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Motivational and Skills Training HIV/STI Sexual Risk Reduction Groups for Men

Donald A. Calsyn, Ph.D.^{1,2}, Mary Hatch-Maillette, Ph.D.^{1,2}, Susan Tross, Ph.D.³, Suzanne R. Doyle, Ph.D.¹, Paul Crits-Christoph, Ph.D.⁴, Yong S. Song, Ph.D.⁵, Judy M. Harrer, Ph.D.⁶, Genise Lalos, M.A.⁷, and Sara B. Berns, Ph.D.¹

¹Alcohol and Drug Abuse Institute, University of Washington, Seattle, WA

²The Department of Psychiatry and Behavioral Science, University of Washington School of Medicine, Seattle, WA

³Department of Psychiatry, Columbia University and New York Psychiatric Institute, New York, NY

⁴Department of Psychiatry, University of Pennsylvania, Philadelphia, PA

⁵Department of Psychiatry, University of California San Francisco and San Francisco General Hospital, San Francisco, CA

⁶Department of Psychiatry, University of Cincinnati and Veteran's Affairs Medical Center, Cincinnati, OH

⁷Pretera Center for Mental Health Services Inc., Huntington, WV

Abstract

The effectiveness of a motivational and skills training HIV/AIDS group intervention designed for men in substance abuse treatment was evaluated. Men in methadone maintenance (n=288) or outpatient psychosocial treatment (n=302) completed assessments at baseline, 2 weeks, 3- and 6-months post intervention. Participants were randomly assigned to attend either "Real Men Are Safe" (REMAS; five sessions containing information, motivational exercises and skills training), or

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Corresponding author: Donald A. Calsyn, Ph.D. Alcohol and Drug Abuse Institute, 1107 NE 45th St., Ste. 120, Seattle, WA, 98105, United States, phone: 206-616-3150, fax: 206-543-2861, calsyn@u.washington.edu.

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Study concept and design: Calsyn, Tross, Berns

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HIV education (HIV-Ed; one session containing HIV prevention information). REMAS participants engaged in significantly fewer unprotected vaginal and anal sexual intercourse occasions (USO) during the 90 days prior to the 3- and 6-month follow-ups than HIV-Ed participants. Completing REMAS resulted in an even stronger effect: completers reduced their number of USO by 21% from baseline to 6-month follow-up. In contrast, HIV-Ed completers increased the number of USO by 2%. A motivational and skills training HIV prevention intervention designed for men was associated with greater sexual risk reduction over standard HIV education. Substance abuse treatment programs can therefore help reduce sexual risk among their clientele by providing a more intensive intervention than what is traditionally provided.

Keywords

HIV prevention; substance abuse treatment; behavioral intervention

1. Introduction

Substance abuse treatment attendees are logical targets for sexual risk reduction interventions as sexual contact and injection drug use behaviors are the most common routes of HIV infection in the United States (Center for Disease Control and Prevention, 2006). High levels of sexual risk behaviors have been reported among adults who are injection drug users (IDU), heavy alcohol users, stimulant users, and MDMA abusers (Avins, Woods, Lindan, Hudes, Clark & Hulley, 1994; Chitwood, Comerford & Sanchez, 2003; Halkitis, Shrem & Martin, 2005; McElrath, 2005; Raj, Saitz & Cheng, 2007; Rosengard, Anderson & Stein, 2006; Rawson, Washton, Domier & Reiber, 2002; Shillington, Cottler, Compton & Spitznagel, 1995).

Substance abuse treatment, especially opioid agonist treatment, has proved to be a powerful deterrent to HIV related drug use risk behaviors, in particular needle sharing behavior (Schroeder, Epstein, Umbricht & Preston, 2006). Sexual risk behavior has received less attention in substance abuse treatment settings, and most evidence suggests that it is slower to change than drug use risk behaviors (Sorensen & Copeland, 2000). Despite some findings that substance abuse treatment is associated with reduced sexual risk; many substance abusers receiving treatment continue to engage in high risk sexual behaviors (Longshore & Hsieh, 1998; Avins et al., 1997; Farrell, Gowing, Marsden, Ling & Ali, 2005).

In 1999 the National Institute on Drug Abuse (NIDA) formed the Clinical Trials Network (CTN), a national network of addiction researchers and community-based treatment programs who partner to conduct multisite clinical trials research on drug abuse treatments in “real life” settings (Hanson, Leshner & Tai, 2002). A 2002 CTN HIV/AIDS workgroup found that most CTN-affiliated drug treatment programs (80.4%) provided some type of HIV education to all clients (Shoptaw, Tross, Stephens, Tai & The NIDA CTN HIV/AIDS Workgroup, 2002). Also in most programs (85.4%), the amount of education provided ranged from 30 to 90 minutes (mode=60 minutes [53.3% of clinics]) and was delivered in a single group or individual session. The bulk of the education provided was limited to basic information about HIV and risk behaviors associated with its transmission. Skill training interventions that used tools such as role-plays and condom skills practice with models were infrequent. Similar findings were reported within CTN community treatment programs by a more extensive survey of HIV/HCV programs (Brown et al. 2006).

Overall, studies of HIV risk reduction interventions conducted in drug abuse treatment programs and other clinical settings have been shown to be effective, particularly if they contain attitudinal arguments, educational information, behavioral skills arguments and behavioral skills training (Prendergast, Urada & Podus, 2001; Semaan et al., 2002; Albarracín, et al.,

2005). These meta-analytic findings are consistent with several behavioral change theories applied to HIV prevention interventions including Theory of Reasoned Action (Fishbein & Ajzen, 1975), Theory of Planned Behavior (Ajzen & Madden, 1986), social-cognitive/self-efficacy models (Bandura, 1989), and the Information-Motivation-Behavioral Skills Model (Fisher & Fisher 1992).

