Number of heavy drinking days.

Figure 5.
Number of days of unprotected sex.

Figure 6.
Number of days of drinking and unprotected sex.

Table 1

Characteristics of Study Participants at Baseline (N = 253)

Characteristic	Treatment (n = 118)		Control (n = 135)	
	n	%	n	%
Race/ethnicity				
African American	66	55.9	70	51.9
Latino/Hispanic	17	14.4	33	24.4
White	21	17.8	22	16.3
Other	14	11.9	10	7.4
Sexual orientation				
Gay/homosexual	89	75.4	96	71.1
Bisexual	26	22.0	37	27.4
Other/unsure	3	2.6	2	1.5
Educational level				
Eighth grade or less	2	1.8	2	1.5
Some high school	12	10.2	20	14.8
Graduated high school/GED	34	28.8	44	32.6
Some college	38	32.2	41	30.4
Bachelor's degree	23	19.5	23	17.0
Postgraduate degree	8	6.7	5	3.7
Employment				
Full-time	28	23.7	26	19.5
Part-time/odd jobs	27	22.9	27	20.3
Unemployed	21	17.8	30	22.5
Disabled	35	29.7	34	25.6
Institutionalized (jail, hospital)	2	1.7	3	2.3
Other	5	4.2	4	3.0
Previous time incarcerated				
None	72	61.0	90	66.7
1–6 months	25	21.2	18	13.3
7–12 months	5	4.2	5	3.7
1–5 years	8	6.8	11	8.2
6–10 years	6	5.1	9	6.6
10+ years	2	1.7	2	1.5
No. of times treated for alcohol abuse				
0 times	52	44.1	66	48.9
1–3 times	43	36.4	39	28.9
4+ times	23	19.5	30	22.2
No. of times treated for drug abuse				
0 times	64	54.2	71	52.6
1–3 times	41	34.8	37	27.4
4+ times	13	11.0	27	20.0

Note. No significant difference was found between treatment and control groups in baseline characteristics.

Table 2

Primary Outcome Variables by Condition

	Effect					
	Time		Treatment		Time × Treatment	
	$\chi^2(11)$	<i>p</i>	$\chi^2(1)$	<i>p</i>	$\chi^2(11)$	<i>p</i>
Outcome/30 days						
No. of standard drinks	47.25	.001	4.36	.037	17.73	.088
No. of days of drinking	30.38	.001	2.71	.100	18.95	.062
No. of heavy drinking days	28.74	.003	5.79	.016	17.82	.086
No. of days of unprotected sex	24.64	.010	0.12	.734	4.96	.933
No. of days of drinking and unprotected sex	16.00	.141	2.30	.130	13.28	.275