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Men in methadone maintenance versus psychosocial outpatient treatment: Differences in sexual risk behaviors and intervention effectiveness from a multisite HIV prevention intervention trial

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Abstract

The effectiveness of the Real Men Are Safe (REMAs) HIV prevention intervention was examined as a function of treatment program modality. REMAS was associated with significantly larger decreases in unprotected sexual occasions than an HIV Education control condition in both treatment modalities. REMAS had superior effectiveness for reducing unprotected sexual occasions in the psychosocial outpatient compared to methadone. At 6-month follow up, the adjusted mean change for REMAS completers in psychosocial outpatient ($M=6.4$, $d=0.38$) was greater than for REMAS completers in methadone programs ($M=2.3$, $d=0.25$). Reasons for why REMAS appears to be especially effective in psychosocial outpatient programs are explored.

Keywords

HIV prevention; substance abuse treatment modality; behavioral intervention; sexual risk reduction

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INTRODUCTION

Drug-involved men continue to be at heightened risk for HIV infection resulting from unsafe injection drug practices and higher rates of sexual risk behaviors, the two primary modes of HIV transmission.¹ Substance use, especially the use of stimulant drugs, has been linked to increased numbers of sexual partners, higher rates of anal intercourse, and decreased condom use.^{2–4} Men with substance use disorders often have partners who also abuse drugs, further increasing the couple's vulnerability to drug related and sexual HIV risk behaviors.

Drug abuse treatment programs have been shown to have a powerful influence on drug use and injection risk reduction,^{5–6} but smaller effects on sexual risk behavior.⁷ These findings, in part, have to do with the intensity of HIV prevention efforts within drug treatment programs. For example, a survey of community-based drug treatment programs in the National Institute on Drug Abuse (NIDA) Clinical Trials Network (CTN) found that standard HIV education consisted of one 30- to 90- minute information group.⁸ Such brief, didactic education has been found to be insufficient for decreasing sexual risk behavior.^{9,10} However, in meta-analyses and reviews of controlled studies of HIV risk reduction interventions among drug users, HIV sexual risk reduction interventions, with certain defining characteristics, have been found to be effective.^{10–12} These characteristics include: gender-specific groups, co-leadership, adequate intensity and length, peer group discussion, and a range of skills-building techniques. The authors recently completed a randomized effectiveness trial of a 5-session, HIV/STD prevention intervention for male drug users, Real Men Are Safe (REMAS), within the NIDA CTN in 14 community-based outpatient drug treatment programs. REMAS contains didactically-delivered informational material, as well as ample role-plays, peer group discussions, and self-assessment motivational exercises. The REMAS intervention drew from The NIMH Multisite HIV Prevention Trial Group's *Project Light* (PL)¹³ and Bartholomew and Simpson's *Time Out! For Men* (TOMen),^{14,15} a manual driven, gender-specific, communication skills and sexuality workshop for men. Additionally, new intervention modules targeting sexual behavior while under the influence of drugs or alcohol were developed specifically for REMAS. In one module a decisional balance approach challenged participants to weigh the pros and cons of sex under the influence, and to brainstorm alternative ways to obtain the “pros” without using. In another module a risk refusal role play scenario was added focused on refusing to use drugs even knowing sex would have accompanied the drug using. Compared to a single HIV education group (HIV-Ed), REMAS was associated with significantly fewer unprotected vaginal and anal sex occasions in the 90 days prior to the 6-month follow up ($M = 16.0$ vs. 19.2 , $d = .167$), with larger differences for participants who completed the intervention ($M = 14.0$ vs. 20.4 , $d = .337$).¹⁶ Men assigned to the REMAS condition reporting sex under the influence at the most recent sexual event decreased from 36.8% at baseline to 25.7% at 3-month follow up compared to an increase from 36.9% to 38.3% in the HIV-Ed condition.¹⁷ The REMAS trial offers further evidence of the effectiveness for more comprehensive HIV risk reduction within drug treatment settings and the important role of intervention exposure to enhance outcomes.

