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A Randomized Controlled Trial Utilizing Motivational Interviewing to Reduce HIV Risk and Drug Use in Young Gay and Bisexual Men

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Abstract

Objective—Young gay and bisexual men (YGBM) are disproportionately at risk of HIV infection due to sexual risk behaviors, which are often exacerbated by recreational drug use. However, there have been no evidence-based interventions targeting young substance-using YGBM. This study was designed to test a brief Motivational Interviewing (MI) intervention to reduce both risky sex and drug use among HIV-negative YGBM.

Method—A total of 143 non-treatment seeking YGBM (ages 18–29) who reported recent unprotected anal intercourse (UAI) and recreational drug use were randomized to four sessions of MI or four sessions of content-matched education. Participants were followed every three months for one year and behavior change was examined across conditions and time for aggregated and day-level drug use and UAI.

Results—Regardless of condition, participants reported significant reductions in UAI and substance use over time. However, YGBM in the MI condition were 18% less likely to use drugs and 24% less likely to engage in UAI than YGBM in the education condition.

Conclusions—The results support the utility of MI, compared to a content-matched education condition, to significantly reduce both UAI and drug use among YGBM. Interventions may benefit from placing emphasis on substance use reductions, which might indirectly lead to less frequent UAI. Future research efforts should examine whether this type of brief MI intervention is effective when delivered by clinic or community settings utilized by YGBM.

Keywords

young gay and bisexual men; HIV prevention intervention; Motivational Interviewing; substance use; sexual risk

INTRODUCTION

Young gay and bisexual men (YGBM) are at disproportionate risk of HIV infection, with 73% of new infections among 13–24 year-old males in the US being attributed to male-to-male sexual transmission (Centers for Disease Control and Prevention, 2011). Particularly susceptible to HIV infection are YGBM who use recreational drugs. In fact, some have argued that drug-using, specifically methamphetamine using, GBM are fueling the epidemic (Shoptaw & Reback, 2006). Polydrug use is common among YGBM (Corliss et al., 2010; Thiede et al., 2003), and “club drugs,” such as cocaine, methamphetamine, ecstasy, ketamine and gamma hydroxybutyrate (GHB), are commonly used, often in association with sexual activity (Kelly, Parsons, & Wells, 2006; Parsons, Halkitis, & Bimbi, 2006; Romanelli, Smith, & Pomeroy, 2003). Further, it is particularly critical to examine the relationship between substance use and sexual risk at a day-level (Vosburgh, Mansergh, Sullivan, & Purcell, 2012), as research with YGBM has shown that the odds of having unprotected anal intercourse (UAI) increase two-fold if the sexual encounter takes place on a day when drugs were used (Parsons, Lelutiu-Weinberger, Botsko, & Golub, 2013).

YGBM who use drugs and engage in UAI are in critical need of behavioral interventions. However, there are several major challenges clinicians and researchers face in working with this population. First, engaging YGBM in interventions has proven to be difficult (Parsons, Vial, Starks, & Golub, 2013) due to several factors such as generational shifts in perception of HIV threat, weakened sense of a gay community, and research fatigue (Jenkins, 2012). Second, as a matter of self-risk perception, YGBM who engage in episodic concomitant substance use and UAI are unresponsive to studies that they believe target those with more serious “problems” (Jenkins, 2012), therefore selecting themselves out of research opportunities. Third, previous intervention efforts to reduce HIV risk among substance-using GBM, although not specifically for YGBM, have lacked robust efficacious outcomes. One RCT utilizing motivational interviewing (MI) compared to an education condition for non-treatment seeking GBM yielded a modest effect size in lowering club drug use for those with low severity of dependence, but did not show significant reductions in UAI (Morgenstern et al., 2009). Further, in a group-based intervention for substance-using GBM in four cities, there were no differential reductions in the sex and drug risk behaviors between men in the intervention and those in the control group (Mansergh et al., 2010). While these interventions were not specifically designed for YGBM, age plays a significant role in individuals’ perceptions of and engagement in risk, given the socio-cultural contexts within which different cohorts of GBM develop, such as developments in HIV treatment and prevention, LGBT-related legislative strides, or increasing societal acceptance of variability in sexual identity (Lelutiu-Weinberger et al., 2013). These socio-cultural changes may buffer against or facilitate risk for GBM of different generations, therefore, an intervention that resonates with older GBM may be less meaningful to YGBM and potentially less efficacious.