Of specific interest to the design of the current study were positive correlations reported for intensity of the intervention, use of peer group discussion, and single-gender session attendance (Prendergast, et al., 2001). Schilling, El-Bassel, and Schinke (1991) developed a five-session behavioral skills-building HIV prevention intervention especially for women in methadone treatment. The intervention contained basic information about HIV/AIDS, condom demonstration and practice, partner negotiation, assertiveness training, problem solving and communication skills. Role-plays were routinely used in the skills-building sessions. Women in methadone treatment attending the Schilling et al. intervention reported more condom use at 2 weeks post intervention and at 15 months follow-up than women attending a one-session HIV/AIDS education group (El-Bassel & Schilling, 1992). Thus, there is correlational evidence and one study of a women-only intervention in methadone clinics that suggest intensity of the intervention, use of peer group discussion, and single gender sessions might be ways of reducing unsafe sex. Such improvements in HIV sexual risk counseling would have clear significance in terms of reducing HIV transmission.

To confirm these findings, Tross and colleagues tested an HIV/STD safer sex skills group for women in substance abuse treatment within the CTN (Tross et al., in press). Simultaneously, a lack of randomized trials with men led to the development of the study presented here, a companion intervention for men in substance abuse treatment.

In their meta-analysis of HIV prevention efforts with drug users, Semaan et al. (2002) found that extended/enhanced interventions typically did not improve sexual risk reduction over standard/control interventions. This finding highlights a need to identify interventions that are more effective than those typically offered. Consistent with Semaan et al's (2002) recommendation, the question of greatest interest to community treatment providers in the current context has been, "Is a single HIV information group session (the modal intervention among community treatment programs) enough or can greater risk reduction be accomplished with state of the art prevention intervention components added over multiple sessions?"

To this end, the primary objective of this study was to compare the effectiveness of the five-session CTN intervention developed specifically for men, Real Men Are Safe (REMAS) to a standard single session HIV/AIDS education group (HIV-Ed). These interventions are described in Methods. It was hypothesized that men provided REMAS would engage in fewer unprotected vaginal and anal sexual intercourse occasions (USO) compared to men provided the standard HIV-Ed intervention. It was also hypothesized that having a high risk partner in the prior 6 months, and years of stimulant use, would be associated with the number of USO at follow-up.

The study design follows the practical clinical trial model (March et al., 2005; Tunis, Stryer & Clancy, 2003) and is consistent with Carroll and Rounsaville's (2003) hybrid model for conducting efficacy/effectiveness studies in substance abuse treatment programs. Specifically, this study utilized efficacy trial elements that supported internal validity (e.g., random assignment, a well defined patient population, manualization of treatment conditions, use of objective outcome measures with assessment independent from treatment delivery, and monitoring of treatment delivery by assessment of therapist fidelity and skill). This study also used effectiveness trial elements that supported external validity (e.g., a comparison condition reflecting "treatment as usual," broad participant inclusion criteria with few exclusion criteria,

and study clinicians drawn from the staff of performance sites). In order to maximize practical utility, the current trial was expressly designed to investigate a research question that clinicians in the field perceived as useful.

2. Methods

2.1. Participants

Men were recruited from 14 CTN sites across the US: seven methadone clinics (Hartford, CT; New York, NY; Philadelphia, PA [2 clinics]; Raleigh, NC; Seattle, WA.; San Francisco, CA.) and seven psychosocial outpatient clinics (Norwalk, CT; Huntington, WV; High Point, NC; Columbia, SC; Toledo, OH; Santa Fe, NM; Rancho Cucamonga, CA). Inclusion criteria were: 1) males at least 18 years of age in drug abuse treatment at a participating CTN-associated clinic; 2) self report of engaging in unprotected vaginal or anal intercourse during the past 6 months (sexual partners could have been women or men or both); 3) agreeable to random assignment to either the one-session standard HIV education session or to the five-session REMAS workshop; 4) agreeable to completing a 2–3 hour assessment battery at baseline, a 90 minute assessment at both 3- and 6-months post intervention, and a shorter battery upon completing the intervention; 5) able to speak and understand English. Exclusion criteria included: 1) observable, gross mental status impairment defined as severe distractibility, incoherence or retardation as measured by the Mini Mental Status Exam (MMSE; Folstein, Folstein & McHugh, 1975; Cockrell & Folstein, 1988); 2) having a primary sexual partner intending to get pregnant while the participant was enrolled in the trial; 3) current treatment episode of methadone maintenance was less than 30 days. Participants self-referred in response to recruitment posters displayed in clinics, announcements at group therapy meetings and clinic “open houses” designed to introduce the study to clinic patients. Participants were also referred to the study by clinic counselors and/or staff.

Of the patients screened for the study (n=993), 332 either did not meet an inclusion criteria and/or met an exclusion criterion (See Figure 1). Of the 661 eligible for the study, 71 were never randomized to a study condition (See Figure 1). The main reason for not being randomized was a loss of contact with the research staff between initial screening and randomization. The remaining 590 participants were randomized to attend either the REMAS intervention (n=291) or the HIV-Ed intervention (n=299). The mean age and education level obtained for the analysis sample described below were 40.4 (sd=10.6) and 12.2 (sd=1.9) years respectively. Marital status was 19.7% married, 34.1% previously married, 46.2% never married. Ethnicity status was 56.2% non-Hispanic white, 27.7% Black, 12.8%, Hispanic, 1.7% Native American, 0.9 Asian, <1% all others.

2.2. Procedures

2.2.1. Screening/eligibility assessment—Research staff obtained written informed consent from all study participants that included permission to audio-tape research interviews and study intervention sessions for supervisory and quality assurance purposes. Procedures were approved by each site’s institutional review board in accord with the Helsinki Declaration of 1975 (revised 2000) and by an independent Data Safety and Monitoring Board convened by NIDA. The consent form was also accompanied by a certificate of confidentiality issued by NIDA. Participants consenting to be screened were administered the following assessments by a research assistant: the CTN Demographic Form, MMSE, and Risk Behavior Survey (RBS; Centers for Disease Control and Prevention, 1993). The CTN Demographic Form collects age, gender, ethnicity, and drug use history. Race/ethnicity data were collected in compliance with National Institutes of Health Guidelines and self-designated by participants, using an item allowing open-ended responses. For this report, responses were categorized as white, black, Hispanic, American Indian, Asian, or other. The MMSE was used to identify potential

participants who were too cognitively impaired to engage in the study. Individuals with scores less than 25 were excluded from study (Crum, Anthony, Bassett & Folstein, 1993). The MMSE has the advantage of: 1) being widely used in research protocols for this purpose; 2) is relatively easy to administer and score; 3) is relatively short; and 4) has a very low ceiling so that only the most grossly cognitively impaired individuals were excluded. The RBS is an abbreviated version of the Risk Behavior Assessment developed by NIDA for a Cooperative Agreement used to measure HIV and HCV risk behaviors in the areas of drug use and sex in the previous 30 days. Sexual behavior questions were repeated for the prior 6 months so study eligibility could be determined. Eligible participants were scheduled to complete the baseline assessment described below.