The majority of HIV prevention trials have been conducted in methadone maintenance treatment programs.⁶ The REMAS trial, conducted in 7 methadone maintenance and 7 outpatient psychosocial treatment programs, offered an ideal context in which to examine the question of whether REMAS had differential effectiveness by treatment program modality. Methadone maintenance and psychosocial outpatient programs differ in ways that may relate to the effectiveness of HIV prevention interventions. For example, patients seeking treatment in psychosocial programs are more likely to present with primary stimulant or alcohol use disorders, whereas methadone programs are largely populated by

those with primary opioid dependence. Stimulant use can result in higher sexual risk due to hypersexuality and disinhibition.^{18–19} For men, both cocaine and methamphetamine use are strongly linked to sexual drive and sexual pleasure, more so than for women.³ In contrast, opioid use has been associated with suppression of sexual drive and function.^{20–21}

Further differences are highlighted by Simpson, et al.,²² using data from the Drug Abuse Treatment Outcome Study (DATOS), who report lower treatment retention in psychosocial programs compared to methadone programs and poorer treatment retention in programs with heavier cocaine use. Treatment retention has also been associated with improvement in drug use outcomes.²³ Core treatment components also differ across program modality. The provision of a medication is central to methadone treatment, whereas psychosocial interventions such as individual counseling and group therapy have a lesser role. The reverse is true in psychosocial outpatient programs, where group and individual counseling are central components, while medication assistance for substance abuse problems has a less prominent role.²⁴ Finally, patients attending a methadone program are much more likely to be injection drug users than those attending psychosocial outpatient programs. Since injection drug use is the second most frequent risk factor associated with HIV infection in the USA, HIV prevention interventions may historically have been more prominent in methadone maintenance programs than psychosocial outpatient programs.

These findings led to the hypothesis that REMAS would have differential effectiveness by program modality, with greater intervention exposure obtained within methadone maintenance programs compared to psychosocial programs due to historically better retention in methadone treatment. Of those patients attending the interventions, we hypothesized the REMAS intervention would be equally effective at reducing the frequency of unprotected sexual occasions. The results from this study will aid in the understanding of how programmatic features affect HIV risk reduction program outcomes and inform the refinement of interventions.

METHODS

Participants

Participants were 590 men enrolled in an HIV risk reduction study that was conducted in 7 methadone maintenance (n = 288) and 7 outpatient, non-medication assisted psychosocial outpatient (n = 302) treatment programs in the United States. These treatment programs were diverse in terms of region, population density, and HIV prevalence rates. Sites were urban (e.g. Philadelphia, PA), suburban (e.g., Norwalk, CT) and rural (e.g., Huntington, WV), and were located in the Northeast, South, Midwest, Southwest, and West. HIV prevalence data at each site was not collected as part of this study, but some sites (e.g. Staten Island, NY, San Francisco, CA) were in cities known to have a higher prevalence of HIV than others (e.g., Santa Fe, NM, Columbia, SC). Specific sites are listed elsewhere.¹⁶ All clinical sites within the CTN who indicated an initial interest in the study and demonstrated a likely ability to recruit the required number of subjects were selected for participation. The study compared a 5-session HIV risk reduction intervention developed specifically for men, Real Men Are Safe (REMAS), to a standard 1-session HIV/AIDS education group intervention (HIV-Ed).

Participants were men aged 18 and above who were in substance abuse treatment, reported engaging in unprotected vaginal or anal intercourse during the prior 6 months, were willing to be randomly assigned to one of two interventions and complete study assessments, and able to speak and understand English. Participants were recruited between May, 2004 and October, 2005, and were 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. Excluded were men who showed gross mental status impairment defined as severe distractibility, incoherence or retardation as measured by the Mini Mental Status Exam^{25–26} or clinician assessment, and men who had a primary sexual partner who was intending to become pregnant while the participant was enrolled in the trial. Men in methadone maintenance were eligible for participation once they had been in treatment 30 days. This was done to increase the likelihood they would have achieved a stable dose of methadone before starting the groups. The HIV status of participants was unknown.