Non-treatment seeking YGBM need to be targeted in a way that is not threatening and reaches those who are ambivalent about changing their risk behavior (Parsons, Vial, et al., 2013). An intervention approach ideally suited for such YGBM is MI, a collaborative, participant-centered therapeutic approach to strengthening motivation for change (Miller & Rollnick, 2009). MI has been validated empirically across several problem behaviors (Arkowitz, Westra, & Miller, 2007; Burke, Arkowitz, & Menchola, 2003; Hettema, Steele, & Miller, 2005), including substance use (Miller, Zweben, DiClemente, & Rychtarik, 1992). Despite support for the efficacy of MI in reducing risk behavior in HIV-seropositive populations (Naar-King, Parsons, & Johnson, 2012), research is inconclusive regarding the effects of MI for HIV-negative GBM. Although Project Explore, a randomized controlled trial (RCT) testing the efficacy of MI over 10 sessions for HIV-negative GBM, found

significant intervention effects on HIV incidence and UAI (Koblin, 2004), some recent reviews have questioned the efficacy of MI for reducing risky sex among GBM (Berg, Ross, & Tikkanen, 2011; Lundahl & Burke, 2009; Smedslund et al., 2011), while others have found that MI was more effective in reducing substance use than UAI among adult GBM (Berg et al., 2011; Morgenstern et al., 2009). Despite some evidence of MI reducing risky behaviors for certain sub-populations, further investigation is needed to determine its efficacy among HIV-negative substance-using YGBM.

Towards this purpose, we conducted an RCT designed to reduce both substance use and UAI among non-treatment seeking YGBM using a brief MI intervention that, if efficacious, could readily be adopted by direct service providers and administered within clinic or community settings. Four sessions of MI focused on reducing drug use and UAI were compared to four sessions of content-matched education, as we did not believe it was ethically appropriate to offer a wait-list control or a time-matched control focused on other behaviors to a sample who reported engagement in both behaviors at baseline. We hypothesized that those randomized to receive MI would report greater reductions in substance use and UAI over time, compared to those randomized to education.

METHODS

Sample and Procedures

Eligible YGBM enrolled in the Young Men's Health Project (YMHP) (Parsons, Lelutiu-Weinberger, et al., 2013) were male, resided in the New York City (NYC) metropolitan area, 18–29 years of age, reported a negative or unknown HIV status, at least five days of drug use (specifically cocaine, methamphetamine, gamma hydroxybutyrate, ecstasy, ketamine, or poppers) and at least one incident of UAI with a high risk male partner (HIV-positive or unknown status main partner, or a casual partner of any HIV status) in the last 90 days. Between September 2007 and August 2010, YGBM were recruited through a multi-method approach implemented in diverse geographic areas of NYC using techniques previously effective in the recruitment and enrollment of substance-using GBM (Groß, Bux, Parsons, & Morgenstern, 2009; Morgenstern et al., 2009; Parsons, Vial, et al., 2013). Both active and passive recruitment strategies were used. For active recruitment, recruiters screened potential participants for eligibility using Palm Pilots in a variety of venues catering to YGBM - including bars, clubs, sex venues, streets in predominately gay neighborhoods, and at LGBT community events. For passive recruitment, tear-off flyers and project recruitment cards were distributed to potential participants or left on premises, and advertisements were placed in gay and non-gay publications. These approaches were supplemented with internet-based efforts (recruitment via chat rooms and banner advertisements) and friendship referrals. For the final sample, 71% were enrolled through active field recruitment, 12% through passive recruitment, 9% through internet-based efforts, and 8% through friendship referrals. In examining the geographic representation of the sample, participants reported residing in 68 NYC zip codes with no more than 3.5% of the sample living in any one zip code.

Contact information from potential participants was used to conduct a more thorough second eligibility screening over the phone. Those eligible and interested were scheduled for a baseline appointment. Upon arrival at the research center, trained staff reviewed together with participants the informed consent forms in a private room, during which all study details were explained and participants' questions were answered. The baseline assessment included the completion of a survey pertaining to participants' psychosocial characteristics, which was conducted via audio computer-assisted self-interview (ACASI) software. Participants also completed an interviewer-administered timeline follow back (TLFB) calendar of substance use and sexual behaviors for the past 30 days (Sobell & Sobell, 1995).

In order to minimize potential bias created by having the same staff who assessed participants' risk behavior deliver the intervention, different staff members were used for TLFB assessment and delivery of MI or education sessions, and assessors were blind to participants' condition as randomization occurred at the end of the baseline assessment. YGBM returned for follow-up assessments at 3, 6, 9, and 12 months post-baseline, and retention was high (See Figure 1). Participants were compensated \$40 for the 2-hour baseline assessment, and this amount increased by \$5 for each subsequent follow-up. All procedures were approved by and conducted in compliance with the Hunter College Institutional Review Board.

