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HERMITAGE – A Randomized Controlled Trial to Reduce Sexually Transmitted Infections and HIV-risk Behaviors among HIV-infected Russian Drinkers

Jeffrey H. Samet, MD, MA, MPH^{1,2}, Anita Raj, PhD³, Debbie M. Cheng, ScD⁴, Elena Blokhina, MD, PhD⁵, Carly Briden, MA, MPH⁶, Christine E. Chaisson, MPH⁷, Alexander Y. Walley, MD, MSc¹, Tibor P. Palfai, PhD⁸, Emily K. Quinn, MA⁶, Edwin Zvartau, MD, PhD, DMSc⁵, Dmitry Lioznov, MD, PhD⁵, and Evgeny Krupitsky, MD, PhD, DMSc^{5,9}

¹Department of Medicine, Section of General Internal Medicine, Clinical Addiction Research and Education (CARE) Unit, Boston University School of Medicine/Boston Medical Center, 801 Massachusetts Avenue, 2nd Floor, Boston, MA 02118, United States

²Department of Community Health Sciences, Boston University School of Public Health, 801 Massachusetts Avenue, 2nd Floor, Boston, MA 02118, United States

³Division of Global Public Health, Department of Medicine, University of California - San Diego School of Medicine, IOA Building, 10111 N. Torrey Pines Rd., San Diego, CA 92137, United States

⁴Department of Biostatistics, Boston University School of Public Health, 801 Massachusetts Avenue, 3rd Floor, Boston, MA 02118, United States

⁵First St. Petersburg Pavlov State Medical University, Lev Tolstoy St. 6/8, St. Petersburg 197022, Russian Federation

⁶Department of Medicine, Section of General Internal Medicine, Clinical Addiction Research and Education (CARE) Unit, Boston Medical Center, 801 Massachusetts Avenue, 2nd Floor, Boston, MA 02118, United States Data Coordinating Center,

⁷Data Coordinating Center, Boston University School of Public Health, 801 Massachusetts Avenue, 3rd Floor, Boston, MA, United States

⁸Department of Psychology, Boston University School, 64 Cummington Street, Boston, MA 02215, United States

⁹St. Petersburg Bekhterev Research Psychoneurological Institute, Bekhtereva St., 3, St. Petersburg 192019, Russian Federation

Abstract

Corresponding Author: Jeffrey H. Samet, MD, MA, MPH Section of General Internal Medicine 801 Massachusetts Ave., 2nd floor Boston, MA, 02118 617-414-7288 (phone) 617-414-4676 (fax) jsamet@bu.edu.

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Aims—This study assessed the effectiveness of HERMITAGE (HIV's Evolution in Russia - Mitigating Infection Transmission and Alcoholism in a Growing Epidemic), an adapted secondary HIV prevention intervention, compared with an attention control condition in decreasing sexually transmitted infections (STIs) and sex and drug risk behaviors among Russian HIV-infected heavy drinkers.

Design—We conducted a single-blinded, two-armed, randomized controlled trial with 12-month follow-up.

Setting—The study was conducted in St. Petersburg, Russia. Participants were recruited from four HIV and addiction clinical sites. The intervention was conducted at Botkin Infectious Disease Hospital.

Participants—HIV-infected persons with past 6-month risky sex and heavy alcohol consumption (n=700) were randomized to the HERMITAGE intervention (n=350) or an attention control condition (n=350).

Intervention—A Healthy Relationships Intervention stressing disclosure of HIV serostatus and condom use, adapted for a Russian clinical setting with two individual sessions and three small group sessions.

Measurements—The primary outcome was incident STI by laboratory test at 12-month follow-up. Secondary outcomes included change in unprotected sex and several alcohol and injection drug use (IDU) variables.

Findings—Participants had the following baseline characteristics: 59% male, mean age 30, 60% past year IDU, 15.4% prevalent STI and mean CD4 cell count 413/ μ l. Assessment occurred among 75% and 71% of participants at 6 and 12-months, respectively. STIs occurred in 20 subjects (8%) in the intervention group and 28 subjects (12%) in the control group at 12-month follow-up; logistic regression analyses found no significant difference between groups (adjusted odds ratio 0.69; 95% CI: 0.36-1.30; P=0.25). Both groups decreased unsafe behaviors, although no significant differences between groups were found.

Conclusions—The HERMITAGE HIV risk reduction intervention does not appear to reduce sexually transmitted infections and HIV risk behaviors in Russian HIV-infected heavy drinkers compared with attention controls.

Keywords

STI; RCT; HIV risk behaviors; Healthy Relationships; Russian HIV; substance users

Introduction

While new HIV infections globally have declined, HIV incidence is high in Russia, as is prevalence, with approximately one million people infected [1-4]. Injection drug use, absence of opioid agonist treatment, and limited access to sterile needles and syringes fueled the spread of HIV into the early 2000s [5, 6]. It has been suggested that heterosexual transmission is playing an increasingly important role in the epidemic [2, 7-11]. The association of alcohol use and both risky sexual behaviors [12-15] and sexually transmitted infections (STIs) [16-21] has been demonstrated in HIV-infected individuals. Thus, sexual

transmission is not surprising given notable prevalence (roughly half) of lifetime alcohol disorders among HIV-infected hospitalized patients [22].