Assessment and case identification procedures

The Sexual Behavior Interview (SBI) was administered as part of assessments conducted at baseline, 3-months post intervention and 6-months post intervention. The SBI items were selected or adapted from the SADAR (Sex and Drug Abuse Relationship Interview)²⁷ and the SERBAS (Sexual Risk Behavior Assessment Schedule).^{28,29} Behaviors assessed included: 1) frequency of unprotected vaginal, anal, and oral sex by partner type (main vs. casual) over the past 90 days; 2) number, gender, and risk status of partners (high risk defined as injection drug using, crack cocaine using, exchanges sex for drugs/money, or is thought to be HIV positive); 3) percentage of times sex occurred under the influence of drugs or alcohol over the prior 90 days, and 4) an assessment of the most recent sexual event that included: number of days since the event, was the participant and/or partner under the influence and if yes, which drug(s), what sex acts took place, and were condoms used. SBI items were administered using the audio computer assisted structured interview (ACASI) method, shown to elicit more self reports of high-risk behaviors, and thus more valid reporting, than face-to-face interviews.^{30,31}

The Addiction Severity Index-Lite,³² a standardized, multidimensional, semi-structured, comprehensive clinical interview that provides information important for formulating treatment plans as well as problem severity profiles in six domains of functioning, was administered at baseline. The domains include drug and alcohol use, medical, psychiatric, legal, family/social and employment/support. Composite Scores for each problem domain are derived.

Of the 590 participants randomized in the parent trial 429 (72.7%) completed either a 3-month or a 6-month follow up; 356 (60.3%) completed assessments at baseline and both 3- and 6-months follow-up. The baseline interviewers' identification of participants' primary substance abuse problem, based on the Addiction Severity Index-Lite, were: one or more drugs but not with alcohol (25.8%); alcohol alone or combined with one or more drugs (38.4%); opioids (14.1%); stimulants (16.6%); and other drugs such as cannabis and sedatives/hypnotics/tranquilizers (5.1%).

Interventions

Participants were randomized to attend either REMAS or HIV-Ed. REMAS was a workshop of five 90-minute group sessions delivered over 3 weeks. In addition to lecture material, there was liberal use of role-plays, peer group discussions and self-assessment motivational exercises.¹⁶ Consistent with the practical clinical trials model,^{33,34} the HIV-Ed group was intended to represent a standardized treatment-as-usual intervention. This intervention consisted of selected educational material from the REMAS intervention. The two group interventions, REMAS and HIV-Ed, were delivered by male counselors already employed in the study clinics. Groups were conducted by co-leaders who shared responsibility for delivery of the treatment. The treatment counselors received approximately 30 hours of training in conducting both of these manual-driven interventions. Both conditions consisted

of groups of 3–8 men. Details concerning randomization and fidelity monitoring are provided in Calsyn et al.¹⁶

Data analyses

The initial analyses compared the psychosocial outpatient program participants to the methadone participants on demographics and sexual risk behaviors in the 90 days prior to baseline assessment. For continuous measures, *t*-tests were used unless the distribution was extremely skewed. In such cases the variable was split into meaningful categories and treated as a categorical variable. For categorical variables, contingency table analysis utilizing the χ^2 statistic was employed. Intervention attendance and intervention completion were also analyzed utilizing the χ^2 statistic. Since there was a delay of a few days up to 4 weeks between baseline assessment and the first intervention session due to cohort formation, there were a subset of participants who had left treatment prior to being able to attend their assigned intervention. The intervention attendance and completion analyses were conducted with and without the participants who had left treatment prior to the first intervention session.