Upon completion of the baseline assessment, YGBM were offered the option to enroll in the trial. Chi-square tests of association and student *t*-tests ($p > .05$) indicated no significant differences in demographics or primary outcome variables between those who agreed to randomization ($n = 143$) and those who refused ($n = 57$). YGBM were randomized using urn randomization procedures, which are systematically biased in favor of balancing groups (Stout, Wirtz, Carbonari, & Del-Boca, 1994). The first intervention session occurred immediately after the baseline assessment, conducted by either a therapist (MI condition) or a research assistant (education condition). Sessions were one hour in duration, and participants had a window of 12 weeks to complete all 4 sessions, regardless of condition.

Motivational Interviewing Intervention

The Motivational Interviewing Intervention (MI) was designed to provide information about club drugs and the risk of UAI with casual male partners, to enhance motivation and personal responsibility, and establish goals for reducing both target behaviors. MI allows therapists to match targeted information to the particulars of each client's motivation for change. The YMHP project specifically targeted non-treatment seeking YGBM who were likely to be ambivalent about change, compared to those who sought treatment or therapy.

MI sessions were delivered by Masters- and PhD-level therapists who participated in a three-day MI training, and received weekly individual and group supervision throughout the project. Therapists were trained by the Principal Investigator, who has substantial experience in conducting MI training, was a member of the Motivational Interviewing Network of Trainers (MINT), and completed the MI train-the-trainer program delivered by Miller and Rollnick. A detailed manual was developed, pilot-tested and further refined for the purposes of training and as a guide for therapists. The initial training included a review of MI principles, techniques, and goals, as well as role-play exercises for each session to familiarize therapists with the nature of the sessions and to reduce idiosyncratic delivery. Upon completion of the initial training, therapists engaged in 2–3 pilot cases. Based on feedback from these cases, the MI manual was revised and relevant supervision provided. In order to control for therapist effects, we trained twelve therapists for the RCT. Post hoc analyses of our time series data sets using multi-level modeling techniques showed that there were no statistically significant cross-time differences in our reported substance use and UAI outcomes by therapist assignment.

All MI sessions were video recorded (with the camera recording the therapist's image and the therapist's and participant's voice), and therapists met bi-weekly in supervision to view videotapes and discuss implementation issues. Eighty percent of all MI sessions were reviewed by a licensed clinical psychologist with expertise in MI. Fidelity was addressed throughout the trial through the use of the Motivational Interviewing Treatment Integrity (MITI) coding system (Moyers, Martin, Manuel, Miller, & Ernst, 2007). The MITI coding system is designed to assess both specific therapist behaviors as well as a gestalt measure of the use of MI style, as displayed in a randomly selected twenty-minute segment of an MI therapy session. The MITI has demonstrated good convergent validity with its parent

measure, the MISC 1.0 (Moyers, Martin, Manuel, Hendrickson, & Miller, 2005). It has also been shown to have good sensitivity documenting improvements in MI as a result of clinical training and is frequently used to supplement and enhance supervision by sharing the results of the coding with therapists (Moyers et al., 2005). For YMHP, ten members of the MITI Coding Team coded sessions. To ensure reliability, each rater coded the same 20-minute portion of a taped session. The intraclass correlation for this coded segment was shown to be highly reliable (Cronbach = .97; intraclass correlation average = 0.97). The MITI codes were also used to provide feedback to the supervisor and therapists on the quality of delivery of MI throughout the trial, in order to reduce therapist drift and sustain fidelity.

In **Session 1**, the therapist provided an overview of the MI approach, emphasizing how the program focused on the participant's readiness to change rather than pressuring an individual into change, as well as a values card sort activity (Miller, C'de Baca, Matthews, & Wilbourne, 2001). YGBM were asked to choose which of the two target behaviors (UAI or substance use) to focus on first, and the therapist elicited the participant's view of the behavior using standard MI techniques. The session focused on increasing commitment to change, or contemplation for those in the earliest stage of change, and the completion of a plan for change including goals and potential barriers. **Session 2** followed a similar format, with focus on the target behavior not addressed in Session 1, followed by a review of structured personalized feedback on both behaviors, and the ways in which the behaviors interact, based on the participant's data from their baseline assessment. Participants also completed a staging ruler and a decisional balance exercise regarding their perceptions of the benefits and risks (pros/cons) for both behaviors. In **Session 3**, the therapist reviewed progress with regard to ambivalence and readiness for change, addressed motivation, and affirmed gains and commitment. The two target behaviors were integrated as the therapist and participant re-examined readiness to change, decisional balance, and goals for both behaviors. **Session 4** focused on termination and included a final review and revision of the participant's goals and change plan. Emphasis was placed on assessing self-efficacy for attaining goals and a continued discussion of the connection between substance use and UAI. The final session also included a review of community resources and support services available, and an individualized referral list, as well as an emphasis on relapse prevention if change had occurred.