In the Russian setting, behavioral interventions that target sexual, injection, and alcohol behaviors are needed [23]. Treatment with antiretroviral therapy (ART) as an HIV prevention strategy holds promise, yet ART coverage in Russia is low [24]. Effective behavioral risk reduction interventions have been demonstrated in a variety of sub-populations [25]. Among HIV-uninfected individuals, many interventions have been effective in reducing risk behaviors among non-drug using heterosexual participants, as well as a few with benefit among drug using groups [26-29]. A small number of studies have been implemented in Russia among mainly HIV-uninfected at-risk individuals [30-33]. A recent study by Abdala et al. conducted among Russian STI clinic patients involving a culturally adapted 1-hour intervention increased condom use at 3-month follow-up with a loss of any statistically significant effect at 6-months [32]. In the Russian PREVENT study [33], we reported statistically significant improvement in self-reported sex risk behaviors at 6-months, not evident at 3-months, among narcology hospital patients after a modified CDC developed intervention (i.e., RESPECT) [34]. In the United States, Kalichman et al. showed promise among HIV-infected men who have sex with men using the Healthy Relationships Intervention (HRI), significantly increasing the percentage of past 3-month condom use (Intervention: 71.7%; Control: 54.6%; $P = 0.05$) [35]. Other randomized behavioral trials demonstrated improvements in knowledge [36] or decreased unprotected sex acts [37, 38], but not STIs.

Effective components of risk reduction interventions include provision of intensive content across multiple sessions [39], group-based formats [40], dissemination of outreach efforts through social networks [41], and access to medical services [42]. Although intervention efficacy has been demonstrated by self-reported risk behaviors, biomarkers have been both less frequently reported and have shown less evidence of impact [37, 43]. Furthermore, adaptability of an intervention is key to generalizability and thus interventions must be culturally tailored [44].

HRI, a CDC classified best-evidence behavioral intervention [45], uses multiple group-sessions with demonstrated fidelity in the United States across 299 agencies [46] that resulted in fewer sex partners and unprotected sex events [47]. Hence, in this study, **HIV's Evolution in Russia - Mitigating Infection Transmission and Alcoholism in a Growing Epidemic (HERMITAGE)**, we adapted HRI for a Russian clinical setting and assessed its effectiveness to reduce STIs and HIV risk behaviors among HIV-infected heavy drinkers.

Methods

Objective and Study Design

The HERMITAGE study was a single-blinded randomized controlled trial conducted to determine whether a secondary HIV prevention intervention, HRI [35], adapted for use in Russia, decreased STIs, unprotected sex, needle sharing, and alcohol use among Russian HIV-infected heavy drinkers.

Participants

From October, 2007, through April, 2010, we recruited 700 HIV-infected heavy drinkers who reported recent unprotected sex from four clinical inpatient and outpatient HIV and addiction sites in St. Petersburg, Russia, including 1) Botkin Infectious Disease Hospital, 2) the St. Petersburg AIDS Center, 3) First St. Petersburg Pavlov State Medical University Clinics, and 4) the St. Petersburg State Drug Treatment Clinic. At these clinical sites, research associates (RAs) approached patients, assessed eligibility, offered participation, obtained written informed consent, and conducted assessments in a private room. Subjects were also recruited from non-clinical sources including a needle exchange program, and through “snowball recruitment”. Participants recruited from non-clinical sources were given information on the study and referred to one of the clinical sites for eligibility assessment.

Eligibility criteria included the following: 18 years of age or older; HIV-infected; report of anal or vaginal sex without a condom in the past 6 months; provision of contact information of two persons; stable home address within 150 kilometers of St. Petersburg; fluency in Russian; possession of a home or cell telephone; ability to provide informed consent; and report of “at risk” drinking levels in the past 30-days (defined as >14 drinks per week or >4 drinks on a single occasion for men, and >7 per week or >3 on a single occasion, for women) [48]. Five months into study recruitment, entry criteria were expanded to include potential participants with at least one binge drinking day in the past 6 months. Exclusion criteria included cognitive impairment or acute illness precluding participation, pending legal issues that could lead to incarceration, or ongoing efforts to conceive.

The Institutional Review Boards of Boston Medical Center and First St. Petersburg Pavlov State Medical University approved the HERMITAGE study.

Participant Assessment

Baseline research assessments occurred at the aforementioned recruitment sites. Follow-up assessments occurred at Botkin and Pavlov. We conducted assessments via a face-to-face interview with an RA; participants completed a self-administered questionnaire comprising approximately 10% of the assessment for particularly sensitive questions. At baseline, we performed a medical chart review when available (e.g., CD4 cell count). All instruments were translated from English to Russian for this study, unless already available in Russian, using steps similar to the WHO GENACIS process [49]. Participants were compensated 200 rubles (US\$7) for the baseline assessment and 800 (US\$28) and 1000 rubles (US\$35) at 6- and 12-month follow-up, respectively.

Primary Outcomes

The primary outcome was any incident sexually transmitted infection (STI) by laboratory test at 12-month follow-up. At baseline and 12-month follow-up, urine specimens were tested for *Neisseria gonorrhea*, *Chlamydia trachomatis* and *Trichomonas vaginalis* and serum was tested for syphilis as previously described [50]. Treatment was offered to those infected.