In the parent study the primary hypothesis that REMAS participants would reduce their number of unprotected vaginal/anal intercourse sexual occasions in the past 90 days more than HIV-Ed participants was tested utilizing a mixed-effects, zero-inflated Poisson (ZIP(τ)) model.^{35,36} Predictor variables in the final model included intervention condition (REMAS/HIV-Ed), time (baseline, 3-month, 6-month), an *a priori* covariate, partner risk (high/low), and completion of study intervention. 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 allowed 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. Intervention completion was defined *a priori* as a single session attended for HIV-Ed participants and three or more sessions attended for REMAS participants. To determine if there was a differential intervention effect as a function of treatment program modality it was added to this final model. In addition, demographic and baseline sex risk variables that were related to change over time in the primary outcome and that differed between the methadone maintenance and psychosocial outpatient treatment modalities were added to control for potential confounding. Potential demographic and baseline sex risk variables to be entered into the final model were identified utilizing separate ZIP(τ), mixed-effects regression models for each variable as a main effect, including time (baseline, 3-month, 6-month) and the time-by-variable interaction. Predictor variables in the final model included intervention condition (REMAS/HIV-Ed), time (baseline, 3-month, 6-month), completion of study intervention, and four covariates related to changes in the outcome variable: age (dichotomized at a median split at age 41), education level (high school or higher vs. less than high school), employment status (employed full- or part-time vs. unemployed) and partner risk (high vs. low). Model-based mean predicted values were used to estimate *d*, the effect size³⁷ at 3- and 6-month follow up.

RESULTS

Demographics

Men recruited from methadone maintenance were older ($M = 42.2$, $SD = 9.8$ vs. $M = 36.1$, $SD = 10.2$, $t = 7.4$, $p < .001$), slightly less educated ($M = 12.0$, $SD = 1.8$ vs. $M = 12.4$, $SD = 1.9$, $t = 2.7$, $p < .01$), less likely to be employed (46.87% vs. 78.74%, $\chi^2 = 64.2$, $p < .001$), and significantly more likely to be Caucasian (63.41% vs. 52.65%, $\chi^2 = 7.0$, $p < .01$) than

men recruited from psychosocial outpatient. Men in methadone maintenance and psychosocial outpatient programs did not differ on marital status.

Baseline sexual risk behavior

Presented in Table 1 are the sexual risk behaviors reported for the 90 days prior to baseline assessment. Men from methadone maintenance, compared to those from psychosocial outpatient, were significantly more likely to report having a high risk sexual partner, and if they had a main sex partner, that person was significantly more likely to be from a high risk group. Men from psychosocial outpatient reported significantly more frequent sex (e.g., vaginal intercourse 40–89 times or >89 times in the prior 90 days) than men from methadone maintenance. Men in methadone maintenance were significantly more likely to report having been under the influence of drugs or alcohol during their most recent sexual event. If the most recent sexual event had been with a casual partner, men from methadone maintenance were no more likely to have been under the influence than men from psychosocial outpatient.

Demographic and baseline sex risk differences between men in methadone maintenance and psychosocial outpatient that were related to statistically significant changes in the primary outcome (number of unprotected sexual occasions) from baseline to 3- and 6-month follow up were age ($p = .010$), education ($p < .001$), employment status ($p < .001$) and partner risk ($p < .001$). Younger men (< 41) tended to decrease the number of unprotected sexual occasions from baseline to 6-month follow up, whereas older men tended to have a lower number of unprotected sexual occasions than younger men at baseline with negligible change over time. Higher educated men (12+ years), men that were employed, and those with low risk partners also tended to decrease the number of unprotected sexual occasions more over time.

Intervention attendance and completion

Presented in Table 2 is the intervention attendance as a function of treatment modality. When all randomized participants are considered, men from methadone programs were more likely to attend each session of both the HIV-Ed and the REMAS interventions than men from psychosocial outpatient programs. However, participants in outpatient psychosocial programs were more likely to have left substance treatment prior to the first opportunity to attend an HIV prevention intervention session ($n = 76, 25.17\%$) than those in methadone maintenance ($n = 12, 4.17\%$; $\chi^2 = 51.22, p < .001$). When only participants still in treatment at the time of the first intervention session are considered, methadone participants were no more likely to attend the HIV Ed session and only more likely to attend session 2 and session 3 of the REMAS intervention.