2.2.2. Assessments—The Sexual Behavior Interview (SBI) was administered during the baseline assessment as part of a larger battery. The SBI items were selected or adapted from the SADAR (Sex and Drug Abuse Relationship Interview; Calsyn, Wells, Saxon, Jackson & Heiman, 2000) and the SERBAS (Sexual Risk Behavior Assessment Schedule; Meyer-Bahlburg, Ehrhardt, Exner & Gruen, 1991; Sohler, Colson, Meyer-Bahlberg & Susser, 2000). Behaviors assessed included: 1) frequency of unprotected vaginal, anal, oral sex by partner type (main versus casual); 2) number, gender, and perceived HIV serostatus of partners; 3) the percentage of time sex occurred under the influence of drugs or alcohol over the prior 90 days. The number of unprotected vaginal and anal sexual intercourse occasions (USO) over the prior 90 days, which serves as the primary outcome measure, was derived from the SBI and is the same primary outcome measure utilized in *Project Light* (The NIMH Multisite HIV Prevention Trial Group, 1998). SBI items were administered using the audio computer-assisted self-interviewing (ACASI) method. Respondents have been shown to disclose more regarding participation in high risk behaviors with ACASI compared to in-person, face-to-face interviews (Metzger, et al., 2000; Gross, et al., 2000). This method lessens the impact of possible social desirability distortions in self reports of risk behaviors. At the beginning of the interview the ACASI programs prompts the respondent to think about memorable events in the 90 day window to help provide anchors for remembering sexual occasions, similar to the timeline follow back procedure. Follow-up assessments, including re-administration of the SBI, were conducted at 3- and 6-months post intervention. The Addiction Severity Index-Lite (ASI-L) drug and alcohol problem scale was administered at each assessment time point. The ASI-L is a standardized, multidimensional, semi-structured, comprehensive clinical interview that provides clinical information important for formulating treatment plans as well as problem severity profiles in six domains commonly affected in substance abusers (McLellan, Cacciola, Kushner, et al. 1992). Participants were financially compensated for their time completing assessments at the prevailing compensation rates in each community.

2.2.3. Randomization—Upon completing the baseline assessment eligible participants were placed in a holding cohort awaiting randomization. Once there were eight men in the cohort or 3 weeks had passed (whichever came first) the entire cohort was randomized to attend either the REMAS or HIV-Ed intervention. If there were fewer than three men in a cohort at the end of 3 weeks, randomization was delayed until three men had been enrolled. Randomizing cohorts instead of individuals lessened the wait time for starting a group. This design element was intended to minimize non-attendance due to participants having left treatment before the groups began. Separate block randomization schedules were developed for each site and managed by an outside contractor. Research staff randomized cohorts by dialing an automated telephone system. Every effort was made to keep research staff assigned to complete follow-up assessments blind to randomization assignment. Blinding procedures were moderately effective: at the 3-month follow-up, research assistants reported knowing the intervention assignment of 41.0% of participants; at 6-month follow-up, this rate was 22.8%. However,

since the primary outcome measure was obtained by computer interview the impact of unblinded research assistants was minimized.

Randomization began May 20, 2004 and follow-up of the last participant ended April 19, 2006. The flow of participants through the study is presented in Figure 1. Usable primary outcome measures at baseline were obtained from 573 of the 590 randomized participants. Of the 573 participants with usable primary outcome measures at baseline, 345 (60.2%) provided follow up data at both 3 and 6 months. An additional 77 (13.4%) provided follow up data at either the 3- or 6-months follow up. An additional 5 cases with follow-up data were eliminated from the completer analysis due to problematic documentation of intervention attendance. This resulted in a primary analysis sample of 422 and a completer analysis sample of 417 participants, with outcome data at baseline, 3- and/or 6-months follow-up.

2.2.4. Interventions—The five-session REMAS intervention drew from The NIMH Multisite HIV Prevention Trial Group's (1998) *Project Light* (PL) and Bartholomew and Simpson's (1996) *Time Out! For Men* (TOMen), a manual driven, gender-specific communication skills and sexuality workshop for men (Bartholomew, Hiller, Knight, Nucatola & Simpson, 2000). In addition, material from Bartholomew and Simpson's (1992) *Approaches to HIV/AIDS Education in Drug Treatment* (HIV-ED) was utilized (Boatler, Knight & Simpson, 1994).

The REMAS intervention was a workshop of five 90-minute group sessions. In addition to lecture material, there was liberal use of role-plays, peer group discussions and self-assessment motivational exercises. There was nearly an equal focus on information delivery and skill building with a somewhat smaller focus on motivation. Sessions 1, 2, 4 and 5 were all adapted from the PL, TOMen, and HIV-ED materials. Some of the PL materials were revised to be more relevant to an in-treatment population. Session 3 was developed specifically for this protocol based on research indicating that combining sexual behavior and drug use is common among drug abusers and is associated with high risk HIV transmission behaviors and drug use relapse (Calsyn, Wells, Saxon & Jackson, 1996; Calsyn et al., 2000; Calsyn, Wells, Saxon & Jackson, 1999). Intervention materials were revised so they would be appropriate for both men who have sex exclusively with women and men who have sex with men. As much as possible, gender neutral terms such as "partner" were used. An outline for the intervention is provided in Appendix A. Taken together, the material addressed all three components of the Information-Motivation-Behavioral change (IMB) model (Fisher & Fisher, 2000). Participants were financially compensated \$10 for their time attending each group.