Secondary Outcomes

Secondary outcomes examined change in number of unprotected sex acts between baseline and follow-up at 6- and 12-months, any needle sharing, distributive needle sharing, self-reported STI, average daily alcohol consumption and number of heavy drinking days in the past 30 days. Change in unprotected sex acts was assessed through questions on past 3-month sex practices [35]. Participants provided detailed information about the 5 most recent partners, including partner HIV serostatus, the total number of sex episodes and condom use. Change in unprotected sex acts included all unprotected sex encounters, regardless of partner HIV status. Any needle sharing was defined as distributive or receptive sharing in the past 30 days captured through the Risk Behavior Survey (RBS) [51, 52], modified to include substances particular to Russia. Self-reported STI was assessed through questions from the Risk Assessment Battery [53]. Average daily alcohol consumption and number of heavy drinking days were assessed and calculated from the Timeline Followback (TLFB) survey [54, 55].

Additional Assessment Measures

Interviews assessed demographics (e.g., living arrangements, education, marital status), addiction treatment [56], HIV and HCV diagnosis, ART use [57], HIV disclosure [58, 59], HIV stigma [60, 61], suicide, social support [62], sexual sensation seeking and risk taking [63, 64] and the Short Form 12 (SF-12) General Health Survey [65]. The CIDI-SF captured past year alcohol and drug dependence diagnoses [66, 67]. The self-administered portion of the assessment consisted of HIV disclosure [58, 59], trauma [68, 69], HIV acquisition route risk [70] and depressive symptoms [71] and RA assistance was available if requested.

HERMITAGE Intervention

A team of American and Russian psychologists and physicians with addiction and HIV expertise adapted HRI [35], a five session group intervention, into the HERMITAGE Intervention, with two individual sessions and three small group (3 to 9 individuals, median 4 across both arms) sessions. Individual sessions were introduced given the Russian preference for privacy regarding personal risk assessments as part of the HIV behavioral intervention. Other modifications included implementing the intervention in a hospital setting, utilizing peer interventionists and using mixed-gender groups. For both treatment arms, participants were assigned to small groups after randomization. We maintained the focus on disclosure of HIV serostatus as a means to facilitate effective communication about the need for condom use with vaginal or anal sex. All intervention sessions took place at Botkin Infectious Disease Hospital, regardless of recruitment site. Further details on the HERMITAGE Intervention and modifications from HRI can be found in the Appendix.

Attention Control Group

To correspond with the structure of the HERMITAGE Intervention we created a five session control program including two individual and three group sessions focused on stress reduction, social support and good nutrition for HIV-infected individuals. These group sessions were similarly led by peer-professional teams and provided education and skills building activities, as well as social support.

Process Evaluation

To ensure high quality implementation of the intervention and control conditions, we provided structured trainings on both conditions and regular supervision and monitoring of the interventionists. Adherence to curriculum for both intervention and comparison programs was monitored by observation of sessions, which occurred for 10% of randomly selected participants using audiotapes made across all sessions. The quality and coverage of material in the session components were scored as low, medium or high. Observations indicated high adherence to curriculum, good capacity of interventionists to implement the program, and high engagement of participants in program sessions. We obtained survey feedback from intervention participants (n=175) in response to the intervention. Participants reported enjoyment of the program (74% very much, 25% somewhat); most also reported that the program met their HIV and sexual health needs (66% very much, 30% somewhat). Survey and interview feedback on the program was obtained from interventionists and hospital staff, who felt that the program should be continued at the hospital (100% and 87%, respectively).

Randomization and Blinding

Participants were assigned to either the intervention or control group using stratified-blocked randomization. The randomization procedure was stratified by gender, injection drug use, and recruitment site (main site [Botkin] vs. all other). Within each stratum, random block sizes of 4, 6, or 8 were used to ensure a comparable number of participants in each treatment group. Randomization was equally likely between the intervention and control groups (i.e., a 1:1 allocation ratio was used).

RAs conducting interview assessments were blinded to the individual's randomization status. The baseline assessment occurred prior to randomization. The research participants could not be blinded due to the nature of the intervention.

Statistical Analysis

For the outcome any STI by laboratory test at 12-months, we used logistic regression models to compare arms. Unadjusted models as well as adjusted models controlling for stratification factors (gender, injection drug use, and recruitment site) were fit to the data. Any self-reported STI, a secondary outcome, was analyzed using a similar approach. The outcome, change in number of unprotected sex encounters, was analyzed using a GEE proportional odds model as the distribution was non-normal and a suitable transformation was not found. The variable was categorized into five ordered categories (< -10 ; -10 to -1 ; 0 ; 1 to 10 ; > 10) and the odds of lower values (i.e. better outcomes) was modeled. GEE logistic regression models were used to analyze longitudinal binary endpoints (e.g. any needle sharing) and GEE overdispersed Poisson regression models were used for count outcomes (e.g. number of drinks per day). The GEE models used an independence working correlation structure and results are reported using empirical standard errors for all analyses. The 6- and 12-month outcomes were treated with equal weight in the GEE models as they were considered of equal importance and there were no a priori hypotheses that intervention effects would change across time. The main goal of the analyses was to compare the time-averaged effects between groups. The longitudinal analyses included participants with any follow-up and