Consistent with the attendance results, men in methadone maintenance (65.6%) were significantly more likely than men in psychosocial outpatient programs (55.9%) to complete their assigned intervention ($\chi^2 = 4.010, p = .045$). However, there was no significant differences between completers and non-completers in terms of the baseline measures of age ($\chi^2 = 1.260, p = .262$), education ($\chi^2 = 0.324, p = .569$), employment ($\chi^2 = 0.088, p = .767$), partner risk ($\chi^2 = 0.445, p = .505$), minority status ($\chi^2 = 0.358, p = .550$), and being under the influence of drugs or alcohol ($\chi^2 = 0.358, p = .550$).

Intervention effectiveness

Controlling for partner risk ($p = .007$), there was a statistically significant Intervention $\times$ time $\times$ treatment modality $\times$ intervention completion interaction ($p < .001$) obtained from the mixed-effects ZIP(τ) model. In addition, there were significant interactions for intervention $\times$ time $\times$ treatment modality ($p < .001$), intervention $\times$ time $\times$ intervention completion ($p < .$

001), and time $\times$ treatment modality $\times$ intervention completion ($p < .001$). The resulting three and four variable interactions were difficult to interpret. Since our main interest was in treatment modality differences for those who completed the intervention, the analyses were repeated for completers only.

The analysis repeated for completers resulted in a more interpretable model (Table 3). There is a significant time $\times$ intervention $\times$ treatment modality interaction ($p = .012$). None of the covariates entered into the final model to control for baseline differences between methadone and psychosocial outpatients were significant. Consistent with the findings from the parent study, inspection of the model-based means graphed in Figure 1 indicate that REMAS completers reduced the number of unprotected sexual occasions more than HIV-Ed completers and that this was true for both methadone and psychosocial outpatient participants. In addition, there was a sharper decline in number of unprotected sexual occasions for REMAS psychosocial outpatient completers than REMAS methadone completers. By 6-months post intervention, the REMAS psychosocial outpatient completers had reduced their adjusted (model-based) mean number of unprotected vaginal/anal intercourse occasions by 6.5 ($d = 0.38$) occasions over the past 90 days, while the REMAS methadone completers had reduced from baseline levels by 2.2 ($d = 0.25$) occasions. Participants completing the single session HIV-Ed showed no improvement whether they were in methadone programs or psychosocial outpatient programs (Figure 1).

DISCUSSION

As hypothesized, methadone maintenance participants were more likely to attend both HIV prevention interventions than psychosocial outpatient participants. However, contrary to our hypothesis, participants in psychosocial outpatient programs who completed the REMAS intervention reduced their unprotected sexual occasions more than participants in methadone programs who completed the REMAS intervention. At 6-months post intervention, the adjusted mean change for REMAS completers in psychosocial outpatients programs was nearly 3 times greater than that for the REMAS completers in methadone programs. Corresponding effect sizes were also robust ($d = 0.38$ versus $d = 0.25$). Thus, REMAS appears to be especially effective for individuals receiving substance abuse treatment in a psychosocial outpatient program. It should be noted, however, that the REMAS intervention was effective even for those who received it in a methadone program compared to participants who completed the 1-session HIV education intervention (the latter did not reduce their unprotected sexual occasions from baseline levels, in either methadone maintenance or psychosocial outpatient programs).