Comparison Condition

The education condition involved the presentation of factual information about club drug use and HIV sexual risk reduction. Each session followed a detailed outline, and deviations from the outline were addressed in supervision. We produced educational video segments for use in these sessions that incorporated standard HIV sexual risk reduction messages, as well as factual information about the physical and cognitive effects of club drugs, and about evidence of the link between club drug use and high-risk sex. Staff used these videos in conjunction with structured discussion questions to deliver the material in this condition. In order to maintain a high level of credibility with YGBM, the video segments and discussion questions focused on objective, factual information, rather than overtly sensational or simplistic messages. Educators were rigorously trained in the content and delivery procedures of each session, completed mock sessions and received feedback prior to delivering sessions to participants, and attended regular supervision meetings to ensure fidelity to protocol. We viewed approximately 80% of all education sessions and provided individual feedback to each educator on their delivery style and material coverage. Finally, much of the focus of reviewing tapes and providing supervision was designed to ensure that the two conditions were accurately delivered according to the treatment manuals, and that the two conditions were adequately differentiated.

Measures

Demographics—Participants self-reported their age, HIV status, sexual identity, race/ethnicity, income, education, and relationship status (see Table 1).

Outcome variables—The outcomes of interest - UAI with a casual partner (overall and under the influence of drugs/alcohol) and number of days of drug use - were collected using a 30-day TLFB (Sobell & Sobell, 1993). Critical life events (e.g., vacations, birthdays, paycheck days, parties) were reviewed retrospectively to prompt recall of daily sex and drug use. The TLFB has previously demonstrated good test-retest reliability, convergent validity, and agreement with collateral reports for drug abuse (Fals-Stewart, O'Farrell, Freitas, McFarlin, & Rutigliano, 2000) and for sexual behavior (Carey, Carey, Maisto, Gordon, & Weinhardt, 2001; Weinhardt et al., 1998), and has been previously utilized with substance-using GBM (Irwin, Morgenstern, Parsons, Wainberg, & Labouvie, 2006; Morgenstern et al., 2009; Velasquez et al., 2009). Staff received extensive training in the administration of the TLFB, and demonstrated skills (reinforced by ongoing review of audiotapes of the TLFB interviews and supervision) in developing rapport with YGBM. They were also trained in being non-judgmental and sex-positive in order to facilitate honest self-reports and to respect the values and behaviors of all participants. Each day was coded for drug use (alone and with sex), heavy drinking (5 or more drinks that day), sexual partner and type (main/casual), and condom use. Poppers were excluded from our time series analyses because their use was ubiquitous; over 87% of participants used poppers within the 30-days prior to baseline across conditions. Inclusion of poppers as part of the club drug series of analyses resulted in limited drug use outcome variability and was not informative.

Data Analysis

Sampling Criteria—The analytic sample was limited to YGBM who reported at least one incident of anal sex with a casual male partner in the 30 days prior to the baseline assessment. All participants who had a main partner that was HIV-positive at baseline ($n = 5$) were excluded from these analyses because there was an insufficient number of serodiscordant couples in the sample to include for moderation effects in the models. We also excluded from analyses those participants who reported only having sex with their main partner 30 days prior to baseline ($n = 9$) because the focus of the intervention was on reduction of UAI with casual sex partners, and sex risk patterns differ contingent upon type of sex partner. While evidence now indicates that UAI with a main partner is a significant risk factor for HIV acquisition (Sullivan, Salazar, Buchbinder, & Sanchez, 2009), this intervention was designed prior to these findings. Our conclusions pertain to casual sex and including sex acts with main partners would be beyond the purposes of the intervention and scope of the current paper. Our final analytic sample was $N = 143$ (see Figure 1). We did not actively seek out the inclusion of participant couples, nor did we exclude them from enrolling, however, to our knowledge, members of the same couple did not enroll together in the intervention. Twenty percent of our sample ($n = 29$) reported having had a main partner (defined as having been in a romantic relationship for the past 3 months or longer) at baseline, however all of these participants also reported recent sex with casual partners.

Analytic Methods—Generalized Estimating Equation (GEE) Modeling techniques were used to assess change in aggregated days of drug use and acts of UAI as reported on the 30-day TLFB within each quarterly reporting period across conditions and time. GEE is an extension of generalized linear modeling used in longitudinal studies to control for clusters of correlated within subject repeated measures using quasi-likelihood methods. GEE permits the inclusion of cases that have follow-up data missing at random. Consequently, GEE produces marginal model parameters that show the sample population's averaged effect holding all other variables in the model constant. In each model we specified that the

working correlation matrix among our repeated measures was exchangeable assuming a constant correlation among any of the repeated measures. The application of an exchangeable correlation structure is reasonable given the number of repeated measures (baseline through 12-months), the clustering of cases within two conditions (MI and education), and that data collected using the TLFB began on a random day. Negative binomial distributions and a logit-link function were specified given the positively skewed distributions of count data. GEE was also used to model both the odds that a substance use or UAI event would 'ever' occur within each of the 30-day TLFB measurement periods and the likelihood that a substance use or UAI event would occur on 'any' given day within each of the 30-day TLFB measurement periods across conditions and time. We also used GEE to assess the relative effect of using drugs on a day when a person had UAI, controlling for both condition and time. All analyses were conducted using SPSS version 19.0.