Consistent with the practical clinical trials model (March et al., 2005; Tunis et al, 2003), the HIV-Ed group was intended to represent a standardized treatment-as-usual intervention that would be appropriate for groups of men, women, or mixed men and women. This intervention consisted of selected educational material from sessions 1 and 2 of the REMAS intervention and served as the standard-of-care HIV/AIDS education (See Appendix A). Using flipchart visual materials, and informational and resource handout materials, the counselors conducted an approximately 60-minute session covering: HIV/AIDS definitions, transmission, testing and counseling, treatment, and prevention. The material addressed primarily the information component only in the IMB model. Participants were financially compensated \$10 for their time attending the group.

The two group interventions, REMAS and HIV-Ed, were delivered by male counselors already employed in the study clinics. The treatment counselors received approximately 30 hours of training in conducting both interventions and were certified to provide the intervention once competence was demonstrated on two randomly selected components of the intervention. Both interventions were manual-driven. In addition to training the program counselors, a clinical

supervisor at each site was trained in conducting the interventions and supervising the interventions. Both conditions consisted of groups of 3–8 men. Groups were conducted by co-leaders who shared responsibility for delivery of the treatment.

2.2.5. Quality Control of Interventions Administered—Five procedures were in place to maintain quality control of the therapies. 1) The design of the HIV-Ed session left little room to add additional information, and there was no time for the role plays and brainstorming that characterized the REMAS condition. 2) Both interventions were manual driven, and the therapists received a total of approximately 30 hours of training in conducting the interventions. 3) Therapists completed an intervention checklist at the end of each session on which they indicated whether each topic and activity for the session was covered. 4) All intervention sessions were audio taped. The clinical supervisor reviewed approximately 50% of tapes and the lead investigator (or designee) reviewed twenty percent of each therapist's tapes (92.9% and 91.4% respectively rated as meeting fidelity criteria). Therapists received feedback on deviations from the manual. 5) Monthly conference calls were held with intervention therapists, their supervisors, and the investigators to problem solve any difficulties encountered with conducting the interventions.

2.3. Data Analysis

The primary outcome measure utilized in the protocol was the number of unprotected vaginal and anal sexual intercourse occasions (USO) in the prior 90 days. This measure was calculated by adding the total number of vaginal and anal intercourse acts reported on the SBI for main female sexual partner, other female sexual partners, main male sexual partner and other male sexual partners, and subtracting the number of those sexual acts for which the participant reported the use of either a male or female condom. To account for excess zeros in the primary outcome measure, a mixed-effects, zero-inflated Poisson, ZIP(τ), model was used for the analysis of the primary outcome (Hedeker & Gibbons, 2006; Lambert, 1992). A more technical description of data analytic procedures is provided in an extended version of the manuscript available from the lead author. Prior to assessing the primary hypothesis, cases with missing data were evaluated to assess potential biases on the outcome.

The ZIP(τ), mixed-effects regression model was evaluated in keeping with the principle of including all randomized participants with baseline and at least one follow-up outcome assessment regardless of the amount of intervention exposure. The primary analysis therefore allows for inclusion of participants that did not actually attend or finish their assigned intervention, and for the inclusion of intervention completion as a factor in a secondary analysis model. Predictor variables include two *a priori* covariates, partner risk (0=low, 1=high) and years of stimulant use, and variables representing treatment (0=HIV-Ed, 1=REMAS) and time (baseline, 3-, and 6-months follow-up) with two-way interactions of these effects in the primary analysis. Low partner risk was defined as having only one “main” partner throughout the entire length of the study who was not thought to be HIV positive, involved as a commercial sex trade worker, or trading sex for drugs. A variable capturing completion of study intervention (0=no, 1=yes) was added to the model for the secondary analysis allowing for both two-way and three-way interactions of these effects. Intervention completion was defined *a priori* as a single session attended for HIV-Ed participants and three or more sessions attended for REMAS participants. In Project Light a similar definition of completion was used. Of the 160 participants in the analysis sample that did not complete the intervention, 75 were assigned to HIV-Ed and 85 to REMAS. Of the 85 participants assigned to REMAS, 43 did not attend any intervention sessions, 21 attended one session, and 21 attended two sessions. Model-based mean predicted values were used to estimate the effect sizes (d) at 3- and 6-months follow-up. The SAS software and the NLMIXED procedure were used for the analysis (SAS, 2003).

To determine if continued substance abuse treatment engagement may explain any differences observed between the intervention conditions the following supplementary analyses were conducted separately for the 3 and 6 month follow up. A ZIP(τ) regression model, with baseline USO and partner risk as covariates, was used to test the three-way interaction effect of number of days in treatment in the past 30 with the intervention condition and completion of intervention on USO. Post hoc analyses including assessing differences in the number of days in treatment between the HIV-Ed and REMAS intervention groups, by completion of intervention status were conducted to assist in interpreting any interaction effects.

Since participants could reduce their number of USO by either engaging in less sex or by using condoms for sexual intercourse it was important to identify the nature of any differential changes in USO observed. To accomplish this, total sexual occasions was calculated in addition to the primary outcome of USO. Since partner risk was a significant covariate, total sexual occasions and number of USO were identified as being with a regular/main partner or with a casual partner. To determine the relationship between these sexual behaviors and intervention condition zero-inflated Poisson regression models were computed with the baseline (log-transformed) as a covariate.

3. Results

3.1. Study Population

The REMAS and HIV-Ed groups were not statistically different from each other on any of the demographic variables listed in the methods section except education where the HIV-Ed group was slightly higher ($m=12.4$, $sd=2.1$ vs. $m=12.0$, $sd=1.8$). The results of the logistic regression analysis to characterize missing cases indicated that participants in methadone maintenance treatment were more likely to have follow-up data than were participants in a psychosocial outpatient treatment program. Of the participants with follow-up data, 57.8% were in methadone maintenance. Additionally, participants with follow-up data were slightly more likely to have an income (odds ratio = 1.6) and tended to be slightly older ($M=40.2$) than participants without follow-up data ($M=35.9$). Additionally, in the randomized sample, the analysis sample, and the sub-sample of participants with missing data at both 3- and 6-month follow-up, there were not statistically significant differences on intervention completion status between men in HIV-Ed versus REMAS (Table 1). Participants without follow up data reported more USO at baseline ($M=26.97$) than the primary analysis sample ($M=21.97$, $\chi^2=122.04$, $p < .001$).