There are several possible factors that might explain the unexpected finding of superior effectiveness of REMAS in psychosocial outpatient programs compared to methadone programs. These factors include aspects of the study design, confounding patient variables between the treatment program types, the effects of methadone as a treatment, and greater relevance of the REMAS intervention to patients in psychosocial outpatients programs. The study design permitted psychosocial outpatients to enroll in the current HIV sexual risk reduction investigation at any point in their participation in their substance abuse treatment program, and methadone patients to enroll anytime past the initial 30 days of treatment. Previous studies have found attrition from psychosocial treatment programs is very high, while patients who initially engage at a methadone program typically continue in treatment.²² Data from the current study is consistent with this pattern; randomized participants in the psychosocial outpatient programs were significantly more likely than those from methadone programs to drop out of the treatment program before obtaining their first REMAS or HIV-Ed session. Increased dropout within psychosocial programs supports our hypothesis of superior intervention exposure in methadone maintenance programs. We can speculate that

the desire for methadone likely promotes continued attendance in methadone programs, regardless of patients' overall level of motivation to participate in substance abuse treatment. In contrast, less motivated patients are likely to drop out of psychosocial outpatient programs early in the process, leaving a more motivated patient sample to participate in treatment and make improvements to their lives. This strengthened motivation may translate into greater skill attainment in the REMAS program, and consequently better outcomes.

Other patient variables may also be confounding the comparison of methadone programs with psychosocial outpatient programs. Patients participating in these programs differed at baseline on a host of demographic variables, (age, education, employment, race) and sexual risk variables (rates of engaging in vaginal intercourse, having high risk sexual partners, and engaging in sex under the influence of drugs or alcohol). However, even when these variables are statistically controlled in the data analysis, the psychosocial outpatient-methadone maintenance program differences remain. REMAS may also have been more effective in psychosocial outpatient programs because a greater percentage of patients in these programs found the content of REMAS to be more relevant to their sexual lives. Thus, it may be that more patients in the psychosocial treatment programs were better able to make use of the skills taught in REMAS in their daily lives.

The REMAS intervention consisted of five 90-minute group counseling sessions. The REMAS modules were more likely to be similar in both process style and content to the group counseling visits already provided to psychosocial outpatients in their treatment program. In contrast, REMAS modules may have seemed somewhat dissimilar to the treatment interventions to which methadone maintenance patients were familiar as most of the psychosocial treatment provided in those settings is via individual counseling. This difference in familiarity may have impacted REMAS effectiveness in the two settings.

Another possible reason for reduced effectiveness of REMAS in methadone programs is the pharmacological effect of methadone. Opiate dependent individuals receiving methadone have been found to show greater cognitive impairments than abstinent heroin abusers entering inpatient rehabilitation as measured by standardized neuropsychological tests.³⁸ In addition methadone maintenance patients demonstrated impaired decision-making and slower cognitive flexibility than buprenorphine maintained patients and matched non-drug abusing controls on the Iowa Gambling Task and the Wisconsin Card Sorting Task.³⁹ These methadone-induced cognitive impairments may interfere with learning of REMAS skills, and the impaired decision-making may result in higher rates of unprotected sex, compared to patients not receiving methadone (and less likely to be opiate dependent) in the psychosocial outpatient programs.⁴⁰ To counter possible cognitive effects of methadone, the REMAS intervention may need to be modified in order to enhance effectiveness. Smaller groups, a slower pace, and extended numbers of sessions are possible modifications that could facilitate learning within this population. Further research into cognitive rehabilitation or remediation (e.g., Grohman and Fals-Stewart⁴¹) to facilitate HIV prevention skill uptake should also be explored.⁴²

In addition to the study limitations mentioned above (i.e., multiple confounding variables; impact of attrition from treatment programs on exposure to study interventions), several other limitations should be mentioned. Participants self-referred to the study. It is unknown how similar or different they were from other patients attending participating clinics who did not participate, thus somewhat limiting generalizability. Study participants may have been more or less motivated to change their sexual risk behavior compared with non-participants. Whatever the impact of self referral might have been on the parent study, we have no reason to believe that self referral differed as a function of treatment modality. It is important to acknowledge that the comparison between methadone programs and psychosocial outpatient