thus did not exclude those who missed a single follow-up visit. To minimize the potential for collinearity, correlations between each pair of variable was assessed and we verified that no pair of covariates included in the same regression model was strongly correlated (i.e., $r > 0.40$). The Wilcoxon signed rank test and McNemar's test were used to assess within group changes between baseline and follow-up for descriptive purposes. All analyses were conducted on an intention-to-treat basis in that study participants were analyzed according to randomized group regardless of whether they received their assigned intervention. For the primary efficacy analyses only the observed data were used, imputation of missing data was not performed. However subsequent sensitivity analyses were performed using multiple imputation to account for missing follow-up data for the primary outcome. Baseline variables used in the imputation were age, gender, education, CD4 cell count, injection drug use, randomization group, marital status, multiple sex partners, unprotected sex episodes and baseline STI. Additional confirmatory analyses were also performed adjusting for all baseline characteristics and examining group session membership as a random effect. Reported *P* values are two-tailed and a significance level of 0.05 was used. We analyzed the data with SAS version 9.2 (SAS Institute, Inc., Cary, NC).

The study was sized to provide adequate power for the primary outcome any incident STI. We estimated the study would have approximately 80% power to detect a difference in incident STIs of 25% vs. 15% for the control and intervention groups, respectively, assuming 20% loss to follow-up and using a chi-square test with continuity correction.

Results

The study flow is outlined in Figure 1 and the participants' baseline characteristics are described in Table 1. Among the intervention and control groups, full (and partial) interventions were delivered to 51% and 54% (81% and 76%) respectively; assessment occurred among 75% and 74% at 6-months, and among 72% and 69% at 12-months, respectively. Overall 81% of participants had at least one follow-up and no differential follow-up by randomization group occurred.

Primary Outcomes

Although there were fewer STIs based on urine tests in the intervention group, logistic regression analyses found no statistically significant difference between groups (see Table 2). The result was similar in sensitivity analyses using multiple imputation to address missing data (AOR 0.72; 95% CI: 0.39-1.34; $P = 0.30$).

Secondary Outcomes

There were no statistically significant differences between intervention and control groups with respect to unprotected sex acts, any needle sharing, distributive needle sharing, self-reported STI, average drinks per day, or number of heavy drinking days. For the proportional odds model examining change in unprotected sex acts, we note that the observed AOR of 0.91 suggests that the intervention group had a lower odds of decreasing unprotected sex acts at follow-up compared to the control group, however the difference between groups was not statistically significant. Post-hoc analyses that examined the more

restrictive definition of unsafe sex involving sex with a partner without known HIV infection confirmed the reported a priori findings (AOR 0.79, 95% CI: 0.59-1.07, $P = 0.13$).

Secondary per protocol analyses were conducted on the subgroup of participants (N=370) who completed the full set of group and individual sessions (intervention and control). The conclusions were similar for all outcomes except the secondary outcome self-reported STI, which suggested the intervention group had a higher odds of reporting STI during follow-up (AOR 2.89, 95% CI: 1.12-7.49, $P = 0.03$). Confirmatory analyses adjusting for all baseline characteristics and accounting for group session membership resulted in similar findings for all outcomes.

We note that within group changes appeared post-baseline for both arms (Table 2). Based on Wilcoxon signed rank and McNemar's tests, the intervention and control groups significantly decreased unprotected sex acts, average drinks per day, and number of heavy drinking days from baseline to 6 and 12-months. The control group also had significant decreases in any needle sharing and distributive needle sharing at both follow-up times. The intervention group had a significant decrease in any needle sharing from baseline to 6 months.

Discussion

The HERMITAGE HIV prevention intervention did not yield statistically significant benefit compared to the attention control group despite the lower observed incidence of STIs at 12-months (8% versus 12% [$P = 0.25$]). Difficulty achieving HIV risk reductions with behavioral interventions among people who consume heavy amounts of alcohol or who inject drugs has been found previously [36, 72, 73].

Russia was an ideal setting to carry out this prevention intervention with a focus on heavy alcohol drinkers. Russia's HIV epidemic is in the setting of one of the highest per capita rates of alcohol consumption in the world [74, 75]. The findings of clinically important decreases in unsafe sex reported between baseline and follow-up among this Russian cohort demonstrate that change can occur among substance-using HIV-infected persons. The forces responsible for this change may be different from other HIV-infected individuals. The observed change among those receiving the attention control intervention of nutrition counseling and stress reduction was unanticipated and yet the improvement was notable and largely consistent across outcomes. Both intervention and control participants had less risky behavior at follow-up, (e.g., fewer unsafe sex episodes), although the difference between randomized groups was not statistically significant. Post-hoc analyses the excluded unsafe sex among known HIV-infected partners confirmed these findings.

Very few behavioral interventions among HIV-infected persons with active substance use have been demonstrated to be effective. While Copenhaver et al., using a four session intervention among people who inject drugs, increased sex and drug risk reduction knowledge and skills, the intervention failed to demonstrate differences in condom use and drug use behavior [36]. Given the lack of effectiveness of the HERMITAGE intervention compared to attention control and paucity of published effective interventions among

substance users to achieve a meaningful impact on risky behaviors and their consequences, the role of pharmacotherapy (e.g. opioid agonist treatment, antiretroviral therapy) and other structural interventions (e.g., needle exchange programs) for HIV-infected alcohol and drug users to prevent transmission is magnified.