RESULTS

Sample Demographics and Attrition

Figure 1 illustrates the study's progression from initial phone screening to completion of the last study follow-up. Of the 1,282 eligibility phone screenings, 266 men provided informed consent, and 143 were randomized and completed at least one session of MI or education. Comparability of demographics, drug use, and UAI risk after baseline intervention assignment were assessed using Chi-square and Fisher exact tests for categorical variables and student *t*-tests for continuous variables, and did not differ by randomized conditional assignment (Table 1). Between-condition sample retention rates did not differ significantly across each quarterly measurement period (baseline by 3- through 12-month follow-ups) and were comparable to or better than those of similar RCTs. The number of sessions completed did not differ significantly between the MI and education conditions ($M = 3.6$, $SD = 0.8$ and $M = 3.5$, $SD = 1.0$, respectively).

Drug Use within and Across Condition over Time

The number and percentage of YGBM in the MI and education conditions who used any drugs or used specific types of drugs within each 30-day TLFB measurement period are presented in Tables 1 and 2. While participants in the two conditions did not significantly differ in their type of drug use, overall drug use or the total number of days in which drugs were used at baseline, there were significant reductions in substance use both within and between conditions over 12-months. Within-condition analyses showed that participants who received MI reduced their cross-time averaged odds of ever using any drug by 67% over the one-year follow-up (Figure 2: OR = 0.33; CI: 0.17–0.63; $p = .0001$), while those who received the educational intervention reduced their drug use by nearly 50% (OR = 0.51; CI: 0.27–0.98; $p = .042$). In addition, the cross condition analysis presented in Table 3 shows that reductions in the odds of using drugs on any day within each of the 30-day TLFB post-intervention follow-up periods were significantly greater among YGBM in the MI condition compared to YGBM assigned to education; participants in MI were 18% less likely to report drug use on any given day of follow-up compared to YGBM in the education condition (Table 3: OR = 0.82; CI: 0.75–0.89; $p = .0001$).

UAI within and Across Condition over Time

Table 2 and Figure 3 show the number and percent of YGBM who reported UAI across time by condition. Within-condition cross-time analyses showed that YGBM in both the MI and education conditions significantly reduced their time averaged odds of ever engaging in UAI (OR = 0.17; CI: 0.10–0.31; $p = .0001$; OR = 0.19; CI: 0.10–0.39; $p = .0001$, 83% and 81% respectively). In addition, day level GEE analysis showed that reductions in UAI, however, were significantly greater among YGBM in the MI condition than those in the education

condition; MI participants were 24% less likely to report UAI on any given day of follow-up relative to the odds of YGBM in the education condition (Table 3: OR = 0.76; CI: 0.68–0.85; $p = .0001$).

Day Level UAI Controlling for Drug Use and Time

As shown in Table 4, both randomized treatment condition and drug use were significantly associated with the odds of engagement in UAI across the quarterly measurement periods. Holding constant both condition and time, the use of drugs significantly increased the odds that a participant would have UAI by over 300% (OR = 4.35; CI: 3.83–4.94; $p = .0001$). However, the association between drug use and sexual risk was significantly moderated by treatment condition. As such, participants in the MI condition were 21% less likely to engage in UAI on any given day when they had sex with a casual partner, holding constant their use of drugs, relative to the odds of participants who received the educational intervention (OR = 0.79; CI: 0.70–0.89; $p = .000$).

DISCUSSION

Our findings support the utility of a brief 4-session MI intervention, compared to a content-matched education condition, to significantly reduce both drug use and UAI among YGBM, a group with some of the highest HIV prevalence and incidence rates in the US. It is important to note that all participants were substance-using YGBM who reported UAI in the past 90 days, and thus were actively engaged in both targeted risky behaviors. Although all participants benefitted from having received their respective interventions (MI or education), those in the MI condition demonstrated significantly greater reductions in both substance use and UAI over the one year follow-up period. These findings are contrary to a recent review of MI-based interventions to prevent HIV risk for GBM (Berg et al., 2011).