3.2. Study Interventions

For the randomized participants there was not a statistically significant difference between the REMAS ($M=22.31$) and HIV-Ed ($M=21.43$) groups at baseline on the primary outcome variable of USO ($p=.70$). Similarly, the REMAS and HIV-Ed groups were not significantly different on USO at baseline for the primary analysis and completer analysis samples. The results of the primary analysis utilizing the mixed-effects, zero-inflated Poisson, ZIP(τ) model indicate that after controlling for partner risk ($p=.02$), there is a statistically significant intervention-by-time interaction ($p<.0001$), which supports the primary hypothesis (technical details of the analysis are provided in the extended report). That is, REMAS participants in comparison to HIV-Ed participants show greater reductions in the number of USO during the 90 days prior to the 3 month ($M=17.8$ vs. 19.7) and 6 month ($M=16.0$ vs. 19.2) follow-ups. However, the effect sizes are small ($d=.098$ at 3-month, $d=.167$ at 6-month), and this analysis sample may reflect a more diluted intervention-by-time effect since it includes participants who did not actually complete the intervention.

Therefore, a revised model for assessing the primary outcome was used that took into account completion of the intervention (REMAS=58.3%, HIV-Ed=64.8%) by including a binary indicator variable (completion versus non-completion). This model followed the primary analysis approach in that it includes all participants with follow-up data, but also controls for the potential attenuation of the intervention effects across time when participants that did not complete are included. The results revealed a statistically significant three-way interaction effect ($p < .0001$) of intervention, time and completion status. By taking into account non-compliance to assigned intervention, a more distinct difference between the intervention groups was evident. That is, REMAS versus HIV-Ed participants who did not complete the intervention differed little on their number of USO at 3 month ($M=19.7$ vs. 19.3) and 6 month ($M=18.0$ vs. 17.3) follow-ups with very small effect sizes ($d=.017$ at 3-month, and $d=.037$ at 6-month). Of the participants who did complete the intervention, however, there was a significant decrease in the number of USO over time for REMAS versus HIV-Ed participants at the 3 month ($M=15.8$ vs. 20.0) and 6 month ($M=14.0$ vs. 20.4) follow ups. The effect sizes were moderate ($d=.213$ at 3-month and $d=.337$ at 6-month). REMAS participants who completed the intervention reduced the number of USO by 21% from baseline to 6 month follow-up compared to HIV-Ed participant completers, who increased the number of USO by 2% over the same time period.

When days in treatment in the 30 days prior to follow up is added to the ZIP(τ) regression models, with baseline USO and partner risk as covariates, there was a statistically significant three-way interaction effect of the number of days in treatment within the past 30 days with the HIV-Ed/REMAS intervention condition and completion of intervention at both 3-month follow-up ($t = 2.37, p = .018$) and 6-month follow-up ($t = 3.22, p = .001$). Post hoc analyses revealed there were no differences in the number of days in treatment in the past 30 days at 3-month follow-up between HIV-Ed ($M = 20.57$) and REMAS ($M = 19.27$) for those that completed the intervention ($t = 0.83, p = .409$) and between HIV-Ed ($M = 16.13$) and REMAS ($M = 15.64$) for participants that did not complete the intervention ($t = 0.23, p = .816$). A similar finding was found at 6-month follow-up for those that completed the intervention ($t = 0.61, p = .540$) and did not complete intervention ($t = 1.38, p = .171$). In contrast, statistically significant differences were found between those that completed the intervention and did not complete intervention. At 3-month follow-up, participants had a significantly ($t = 3.14, p = .002$) higher mean number of days in treatment if they completed the intervention ($M = 19.95$) than if they did not ($M = 15.87$). A similar finding ($t = 2.40, p = .018$) was found at 6-month follow-up (completers $M = 17.50$ and non-completers $M = 14.18$). The larger decrease in USO by the REMAS group compared to the HIV-Ed group therefore cannot be attributed to continued treatment engagement as the REMAS and HIV-Ed intervention completers did not differ on continued treatment engagement during the 6 months after intervention completion.

The remaining supplementary analyses focused only on those who completed the interventions. Presented in Table 2 are characteristics of REMAS and HIV-Ed completers' sexual activity at each assessment point, including the number and percent who are a) sexually active; b) have at least one casual sexual partner; c) use condoms with regular partners; and d) use condoms frequently (80% of the time or more) with casual partners. A repeated measures regression model indicated that fewer participants were sexually active during the follow up periods than at baseline, but this decline did not differ by intervention status. Similarly, fewer men reported having casual partners at six months compared to baseline and three months, but this did not differ by intervention condition. Analyses also showed that at baseline fewer REMAS than HIV Ed completers had used condoms frequently with casual partners, but by the 3 and 6 month follow ups the intervention groups did not differ.

Table 3 shows the mean number of total sexual occasions and USO as a function of intervention condition, assessment period and partner type. These data show that the significant decrease

in USO for REMAS completers reported in the primary analysis above is driven by two factors. First, the reduction in number of unprotected sexual occasions with regular partners is due to a decrease in overall sexual activity at both 3 and 6 months. Second, and more importantly for population risk reduction, there was an increase in total sexual occasions with casual partners at 3 months for both intervention conditions, but the increase was greater for HIV-Ed participants. In contrast, the REMAS participants decreased the number of USO with casual partners from baseline to 3 months, while there was no change in number of USO for HIV-Ed participants. Thus for casual partner sex, REMAS participants increased their condom use more than did HIV-Ed participants. These results are consistent with the findings in Table 2 for a greater increase in frequent condom use with casual partners for REMAS participants.

4. Discussion

The primary hypothesis of this randomized clinical trial was confirmed: male participants receiving an intensive HIV prevention intervention in the context of substance abuse treatment showed a relatively greater reduction in the number of USO during the 3- and 6-month follow-up periods compared to patients receiving a standard HIV-education intervention. The difference between the treatment groups was even more pronounced among those patients who met an *a priori* definition of intervention completion (for HIV-Ed: attended the single session; for REMAS: attended three or more sessions). Although continued engagement in substance abuse treatment is also associated with sexual risk reduction, the REMAS intervention contributed to sexual risk reduction over and above that which can be attributed to continued treatment engagement.