The HERMITAGE study had both strengths and limitations. Its focus on HIV-infected heavy drinkers is important as these individuals have particular challenges when it comes to behavior change and are exceedingly common both in Russia, Africa and internationally including the United States. Alcohol's pervasiveness in Russia was exemplified during HERMITAGE recruitment in which less than 15% (110/921) of the individuals screened for HERMITAGE did not meet study entry criteria due to not consuming sufficient alcohol in the past 6-months.

The recruitment of 700 participants and their randomization to either a multisession behavioral intervention or attention control in Russia was a notable accomplishment. However, the delivery of the full intervention was sub-optimal and likely reflected the reality of delivering such an intervention to this particular population who may have competing priorities. Poor compliance with the intervention may have resulted in the smaller than anticipated effect sizes. However, the secondary per protocol analyses on those 370 who completed the full set of intervention and control sessions resulted in similar conclusions for all outcomes except the secondary outcome, self-reported STI, for which the intervention group had a higher odds at follow-up.

Another limitation was that follow-up was not optimal with 75% and 70% at 6 and 12-months, respectively. In part, this was due to death ($n=40$), which occurred at a surprisingly high rate. However, sensitivity analyses using multiple imputation to account for the missing observations resulted in similar conclusions.

Several phenomena may have obscured demonstrating effectiveness of the HERMITAGE intervention. The control intervention, which was designed to be an attention control condition without impact on the study outcomes, may have inadvertently changed behavior. Alternatively, the changed behavior could have been due to increased health awareness subsequent to enrolling in a study, the observation of regression to the mean (i.e., recruited subjects were engaging in riskier behaviors and would have naturally decreased their behaviors), or a combination of these factors. Secondly, HIV-infected substance users are a community which interact among themselves and thus contamination of the contents of the intervention could have occurred between intervention and control participants. Thirdly, the study subjects were already engaged in care. The possibility cannot be excluded that the intervention could have had greater effectiveness in patients not linked to care. Finally, the biological outcome, seemingly straightforward, has the complexity that it would not be positive if the individual sought and received medication for a symptomatic urethritis prior to the 12-month research interview. Alternatively, antibiotics taken for unrelated reasons could obscure STI testing findings. These phenomena could have affected the study's findings.

Development and dissemination of evidence-based behavioral HIV interventions is a national and international priority that is particularly challenging in substance using populations. The mission of public health institutions, such as the Center for Disease Control and Prevention with its Diffusion of Effective Behavioral Interventions (DEBI) program, is to disseminate the best of the tested interventions. Despite these efforts, the evidence for improved outcomes from HIV behavioral interventions has never met the highest standard in randomized controlled trials, fewer HIV infections. Nonetheless, the next best quality of evidence suggestive of decreased HIV infection by sexual transmission as a consequence of implementation of a behavioral intervention, arguably is evidence of fewer STIs [76-78]. The results of the HERMITAGE study did not achieve this high bar for demonstrating the effectiveness of a behavioral intervention. Among Russian HIV-infected heavy drinkers, there were no statistically significant differences in sexually transmitted infections and HIV sex and drug risk behaviors between the HERMITAGE HIV risk reduction intervention and an attention control group. Behavioral change consistent with risk reduction among this Russian HIV-infected population occurred for both groups but the basis of this change is unknown.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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References

1. Joint United Nations Programme on HIV/AIDS (UNAIDS). [Accessed on July 23, 2012] Regional Fact Sheet: Russian Federation. 2012. Available at: http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/2012_FS_regional_ecca_en.pdf (Archived by WebCite® at <http://www.webcitation.org/6GoBNlaK8>)
2. Cohen J. Late for the epidemic: HIV/AIDS in Eastern Europe. *Science*. 2010; 329:160, 162–164. [PubMed: 20616262]
3. Beyrer C, Abdool Karim Q. The changing epidemiology of HIV in 2013. *Curr Opin HIV AIDS*. 2013; 8:306–10. [PubMed: 23743721]
4. The Henry J Kaiser Family Foundation. The Global HIV/AIDS Epidemic Fact Sheet. 2013. Available at: <http://kaiserfamilyfoundation.files.wordpress.com/2013/10/3030-17-global-hiv.pdf> (Archived by WebCite® at <http://www.webcitation.org/6R6xqqiVp>)
5. Rhodes T, Sarang A, Bobrik A, Bobkov E, Platt L. HIV transmission and HIV prevention associated with injecting drug use in the Russian Federation. *Int J Drug Policy*. 2004; 15:1–16.
6. Krupitsky E, Zvartau E, Karandashova G, Horton NJ, Schoolwerth KR, Bryant K, et al. The onset of HIV infection in the Leningrad region of Russia: a focus on drug and alcohol dependence. *HIV Med*. 2004; 5:30–3. [PubMed: 14731167]