There are a number of potential explanations for why MI was more efficacious than education in reducing UAI and substance use. First, this study enrolled a sample of YGBM who, although demonstrated risk in both target behaviors, was not a treatment-seeking sample. MI focuses on the unique needs of those ambivalent about behavior change, and thus it is possible that MI is best suited to those who are less ready to change. Second, over 60% of our participants were YGBM of color, and a previous meta-analysis of MI interventions suggested that stronger effect sizes are found in predominately minority samples (Hettema et al., 2005). Research has shown that homophobia, and racism decrease motivation for accessing HIV prevention services (Voisin, Bird, Shiu, & Krieger, 2012). Further, YGBM of color, who face increased discrimination and stigma as a “double minority,” often experience increased bullying, depression, and emotional distress (Hightow-Weidman et al., 2011). An MI-based intervention, in which the therapist demonstrates empathy and a lack of judgment, could especially resonate with a group that is not used to such interactions with providers, increasing the efficacy of MI with this population. Third, MI may have worked significantly better than education in reducing the two target behaviors because the MI intervention did focus on both behaviors. Most MI interventions aimed at reducing HIV risk among GBM have only focused on UAI (Berg et al., 2011); these MI interventions may have been less effective because they failed to focus on the intersection of substance use and risky sex. Targeting concurrent and related risk behaviors provides those receiving an MI intervention with the option to choose which behavior to focus on first in the intervention, potentially leading to more autonomy in making the decision to engage in behavior change. Our work is in line with emerging evidence showing the efficacy of MI-based interventions in concomitantly affecting two behaviors of interest, such as cocaine use and HAART adherence (Ingersoll et al., 2011), as

well as alcohol use and contraception adoption to avoid alcohol exposed pregnancies (Velasquez et al., 2010).

We found that frequency of substance use, operationalized as days of drug use in the past 30 days, decreased in both groups over time. However, there were significantly greater drug use reductions in the MI group at each follow-up. These findings suggest that MI is significantly more efficacious than psycho-educational approaches to individual intervention, and support a previous study with adult GBM in which MI reduced drug use more effectively than an educational control, but only for those with lower severity of drug dependence (Morgenstern et al., 2009). Similar patterns were observed in regards to UAI, although the differences between the two conditions were even greater than with substance use. Specifically, significantly greater reductions in UAI were reported by the YGBM in the MI group over time in comparison to those in education during the 12-month follow-up period. This is, to our knowledge, the first study of MI with HIV-negative YGBM to show significant effects on sexual risk reduction, as previous studies have only shown MI to be efficacious in samples of older GBM and/or GBM of mixed HIV status (Koblin, 2004; Picciano, Roffman, Kalichman, Rutledge, & Berghuis, 2001). It is plausible that for days when drug use and sex co-occurred, drug use reductions led to decreases in UAI. Interventions may thus benefit from placing special emphasis on reducing substance use, which would in turn lead to less frequent UAI. Approaching HIV prevention in a two-pronged manner, by directly targeting UAI for behavior change, as well as by attempting to decrease UAI through reductions in substance use, may be an advantageous strategy.

Despite the finding that MI produced significantly greater reductions in both substance use and UAI over time than education, both conditions did improve, and those improvements continued over the 12 months of follow-up. Certainly, reductions across both groups could be attributed to assessment effects (Epstein et al., 2005; Weinhardt, Carey, & Carey, 2000).

There were several limitations to this study. The inclusion criteria required that self-reported UAI occurred in the past 90 days, whereas our analyses focused on the 30-day TLFB data, given that only this time period was assessed at a day level. The 60 days prior to these 30 days were reviewed with each participant in a summary manner; therefore, we did not have day-level sexual behavior and substance use data for a longer period of assessment. Future studies could consider the use of daily diary assessments of sexual behavior and substance use in order to obtain day-level data on a longer assessment period. Additionally, because the time period for eligibility was the past 90 days, and our day-level analyses examined the past 30 days, 14% of education participants and 18% of MI participants did not report UAI in the past 30 days. Similarly, 20% of education participants and 18% of MI participants did not report drug use in the past 30 days at baseline. Consequently, reductions in risk behavior may have been underestimated in our analyses as a result, given that we were unable to account for the entire sample's risk behavior. Another limitation is the absence of cost effectiveness data, which would have shed light on whether or not using MI over education is cost effective. It will be worthwhile for other MI intervention trials to build in cost effectiveness measures in order to couple efficacy findings with the pragmatism of employing an MI-based condition over control arms. Lastly, our outcomes are based on self-report, which could generate unreliable data. However, in order to increase accuracy of self-report of sensitive data, we allowed participants to report on various behaviors via ACASI, which, as stated previously, increases participants' level of comfort and minimizes socially desirable answers, which may otherwise lead to underestimation of risk. Further, all our staff underwent initial extensive trainings and monthly refreshers on participant interaction issues, especially around eliciting accurate data in a sensitive and non-judgmental manner to increase participant comfort and assurance of privacy and confidentiality. A recent study comparing diary and retrospective survey data strengthens our confidence in the validity of

the data reported by participants in this study, as those findings indicate that retrospective self-report maintains its validity and shows high agreement with daily diary data (Glick, Winer, & Golden, 2013).