These findings are consistent with other studies. In a meta-analysis of HIV prevention interventions provided within substance abuse treatment programs Prendergast et al. (2001) calculated a medium effect size of 0.26 for sexual behavior outcomes. The present study revealed consistent effect sizes of 0.21 (3 month follow-up) and 0.34 (6 month follow-up) for USO for intervention completers. Furthermore, in exploratory analyses, Prendergast et al. found significant effect sizes for sexual behavior outcomes when separate gender sessions, didactic lectures, self-control coping, and peer group discussion intervention techniques were implemented. Although the current study did not investigate separately which elements of the REMAS interventions were efficacious, these intervention components were integrated into the five-session skills-based REMAS intervention. Semaan et al. (2002) found in their meta-analysis of HIV prevention interventions with drug users that differential sexual risk reductions were often not observed when extended/enhanced interventions were compared to standard or control interventions. Thus finding differential sexual risk reduction for REMAS over the standardized control (HIV-Ed) speaks to the potential saliency of REMAS compared to other enhanced interventions.

There are several aspects of the REMAS which substance abuse treatment programs may find desirable when considering adopting an HIV prevention intervention. REMAS was specifically designed for use in a substance treatment program. Similar to all HIV prevention interventions basic knowledge about HIV/STI are presented, including a strong focus on behaviors that facilitate or prevent transmission. Similar to other “enhanced” interventions there is a focus on increasing motivation to reduce transmission risk, and on the use of role plays and skills practice to increase prevention skills. Unique to REMAS is an extended focus on the interplay between substance use and sexual risk behavior. Emphasis is placed not only on how sex under the influence may lead to unsafe sex, but also on how sexual desires/needs/past experiences may lead to drug or alcohol relapse. In addition, many aspects of the REMAS intervention were designed to be consistent with many of the substance abuse treatment interventions commonly employed by treatment programs. For example, there is a focus on empathizing with potential partners and viewing the world from another person’s perspective. The communication skills

training encourages the use of “I” statements and other aspects of an assertive (rather than passive or aggressive) style. Role plays focus on communication skills such as drug refusal for situations where sex would be likely if drugs were used, and negotiation of condom use or non-penetrative safe sex. Motivational components focus on empowering people to make safe choices, to determine for themselves the level of risk they wish to have in their life, and to take responsibility for the risks their behavior imparts to them and their partners.

Counselors wishing to obtain training in the REMAS intervention will not need 30 hours of training as was necessary in this protocol because they will not need to learn research specific protocol procedures. Investigators found that counselors who were experienced in conducting skills groups in general learned the REMAS intervention easily and were able demonstrate competence on the first trial. Counselors less experienced in conducting these types of interventions needed more practice before they could demonstrate competence. Replacement counselors throughout the trial learned the intervention by viewing tapes of the training. All were able to demonstrate competence utilizing this method. Future REMAS training efforts may therefore use both traditional in-person workshop approaches as well as video training.

Which elements of REMAS contributed to its enhanced effectiveness compared to standard HIV counseling cannot be determined from the current clinical trial. REMAS is intensive (five sessions versus one for standard HIV counseling), involves skill building through role plays, and provides substantially more HIV risk information compared to standard HIV counseling. Any of these facets of the program, or some combination of them, might be contributing to its increased effectiveness. Future studies can investigate these factors to see if the program can be shortened, or whether certain factors should be given greater weight and attention in the delivery of the intervention. When queried at the end of the study, counselors rated the various REMAS components on a 1 (“not at all useful”) to 5 (“extremely useful”) scale. All components were viewed favorably (range of means 3.77 to 4.16) with “discussion about sex roles,” “risky sex self assessment exercise,” “brainstorming about barriers to condom use,” and “exploration of the interplay between drug use and sexual behavior” being rated the highest.

Regardless of which aspects of the program are responsible for its effectiveness, the findings of the current study suggest that substance abuse treatment programs should consider offering HIV counseling that is longer than a single session in duration to achieve greater reductions in HIV sex risk behaviors. It is premature to recommend the clinical adoption of REMAS or another gender-based programs since the current study did not directly control for duration of treatment or gender-based vs. non-gender-based interventions. Future research can address these factors. In the meantime, it is clear that a five-session program is superior to a one-session program. Although the size of the effect comparing REMAS to a single session of standard counseling was not large, the small to moderate advantage of REMAS, when extrapolated to the large numbers of patients participating in substance abuse treatment programs who are currently engaging in unprotected sex, could help reduce the numbers of such patients who are exposed to HIV and other sexually transmitted infections. If implemented in a clinical setting, the data from the current study suggest that program directors should recognize the importance of having patients attend the treatment sessions. As completion of the REMAS intervention was associated with greater effects on sexual risk outcomes, novel strategies such as tying attendance at such sessions to continued enrollment in other clinic services, or other ways of providing incentives for attendance (e.g., use of contingency management), should be considered so that maximum benefits are achieved.

Several limitations of the current study should be considered to place the results in context. Although the study was conducted in a variety of settings and had few exclusion criteria, the limits on generalizability in terms of patient factors such as self referral to the study, age, type of substance of abuse, psychiatric and substance abuse diagnosis, and sexual history, have not

been explored. Another limitation is that the counselors who participated in the program received 30 hours of special training in REMAS and ongoing supervisory feedback. It is not clear if similar results would be obtained if less intensive training is provided. As mentioned, the current study was not designed to identify the active ingredients of REMAS. In particular, it may be that five sessions of standard HIV counseling would achieve comparable results to REMAS. Finally, this study provided modest financial incentives to encourage attendance in the intervention groups, which most drug treatment programs typically cannot provide.

In summary, this study found that an intensive skills-based HIV prevention intervention was associated with greater sexual risk reduction among men in substance abuse treatment compared to a standard HIV education intervention. Among those patients who attended study intervention sessions, an even larger effect was observed. Whether the effects found here are due to the length (five sessions) of HIV sexual risk counseling or the specific content and format of the REMAS intervention, the current study suggests that treatment programs should re-evaluate the commonly used single session format of HIV counseling, weighing the cost of additional sessions with the potential reduction in public health risk.