7. Niccolai LM, Shcherbakova IS, Toussova OV, Kozlov AP, Heimer R. The potential for bridging of HIV transmission in the Russian Federation: sex risk behaviors and HIV prevalence among drug users (DUs) and their non-DU sex partners. *J Urban Health*. 2009; 86:s131–43.
8. Burchell AN, Calzavara LM, Orekhovsky V, Ladnaya NN. Russian HIV Response Network. Characterization of an emerging heterosexual HIV epidemic in Russia. *Sex Transm Dis*. 2008; 35:807–13. [PubMed: 18496470]
9. Mills HL, White E, Colijn C, Vickerman P, Heimer R. HIV transmission from drug injectors to partners who do not inject, and beyond: modelling the potential for a generalized heterosexual epidemic in St. Petersburg, Russia. *Drug Alcohol Depend*. 2013; 133:242–7. [PubMed: 23692991]
10. Abdala N, Krasnoselskikh TV, Durante AJ, Timofeeva MY, Verevchkin SV, Kozlov AP. Sexually Transmitted Infections, Sexual Risk Behaviors and the Risk of Heterosexual Spread of HIV among and beyond IDUs in St. Petersburg, Russia. *Eur Addict Res*. 2008; 14:19–25. [PubMed: 18182769]
11. Krupitsky EM, Zvartau EE, Lioznov DA, Tsoy MV, Egorova VY, Belyaeva TV, et al. Co-morbidity of infectious and addictive diseases in St. Petersburg and the Leningrad Region, Russia. *Eur Addict Res*. 2006; 12:12–9. [PubMed: 16352898]
12. Kalichman SC, Cain D, Simbayi LC. Multiple recent sexual partnerships and alcohol use among sexually transmitted infection clinic patients, Cape Town, South Africa. *Sex Transm Dis*. 2011; 38:18–23. [PubMed: 20625349]
13. Shuper PA, Joharchi N, Irving H, Rehm J. Alcohol as a correlate of unprotected sexual behavior among people living with HIV/AIDS: review and meta-analysis. *AIDS Behav*. 2009; 13:1021–36. [PubMed: 19618261]
14. Samet JH, Pace CA, Cheng DM, Coleman S, Briden C, Pardesi M, et al. Alcohol use and sex risk behaviors among HIV-infected female sex workers (FSWs) and HIV-infected male clients of FSWs in India. *AIDS Behav*. 2010; 14:S74–83. [PubMed: 20544381]
15. Scott-Sheldon LA, Walstrom P, Carey KB, Johnson BT, Carey MP. Alcohol use and sexual risk behaviors among individuals infected with HIV: a systematic review and meta-analysis 2012 to Early 2013. *Current HIV/AIDS Reports*. 2013; 10:314–23. [PubMed: 24078370]
16. Hayes R, Watson-Jones D, Celum C, van de Wijgert J, Wasserheit J. Treatment of sexually transmitted infections for HIV prevention: end of the road or new beginning? *AIDS*. 2010; 24:15–26.
17. Kalichman SC, Rompa D, Cage M. Sexually transmitted infections among HIV seropositive men and women. *Sex Transm Infect*. 2000; 76:350–4. [PubMed: 11141850]
18. McClelland RS, Lavreys L, Katingima C, Overbaugh J, Chohan V, Mandaliya K, et al. Contribution of HIV-1 infection to acquisition of sexually transmitted disease: a 10-year prospective study. *J Infect Dis*. 2005; 191:333–8. [PubMed: 15633091]
19. Phipps W, Stanley H, Kohn R, Stansell J, Klausner JD. Syphilis, chlamydia, and gonorrhea screening in HIV-infected patients in primary care, San Francisco, California, 2003. *AIDS Patient Care STDS*. 2005; 19:495–8. [PubMed: 16124843]
20. Mayer KH, O'Cleirigh C, Skeer M, Covahey C, Leidolf E, Vanderwarker R, et al. Which HIV-infected men who have sex with men in care are engaging in risky sex and acquiring sexually transmitted infections: findings from a Boston community health centre. *Sex Transm Infect*. 2010; 86:66–70. [PubMed: 19720603]
21. Guthrie BL, Kiarie JN, Morrison S, John-Stewart GC, Kinuthia J, Whittington WL, et al. Sexually transmitted infections among HIV-1-discordant couples. *PLoS One*. 2009; 4:e8276. [PubMed: 20011596]
22. Krupitsky EM, Horton NJ, Williams EC, Lioznov D, Kuznetsova M, Zvartau E, et al. Alcohol use and HIV risk behaviors among HIV-infected hospitalized patients in St. Petersburg, Russia. *Drug Alcohol Depend*. 2005; 79:251–6. [PubMed: 16002034]
23. de Wit JB, Aggleton P, Myers T, Crewe M. The rapidly changing paradigm of HIV prevention: time to strengthen social and behavioural approaches. *Health Educ Res*. 2011; 26:381–92. [PubMed: 21536716]
24. WHO, UNODC, UNAIDS. Technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users. 2009. Available at: <http://www.unodc.org/>

documents/hiv-aids/idu_target_setting_guide.pdf(Archived by WebCite® at <http://www.webcitation.org/6REouXTqB>)