Despite these limitations, this trial provides evidence that, contrary to equivocal findings regarding the utility of MI as a therapeutic technique to reduce risky behavior (Barnett, Sussman, Smith, Rohrbach, & Spruijt-Metz, 2012; Hettema et al., 2005; Smedslund et al., 2011), its use in a brief intervention for non-treatment seeking YGBM at risk for HIV proved to be significantly more efficacious than a content-matched education condition. In terms of future directions, our findings set the stage for a comparative effectiveness trial in order to determine whether this type of MI-based intervention may be more effective than either an education condition or the standard of care within clinics or community organizations serving YGBM, such as routine HIV risk reduction modules provided during STI testing or regularly scheduled annual clinic visits. YGBM in the MI group indicated acceptability of this intervention, as they reported a significantly higher alliance with their therapist than YGBM in the education condition did with their facilitator, which indicates favorable attitudes towards this type of counseling, with shared therapist-participant agreement regarding goals and collaboration towards the desired behavioral change. This intervention has the potential to be adopted by direct service staff, while still being able to preserve fidelity to MI techniques. Although the MI therapists in our study were PhD and Master's level therapists, studies have shown that with appropriate training and supervision, this type of MI intervention can be delivered with fidelity by individuals in community settings, with or without graduate-level training (Naar-King, Outlaw, Green-Jones, Wright, & Parsons, 2009). Further, Train-the-Trainer programs can be used by community-based supervisors, who can then train and supervise their own staff. Lastly, although incentives were used in the current study at every study visit, non-incentivized uptake of this MI intervention could be possible if it were to be integrated into the standard programming of community-based agencies servicing YGBM, who would have an interest in participating as part of their existing service utilization. Ultimately, comparative effectiveness research could address these potential issues with scalability of the MI intervention.

Further, in order to expand individual prevention efforts to address cost effectiveness and capitalize on shared experiences among YGBM, which can be cathartic or constitute mechanisms for change, group-level components could be added as part of the current intervention. As such, components of the individual-based MI intervention could be incorporated into regularly occurring support groups or social events attended by YGBM as part of existing infrastructures and operations within real-life settings. Such a next step would be in line with the recommendations of Herbst and colleagues (2005) that individual-based prevention research and practice expand into real-life settings and be integrated at a community level to achieve greater effect sizes and durability, and have a wider reach. Additionally, we hypothesize that in order to create stronger effect sizes and durability, future iterations of MI-based interventions such as YMHP could be modified by adding booster sessions coinciding with regularly scheduled clinic or other appointments, and adopting enhanced elements by incorporating cognitive-behavioral techniques to facilitate skills development necessary to implement desired behavior changes towards risk reduction and healthy outcomes. Further, most successful MI-based interventions have changed behaviors that are under the control of individuals, such as substance use, smoking, exercise, or medication adherence. Given that sexual risk behavior involves at least a dyad, individual MI-based interventions could benefit from not just the addition of skills-based training to address sexual agreement and practice negotiations with partners, but also include main partners in these interventions, as well as identify and involve individuals' sexual networks.

Conclusion

MI reduced UAI and substance use significantly more than an education attention control condition, among a population disproportionately at risk for HIV infection, YGBM. The enhanced efficacy of MI over education was sustained across a one year period of follow-up. The study benefited from a number of elements which strengthen the internal validity of our findings – random assignment, thorough consideration of treatment fidelity for MI delivery, and a strong comparison condition with no differential rates of drop-out. External validity was strengthened by having a socio-demographically diverse population of YGBM which was distributed across the entire NYC area, and the fact that those who enrolled in the intervention trial did not differ significantly from those who did not on any demographic or outcome variables. Although future research studies can certainly improve on some of the limitations of this particular trial, these results suggest that a brief four-session MI intervention dually-targeting substance use and UAI among urban YGBM meets the criteria for best-evidence intervention for HIV prevention (Lyles et al., 2007).

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

Figure 2.
Any drug use in the past 30 days by condition.

Figure 3.
Any Unprotected Anal Intercourse (UAI) in the past 30 days by condition

Table 1

Demographic characteristics of participants at baseline for full sample and by condition (N=143).