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Pacific Northwest Node RRTC, *University of Washington Alcohol and Drug Abuse Institute*, Seattle, Washington. Lead investigator and RRTC investigator: Donald Calsyn; national project managers, Sara Berns, Mary Hatch-Maillette; lead statistician, Suzanne Doyle; local project manager, Mary Hatch-Maillette; lead quality assurance, Anthony Floyd, Donna Hertel; lead data management, Molly Carney, Katie Weaver, Michael Dudley, Brooke Leary, Viki Stanmour; lead node coordinator, Brenda Stuvek; lead training director, John Baer, with training consultation from Jennifer Sharpe-Potter (*Harvard Medical School*) and Norma Bartholomew (*Texas Christian University*). **Pacific Northwest Node CTP,** *Evergreen Treatment Services*, Seattle, WA. Site investigator, T. Ron Jackson; research coordination, Esther Ricardo-Bulis, Clark Reed, Megan Swan; intervention therapists and supervisors, John Williams, Doug Stenchever, Carol Davidson. **California/Arizona Node RRTC,** *University of California San Francisco*, San Francisco, CA. RRTC investigator, Yong Song; data/QA/protocol management, TeChieh Chen, Ellen Silber. **California/Arizona Node CTP,** *San Francisco General Hospital*, San Francisco, CA. Site PI, Yong Song, research coordination, Sarah Pelta, Rhodri Dierst-Davies, TeChieh Chen; intervention therapists and supervisors, Luis Ramos, William Buehlman, Yong Song. **Delaware Valley Node RRTC,** *University of Pennsylvania*, Philadelphia, PA. RRTC investigator, Paul Crits-Christoph; data/QA/protocol management, Charlotte Royer-Malvestuto. **Delaware Valley Node CTP,** *The Consortium*, Philadelphia, PA. Site investigator, Mark Hirschman; research coordination, Mark Hirschman, Sheila Clark; intervention therapists and supervisors, Jerome Wells, Mark Hirschman. **Delaware Valley Node CTP,** *Thomas Jefferson Intensive Substance Abuse Treatment Program*, Philadelphia, PA. Site investigators, Robert Sterling, Stephen Weinstein; research coordination,Carolynn Laurenza, Diane Losardo, Ellen Fritch; intervention therapists and supervisor, Charles Holman, Henry Bates. **Long Island Node RRTC,** *Columbia University*, New York, NY. Co-lead investigator and RRTC investigator, Susan Tross; protocol/data/quality assurance management, Jennifer Manual, Aimee Campbell, Megan Ghiroli; Jennifer Lima, Karen Loncto, Jim Robinson, Terri DeSouza. **Long Island Node CTP,** *Staten Island University Hospital*, Staten Island, NY. Research coordination, Brian Smith, Megan Ghiroli; intervention therapists and supervisors, Arthur Sagevick, Patrick Walsh, Joe Grossman. **North Carolina Node RRTC,** *Duke University Medical Center*, Durham, NC. RRTC investigator, Leonard Handelsman*; data/QA/protocol management, Tamara Owens, Tammy Day. **North Carolina Node CTP,** *Alcohol Drug Services*,

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Highpoint, NC. Site investigator, Jackie Butler; research coordination, Barbara Hobbs, Lester Flemming^{*}. **North Carolina Node CTP**, *Southlight, Inc.*, Raleigh, NC. Site investigator, Tad Clodfelter; research coordination, Allison Hartsock, Denise McRae, Tracey Vann. **New England Node RRTC**, *Yale University*, New Haven, CT. RRTC investigator, Samuel Ball; data/QA/protocol management, Kristie Smith, Julie Matthews. **New England Node CTP**, *Connecticut Renaissance, Inc.*, Bridgeport, CT. Site investigator, Pat McAuliffe; research coordination, Lisa (Markiewicz) Budris, Patrick Worhunsky; intervention therapists and supervisors, Richard Dable, Frank Shimko, Melodie Keen. **New England Node CTP**, *Hartford Dispensary*, Hartford, CT. Research coordination, Nicole Moodie, Brandi Buchas; intervention therapists and supervisors, Jimmy Moutinho, Sarah Sperrazza. **Ohio Valley Node**, *University of Cincinnati College of Medicine*, Cincinnati, OH. RRTC investigator, Judy Harrer; data/QA/protocol management, Peggy Samoza, Emily DeGarmo. **Ohio Valley Node CTP**, *Comprehensive Addiction Services System*, Toledo, OH. Research coordination, Al Woods, Scott Herr; intervention therapists and supervisors, Will Pescock, Al Woods. **Ohio Valley Node CTP**, *Presteria Center for Mental Health Services, Inc.*, Huntington, WV. RRTC investigator, Genise Lalos; research coordination, Parrish Harless, Aaron Upton; intervention therapists and supervisors, Fred Clark, George Cantees, Susan Coyer. **Pacific Node RRTC**, *University of California-Los Angeles*, Los Angeles, CA. RRTC investigator, Sara Simon; data/QA/protocol management, David Bennett, Sara Simon. **Pacific Node CTP**, *Matrix Institute on Addictions*, Rancho Cucamonga, CA. Research coordination, Gina Richardson, Sarah Cousins; intervention therapists and supervisors, Louis Battistone, Nick Nardone, Deborah Service. **South Carolina Node RRTC**, *Medical University of South Carolina*, Charleston, SC. Data/QA/protocol management, Royce Sampson. **South Carolina Node CTP**, *Lexington/Richland Alcohol and Drug Council*, Columbia, SC. Site investigator, Louise Haynes; research coordination, Kimberly Pressley, Beverly Holmes; intervention therapists and supervisors, Ulysses Rogers, Andre Walker, Louise Haynes. **Southwest Node RRTC**, *University of New Mexico*, Albuquerque, NM. RRTC investigator, Michael Bogenschutz; data/QA/protocol management, Diane Pallas, Rowena Bacca. **Southwest Node CTP**, *The LifeLink*, Santa Fe, NM. Site investigator, Diana Pallas; intervention therapists and supervisors, Art Panero, Michael DeBernardi.^{**}

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Figure 1.