25. Center for Disease Control and Prevention. Compendium of Evidence-Based HIV Prevention Interventions. 2009. 2009. Available at: <http://www.cdc.gov/hiv/topics/research/prs/evidence-based-interventions.htm>(Archived by WebCite® at <http://www.webcitation.org/6REpP6gpO>)
26. Crepaz N, Tungol-Ashmon MV, Higa DH, Vosburgh W, Mullins MM, Barham T, et al. A systematic review of interventions for reducing HIV risk behaviors among people living with HIV in the United States, 1988-2012. *AIDS*. 2014; 28:633–56. [PubMed: 24983541]
27. Des Jarlais DC, Semaan S. HIV prevention for injecting drug users: the first 25 years and counting. *Psychosom Med*. 2008; 70:606–11. [PubMed: 18519886]
28. Semaan S, Des Jarlais DC, Sogolow E, Johnson WD, Hedges LV, Ramirez G, et al. A meta-analysis of the effect of HIV prevention interventions on the sex behaviors of drug users in the United States. *J Acquir Immune Defic Syndr*. 2002; 30:S73–93. [PubMed: 12107362]
29. Neumann MS, Johnson WD, Semaan S, Flores SA, Peersman G, Hedges LV, et al. Review and meta-analysis of HIV prevention intervention research for heterosexual adult populations in the United States. *J Acquir Immune Defic Syndr*. 2002; 30:S106–17. [PubMed: 12107364]
30. Hoffman IF, Latkin CA, Kukhareva PV, Malov SV, Batluk JV, Shaboltas AV, et al. A peer-educator network HIV prevention intervention among injection drug users: Results of a randomized controlled trial in St. Petersburg, Russia. *AIDS and Behavior*. 2013; 17:2510–20. [PubMed: 23881187]
31. Wechsberg WM, Krupitsky E, Romanova T, Zvartau E, Kline TL, Browne FA, et al. Double jeopardy--drug and sex risks among Russian women who inject drugs: initial feasibility and efficacy results of a small randomized controlled trial. *Subst Abuse Treat Prev Policy*. 2012; 7:1. [PubMed: 22233728]
32. Abdala N, Zhan W, Shaboltas AV, Skochilov RV, Kozlov AP, Krasnoselskikh TV. Efficacy of a brief HIV prevention counseling intervention among STI clinic patients in Russia: a randomized controlled trial. *AIDS and Behavior*. 2013; 17:1016–24. [PubMed: 22987210]
33. Samet JH, Krupitsky EM, Cheng DM, Raj A, Egorova VY, Levenson S, et al. Mitigating risky sexual behaviors among Russian narcology hospital patients: the PREVENT (Partnership to Reduce the Epidemic Via Engagement in Narcology Treatment) randomized controlled trial. *Addiction*. 2008; 103:1474–83. [PubMed: 18636998]
34. Kamb ML, Fishbein M, Douglas JM Jr, Rhodes F, Rogers J, Bolan G, et al. Project RESPECT Study Group. Efficacy of risk-reduction counseling to prevent human immunodeficiency virus and sexually transmitted diseases: a randomized controlled trial. *JAMA*. 1998; 280:1161–7. [PubMed: 9777816]
35. Kalichman SC, Rompa D, Cage M, DiFonzo K, Simpson D, Austin J, et al. Effectiveness of an intervention to reduce HIV transmission risks in HIV-positive people. *Am J Prev Med*. 2001; 21:84–92. [PubMed: 11457627]
36. Copenhaver MM, Lee IC, Baldwin P. A randomized controlled trial of the Community-friendly Health Recovery Program (CHRP) among high-risk drug users in treatment. *AIDS Behav*. 2013; 17:2902–13. [PubMed: 23835735]
37. El-Bassel N, Jemmott JB, Landis JR, Pequegnat W, Wingood GM, Wyatt GE, et al. National Institute of Mental Health multisite eban HIV/STD prevention intervention for African American HIV serodiscordant couples: a cluster randomized trial. *Arch Intern Med*. 2010; 170:1594–601. [PubMed: 20625011]
38. Golin CE, Earp JA, Grodensky CA, Patel SN, Suchindran C, Parikh M, et al. Longitudinal effects of SafeTalk, a motivational interviewing-based program to improve safer sex practices among people living with HIV/AIDS. *AIDS Behav*. 2012; 16:1182–91. [PubMed: 21964975]
39. Johnson BT, Scott-Sheldon LA, Smoak ND, Lacroix JM, Anderson JR, Carey MP. Behavioral interventions for African Americans to reduce sexual risk of HIV: a meta-analysis of randomized controlled trials. *J Acquir Immune Defic Syndr*. 2009; 51:492–501. [PubMed: 19436218]
40. Chin HB, Sipe TA, Elder R, Mercer SL, Chattopadhyay SK, Jacob V, et al. The effectiveness of group-based comprehensive risk-reduction and abstinence education interventions to prevent or reduce the risk of adolescent pregnancy, human immunodeficiency virus, and sexually transmitted