	Total Sample		MI (n = 73)		Education (n = 70)	
	n	%	n	%	n	%
<i>Race/Ethnicity</i>						
White	53	37.1	30	41.1	23	32.9
Latino	41	28.7	18	24.7	23	32.9
Black	30	21.0	17	23.3	13	18.6
Other/Mixed	19	13.3	8	10.1	11	15.7
<i>Sexual Orientation</i>						
Gay	131	91.6	67	91.8	64	91.4
Bisexual	12	8.4	6	8.2	6	8.6
<i>Education</i>						
Not High School Grad	8	5.6	5	5.6	3	4.3
High School/GED	19	13.3	12	16.4	7	10.0
Some College	60	42.0	30	41.1	30	42.9
College Grad and Plus	56	39.2	26	34.6	30	42.9
<i>Income</i>						
Less Than 30K	97	67.8	52	71.3	45	64.3
30K Plus	46	32.2	21	28.7	17	35.7
<i>Substance use 30-days pre-baseline</i>						
Any Cocaine	97	67.8	48	65.8	49	70.0
Any Ecstasy	44	30.7	22	30.1	22	31.4
Any Methamphetamine	24	16.7	13	17.8	11	15.7
Any GHB	15	10.4	8	11.0	7	10.0
Any Ketamine	13	9.1	7	9.6	6	8.7
Any UAI 30-days pre-baseline	120	83.9	60	82.2	60	85.7

Note: There were no significant cross-condition differences on any of the demographic characteristics.

Note: MI (Motivational Interviewing Condition); Education (Educational Intervention).

Table 2

Substance use and UAI Engagement 30 days prior to each quarterly assessment period by condition.

	MI Therapy Intervention											
	Baseline (n = 73)			3M (n = 61)			6M (n = 54)			9M (n = 55)		
	n	%		n	%		n	%		n	%	
Any Drug Use	60	82.2		41	68.9		34	63.0		56	52.7	
Any Cocaine	48	65.8		35	57.4		28	51.9		49	45.5	
Any Ecstasy	22	30.1		12	19.7		7	13.0		22	16.4	
Any Meth	13	17.8		4	6.6		5	9.3		11	7.3	
Any GHB	8	11.0		3	4.9		4	7.4		7	3.6	
Any Ketamine	7	9.6		3	4.9		3	5.6		6	5.5	
	Education Intervention											
	Baseline (n = 70)			3M (n = 62)			6M (n = 55)			9M (n = 57)		
	n	%		n	%		n	%		n	%	
Any Drug Use	56	80.0		44	71.0		41	74.5		35	61.4	
Any Cocaine	49	70.0		33	53.2		31	56.4		24	42.1	
Any Ecstasy	22	31.4		16	25.8		9	16.4		9	15.8	
Any Meth	11	15.7		11	17.7		7	12.7		10	17.5	
Any GHB	7	10.0		9	14.5		5	9.1		6	10.5	
Any Ketamine	6	8.7		4	6.5		3	5.5		6	10.5	
	MI Therapy Intervention											
	Baseline (n = 73)			3M (n = 61)			6M (n = 54)			9M (n = 55)		
	n	%		n	%		n	%		n	%	
Any UAI	60	82.2		33	54.1		25	46.3		25	45.5	
Any UAI and/or Drugs	62	84.9		35	57.4		31	57.4		33	60.0	
	Education Intervention											
	Baseline (n = 70)			3M (n = 62)			6M (n = 55)			9M (n = 57)		
	n	%		n	%		n	%		n	%	
Any UAI	60	85.7		35	56.5		29	52.7		35	61.4	
Any UAI and/or Drugs	61	87.1		42	67.7		36	65.5		43	75.4	

Table 3

Day level odds of drug use and UAI controlling for condition and quarterly assessment period.

	Day Level Drug Use			
	β	OR	C.I.	p
Intercept	-1.40	0.25	0.23/0.27	.000
Therapy (Education)	-0.20 0	0.82 1	0.75/0.89	.000
3-month	-0.56	0.57	0.50/0.65	.002
6-month	-0.65	0.52	0.46/0.60	.001
9-months	-0.79	0.45	0.39/0.52	.000
12-months (Baseline)	-0.78 0	0.46 1	0.40/0.53	.000

	Day Level UAI			
	β	OR	C.I.	p
Intercept	-2.01	0.13	0.11/0.14	.000
Therapy (Education)	-0.27 0	0.76 1	0.68/0.85	.000
3-month	-0.25	0.78	0.67/0.91	.002
6-month	-0.40	0.67	0.57/0.79	.000
9-months	-0.86	0.42	0.35/0.51	.000
12-months (Baseline)	-0.85 0	0.43 1	0.35/0.52	.000

Table 4

Day level odds of a participant engaging in UAI on a day that they used drugs by condition and across quarterly measurement periods.

	β	OR	C.I.	p
Intercept	-2.49	0.08	0.07/0.09	.000
Therapy (Education)	-0.24 0	0.79 1	0.70/0.89	.000
Used Drug Day (No Drug Day)	1.47 0	4.35 1	3.83/4.94	.000
3-month	-0.12	0.89	0.76/1.04	.152
6-month	-0.25	0.78	0.65/0.92	.004
9-months	-0.69	0.50	0.41/0.61	.000
12-months (Baseline)	-0.68 0	0.51 1	0.42/0.61	.000