CONSORT Flow Diagram

*Participants may be ineligible for multiple reasons, thus total is >332

Table 1
Percentage of Participants Completing the Intervention

Group	Yes	No	χ^2 (p)
Total Sample (n=563)			
HIV-Ed	164 (57.34)	122 (42.66)	2.62 (0.11)
REMAS	140 (50.54)	137 (49.46)	
Analysis Sample (n=417)			
HIV-Ed	138 (64.79)	75 (35.21)	1.84 (0.18)
REMAS	119 (58.33)	85 (41.67)	
Sub-sample with Missing Data at Both 3- and 6-month Follow-up (n=146)			
HIV-Ed	26 (35.61)	47 (64.39)	0.78 (0.38)
REMAS	21 (28.77)	52 (71.23)	

^a Intervention completion is defined as 1 session attended for HIV-Ed participants and 3 or more sessions attended for REMAS participants.

Note: Sample sizes are slightly smaller due to problematic documentation of intervention attendance.

Table 2

Sexual activity characteristics for REMAS and HIV-Ed completers (n=257)

Variable / Assessment Period	Intervention condition		Analysis
	REMAS	HIV-Ed	
Sexually active	<i>n</i> (%)	<i>n</i> (%)	<i>t</i> / <i>p</i>
Baseline (<i>n</i> =119/138)	113 (95.0)	133 (96.4)	
3 month (<i>n</i> =112/127)	101 (90.2)	109 (85.8)	<i>t</i> =-3.23 ^{<i>a</i>}
6 month (<i>n</i> =110/132)	89 (80.9)	113 (85.6)	<i>p</i> =0014
Sex with a casual partner			
Baseline (<i>n</i> =119/138)	51 (42.9)	70 (50.7)	
3 month (<i>n</i> =112/127)	50 (44.6)	56 (44.1)	<i>t</i> =-3.37 ^{<i>a</i>}
6 month (<i>n</i> =110/132)	38 (34.5)	47 (35.6)	<i>p</i> =0009
Any Condom Use-Regular Partner			
Baseline (<i>n</i> =73/87)	15 (20.5)	23 (26.4)	
3 month (<i>n</i> =59/64)	20 (33.9)	21 (32.8)	ns
6 month (<i>n</i> =57/77)	22 (38.6)	26 (33.8)	
High Condom Use (80%)-Casual Partner			
Baseline (<i>n</i> =45/68)	2 (4.4)	12 (17.6)*	
3 month (<i>n</i> =51/56)	15 (38.5)	20 (38.5)	<i>t</i> =-1.99 ^{<i>b</i>}
6 month (<i>n</i> =39/52)	11 (21.6)	11 (19.6)	<i>p</i> =.049

^{*a*}Significant *t* value for “time” main effect in repeated measures logistic regression model^{*b*}Significant *t* value for “intervention” main effect in repeated measures logistic regression model

Table 3
For intervention completers, differences in number of sexual occasions and unprotected sexual occasions as a function of partner type and intervention condition at 3 and 6 months

Regular Partner Sexual Behavior	REMAS		HIV-Ed		Analyses statistics	
	Baseline Mean ^a (n)	Follow up Mean (n)	Baseline Mean (n)	Follow up Mean (n)	<i>b</i>	<i>p</i> <i>Effect size</i>
Sexual occasions at 3 mo.	21.84 (62)	16.40 (62)	27.20 (66)	25.71 (66)	-6.84	<.0001
Unprotected sexual occasions at 3 mo.	20.74(62)	13.90 (62)	24.71(66)	18.85(66)	-4.93	<.0001
Sexual occasions at 6 mo.	24.16 (50)	20.70 (50)	26.42 (78)	27.91 (78)	-8.06	<.0001
Unprotected sexual occasions at 6 mo.	22.34 (50)	16.80 (50)	23.45 (78)	22.35 (78)	-8.95	<.0001
Casual Partner Sexual Behavior						
Sexual occasions at 3 mo.	16.33 (30)	20.9 (30)	19.76 (38)	27.00 (38)	0.85	0.40
Unprotected sexual occasions at 3 mo.	12.07 (30)	10.97 (30)	16.63 (38)	16.58 (38)	-4.02	.0002
Sexual occasions at 6 mo.	20.00 (25)	16.52 (25)	20.47 (35)	16.17 (35)	-0.44	0.66
Unprotected sexual occasions at 6 mo.	15.27 (25)	11.08 (25)	14.67 (35)	12.03 (35)	-.029	0.77

^a Baseline means are those for the cases for whom there is follow up data for each follow up data analysis.

^b *t* value for zero inflated Poisson regression model with baseline (log transformed) as a covariate.

Appendix A

Intervention session outlines for HIV-Ed and REMAS

Session Number	Intervention topics	Suggested Time (min)
HIV-Ed	Group Introductions. Goals and Guidelines	5
	HIV/AIDS Update (definitions, HIV/AIDS progression, transmission routes)	10
	HIV Risky Behaviors, injection practices	5
	HIV Risky Behaviors, sexual practices	10
	Condom demonstration	10
	Barriers to Condom Use	10
	Healthy options	10
<hr/>		
REMAS 1 - HIV/AIDS Update: Identifying Risks		
	Group Introductions. Goals and Guidelines	10
	Getting Started	10
	HIV Risky Behaviors Exercise	15
	HIV/AIDS Update	15
	HIV Risky Behaviors, injection practices	5
	HIV Risky Behaviors, sexual practices	15
	Condom demonstration	10
	Revisit Risky Behaviors Exercise	10
REMAS 2 - HIV/AIDS Update: Planning Prevention		
	Welcome, redo introductions	5
	Healthy options	10
	Barriers to Condom Use	20
	Condom Practice	25
	Identifying Triggers	15
	Risk Reduction Problem Solving	15
REMAS 3 - Sex without drugs. Can it happen? Is it Pleasurable?		
	Welcome, redo introductions	5
	Personalizing commitment to sexual safety	15
	Experience with combining sex & drugs	35
	Enhancing sex without drugs	20
	Coping with sexual impairment without drugs	15
REMAS 4 - Beyond the pick up line, communicating about safe sex		
	Welcome, redo introductions	5
	Challenging Stereotypes	20
	Unwritten rules	10
	Responsibility in sexual relationships	20
	Communicating about Safe Sex I (TALK Tools)	35
REMAS 5 - Communicating about safe sex II		
	Welcome, redo introductions	5
	Practice TALK	25

Session Number	Intervention topics	Suggested Time (min)
	Turning Around Partner Objections	25
	Workshop Summary	25
	Closing/Wrap-up	10