programs was a secondary aim of the study evaluating the effectiveness of REMAS. The results presented here need to be confirmed with a prospective study that is designed, and statistically powered, to evaluate differences in effectiveness between program modalities. Another limitation is that it is difficult to attribute with any certainty the differences between REMAS and the 1-session HIV education intervention to the specific content of the REMAS model. Because REMAS was 5 sessions, any differences between these interventions may have been due to the duration, rather than the content, of the interventions. A final limitation relates to our ability to extrapolate the current findings to the clinical implementation of REMAS in drug treatment programs. In our study, participants were provided with modest financial incentives to encourage attendance in the intervention groups. These financial incentives may have increased attendance, and we highlighted results that emerged from the sample of participants who completed the interventions. Most drug treatment programs do not provide financial incentives to patients and therefore in clinical practice fewer patients might be expected to complete, and therefore benefit from, such interventions if attendance is voluntary.

In summary, a 5-session sexual risk reduction intervention for men involving didactically-delivered informational material, role-plays, peer group discussions, and self-assessment motivational exercises was found to have superior effectiveness in reducing unprotected sexual occasions, compared to a 1-session HIV education intervention, among patients in psychosocial outpatient substance abuse treatment programs compared to patients in methadone programs. Modifications of the REMAS approach may be needed to further enhance effectiveness with methadone maintained patients.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.

Table 1

Baseline sexual risk behaviors for men in outpatient psychosocial and methadone maintenance treatment programs

Sexual Risk Variables (90 days prior to baseline assessment)	Treatment Program		Statistical Analyses
	Outpatient Psychosocial (n=302)	Methadone Maintenance (n=288)	
	n (%)	n (%)	χ^2
Number of Sexual Partners			
0	28 (9.4)	18 (6.3)	7.4
1	142 (47.7)	160 (55.8)	
2	45 (15.1)	43 (15.70)	
3	30 (10.1)	17 (5.9)	
4	21 (7.1)	23 (8.0)	
>4	32 (10.7)	26 (9.1)	
Have a Main Sexual Partner			
Yes	196 (65.8)	194 (67.6)	0.2
No	102 (34.2)	93 (32.4)	
Live with Main Sex Partner			
Yes	100 (52.1)	112 (59.6)	2.2
No	92 (47.9)	76 (40.4)	
Main Partner Is High Risk ^a			
Yes	28 (14.6)	70 (37.0)	25.1 ***
No	164 (85.4)	119 (63.0)	
Any High Risk Partners ^a			
Yes	96 (37.2)	136 (55.1)	16.2 ***
No	162 (62.8)	111 (44.9)	
Frequency of Penile-Vaginal Sex (number of occasions) ^b			
0	7 (2.8)	6 (2.4)	11.8 *** c
1 – 13	101 (40.1)	114 (45.4)	
14 – 39	58 (23.0)	78 (31.1)	
40 – 89	54 (21.4)	35 (13.9)	
90 +	32 (12.7)	18 (7.2)	
Frequency of Penile-Anal Sex with women(number of occasions)			
0	161 (63.9)	161 (64.1)	0.03
1–13	74 (29.4)	74 (29.5)	
>13	17 (6.8)	16 (6.4)	
Percent of Condom Use for Penile-Vaginal/Anal sex with main partners.			
0	140 (80.0)	136 (75.6)	1.4
1–50	20 (11.4)	22 (12.2)	
>51	15 (8.6)	22 (12.2)	
Percent of Condom Use for Penile-Vaginal/Anal sex with casual partners.			
0	70 (52.2)	69 (55.2)	0.3

Sexual Risk Variables (90 days prior to baseline assessment)	Treatment Program		Statistical Analyses
	Outpatient Psychosocial (n=302)	Methadone Maintenance (n=288)	
	n (%)	n (%)	χ^2
1-50	33 (24.6)	28 (22.4)	
>51	31 (23.1)	28 (22.4)	
Any Sex Under the Influence of Drugs or Alcohol ^d			
Yes	175 (67.8)	217 (82.2)	14.4 ***
No	83 (32.2)	47 (17.8)	
Sex Under the Influence of Drugs/Alcohol During Most Recent Sexual Event, Regular Partner			
Yes	56 (26.4)	92 (42.8)	12.6 ***
No	156 (73.6)	123 (57.2)	
Sex Under the Influence of Drugs/Alcohol During Most Recent Sexual Event, Casual Partner			
Yes	56 (62.9)	45 (61.6)	0.03
No	33 (37.1)	28 (38.4)	

^a High risk defined as being one of the following: injection drug user, crack cocaine user, traded sex for money or drugs, is thought to be HIV⁺.

^b Includes only men who report sex with women

^c Simple effects testing (not shown) indicates more of the Psychosocial Outpatient participants were in the 40-89 and 90+ categories than methadone maintenance participants.

^d Sexually active only.

* $p < .05$

** $p < .01$

*** $p < .001$.

Table 2

Intervention session attendance as a function of treatment modality

Treatment modality-all participants			
Intervention Session	Methadone maintenance n (%)	Psychosocial outpatient n (%)	Statistic χ^2 (p-value)
HIV Education			
Session 1	91/146 (62.3)	74/148 (50.0)	4.5 (.033)
Real Men Are Safe			
Session 1	91/141 (64.5)	64/145 (44.1)	12.0 (<.001)
Session 2	96/141 (68.1)	59/143 (41.3)	20.6 (<.001)
Session 3	85/140 (60.7)	55/141 (39.0)	13.2 (<.001)
Session 4	71/140 (50.7)	52/141 (36.9)	5.5 (.019)
Session 5	75/140 (53.4)	56/139 (40.3)	4.9 (.026)
Attended ≥ 3 sessions	85/142 (59.9)	61/149 (40.9)	10.4 (.001)
Treatment modality-participants still in treatment			
Intervention Session	Methadone maintenance n (%)	Psychosocial outpatient n (%)	Statistic χ^2 (p-value)
HIV Education			
Session 1	91/141 (62.5)	74/107 (69.2)	0.6 (.445)
Real Men Are Safe			
Session 1	91/135 (67.4)	64/113 (56.6)	3.0 (.081)
Session 2	96/135 (71.1)	59/113 (52.2)	9.4 (.002)
Session 3	85/135 (63.0)	55/112 (49.1)	4.8 (.029)
Session 4	71/135 (52.6)	52/112 (46.4)	0.9 (.335)
Session 5	75/135 (54.4)	56/110 (50.9)	0.5 (.468)
Attended ≥ 3 sessions	85/135 (63.0)	61/115 (53.0)	2.5 (.113)

Table 3

Results of the regression model for the number of sexual events without condoms at baseline, 3-, and 6-month follow-ups as a function of treatment modality and intervention for intervention completers only.

Completers only				
	Parameter Estimate	Standard Error	t - value	Prob. < t
Fixed Effects				
Intercept	3.04	0.27	11.35	<.001
Age (< 41 vs. 41+)	-0.55	0.16	-3.53	<.001
Education (< 12 vs. 12 + years)	0.21	0.19	1.10	.274
Employed (No vs. Yes)	-0.05	0.25	-0.58	.560
Partner Risk (Low vs. High)	-0.29	0.16	-1.75	.081
Time	0.04	0.02	1.92	.056
Intervention	-0.03	0.25	-0.13	.898
Treatment Modality	-0.23	0.22	-1.06	.288
Intervention × Time	-0.19	0.03	-5.65	<.001
Intervention × Treatment Modality	-0.17	0.31	-0.54	.593
Time × Treatment Modality	-0.04	0.03	-1.40	.162
Intervention × Time × Treatment Modality	0.12	0.05	2.55	.012
Random Effects				
Logistic ($\hat{\nu}$)	2.03	0.66	3.07	.002
Poisson ($\hat{\nu}$)	1.28	0.14	8.88	< .001
Covariance ($\hat{\nu}$, $\hat{\nu}$)	-0.96	0.20	-4.77	<.001
Scale Parameter				
τ	-0.58	0.067	-8.77	< .001