- infections: two systematic reviews for the Guide to Community Preventive Services. *Am J Prev Med.* 2012; 42:272–94. [PubMed: 22341164]
41. Tobin KE, Kuramoto SJ, Davey-Rothwell MA, Latkin CA. The STEP into Action study: a peer-based, personal risk network-focused HIV prevention intervention with injection drug users in Baltimore, Maryland. *Addiction.* 2011; 106:366–75. [PubMed: 21054614]
 42. Henny KD, Crepaz N, Lyles CM, Marshall KJ, Aupont LW, Jacobs ED, et al. Efficacy of HIV/STI behavioral interventions for heterosexual African American men in the United States: a meta-analysis. *AIDS Behav.* 2012; 16:1092–114. [PubMed: 22234436]
 43. Simoni JM, Nelson KM, Franks JC, Yard SS, Lehavot K. Are peer interventions for HIV efficacious? A systematic review. *AIDS Behav.* 2011; 15:1589–95. [PubMed: 21598034]
 44. Dawson Rose C, Gutin SA, Reyes M. Adapting positive prevention interventions for international settings: applying U.S. evidence to epidemics in developing countries. *J Assoc Nurses AIDS Care.* 2011; 22:38–52. [PubMed: 20538491]
 45. Centers for Disease Control and Prevention. Compendium of Evidence-Based HIV Behavioral Interventions: Healthy Relationships. 2013. Available at: <http://www.cdc.gov/hiv/prevention/research/compendium/rr/healthyrelationships.html> (Archived by WebCite® at <http://www.webcitation.org/6IEYDKY0I>)
 46. Kalichman SC, Hudd K, Diberto G. Operational fidelity to an evidence-based HIV prevention intervention for people living with HIV/AIDS. *J Prim Prev.* 2010; 31:235–45. [PubMed: 20582629]
 47. Heitgerd JL, Kalayil EJ, Patel-Larson A, Uhl G, Williams WO, Griffin T, et al. Reduced sexual risk behaviors among people living with HIV: results from the Healthy Relationships Outcome Monitoring Project. *AIDS Behav.* 2011; 15:1677–90. [PubMed: 21390538]
 48. National Institute on Alcohol Abuse and Alcoholism. Helping patients who drink too much: a clinician's guide: Updated 2005 edition. National Institutes of Health; Bethesda, MD: 2007.
 49. Obot, I.; Room, R. Alcohol, Gender and Drinking Problems: Perspectives from Low and Middle Income Countries. Department of Mental Health and Substance Abuse; Geneva: World Health Organization: 2005.
 50. Pace CA, Lioznov D, Cheng DM, Wakeman SE, Raj A, Walley AY, et al. Sexually transmitted infections among HIV-infected heavy drinkers in St. Petersburg, Russia. *Int J STD AIDS.* 2012; 23:853–8. [PubMed: 23258823]
 51. Needle R, Fisher DG, Weatherby N, Chitwood D, Brown B, Cesari H, et al. Reliability of self-reported HIV risk behaviors of drug users. *Psychology of Addictive Behaviors.* 1995; 9:242–50.
 52. Weatherby N, Needle R, Cesar H, Booth R, McCoy C, Watters J, et al. Validity of self-reported drug use among injection drug users and crack smokers recruited through street outreach. *Eval Program Plann.* 1994; 17:347, 347–355.
 53. Metzger, DS.; Navaline, HA.; Woody, GE. Assessment of Substance Abuse: HIV Risk Assessment Battery. In: Carson-Dewitt, R., editor. *Encyclopedia of drugs, alcohol, and addictive behavior.* Macmillan Reference USA; New York, NY: 2001.
 54. Sobell, LC.; Sobell, MB. Timeline follow-back: a technique for assessing self-reported alcohol consumption. In: Litten, RZ.; Allen, JP., editors. *Measuring alcohol consumption: psychosocial and biochemical methods.* Humana Press; Totowa, NJ: 1992. p. 41-72.
 55. Sobell, LC.; Sobell, MB. Alcohol Timeline Followback (TLFB) Users' Manual. Addiction Research Foundation; Toronto, Canada: 1995.
 56. McLellan AT, Luborsky L, Cacciola J, Griffith J, Evans F, Barr HL, et al. New data from the Addiction Severity Index. Reliability and validity in three centers. *J Nerv Ment Dis.* 1985; 173:412–23. [PubMed: 4009158]
 57. Chesney MA, Ickovics JR, Chambers DB, Gifford AL, Neidig J, Zwickl B, et al. Self-reported adherence to antiretroviral medications among participants in HIV clinical trials: the AACTG adherence instruments. Patient Care Committee & Adherence Working Group of the Outcomes Committee of the Adult AIDS Clinical Trials Group (AACTG). *AIDS Care.* 2000; 12:255–66. [PubMed: 10928201]

58. Stein MD, Freedberg KA, Sullivan LM, Savetsky J, Levenson SM, Hingson R, et al. Sexual ethics. Disclosure of HIV-positive status to partners. *Arch Intern Med*. 1998; 158:253–7. [PubMed: 9472205]
59. Raj A, Cheng DM, Levison R, Meli S, Samet JH. Sex trade, sexual risk, and nondisclosure of HIV serostatus: findings from HIV-infected persons with a history of alcohol problems. *AIDS Behav*. 2006; 10:149–57. [PubMed: 16482406]
60. Berger BE, Ferrans CE, Lashley FR. Measuring stigma in people with HIV: psychometric assessment of the HIV stigma scale. *Res Nurs Health*. 2001; 24:518–29. [PubMed: 11746080]
61. Wright K, Naar-King S, Lam P, Templin T, Frey M. Stigma scale revised: reliability and validity of a brief measure of stigma for HIV+ youth. *J Adolesc Health*. 2007; 40:96–8. [PubMed: 17185215]
62. Sherbourne CD, Stewart A. The MOS social support survey. *Soc Sci Med*. 1991; 32:705–14. [PubMed: 2035047]
63. Wood PB, Cochran JK, Pfefferbaum B, Arnelev BJ. Sensation-seeking and delinquent substance use: an extension of learning theory. *J Drug Iss*. 1995; 25:173–93.
64. Kalichman SC, Johnson JR, Adair V, Rompa D, Multhau K, Kelly JA. Sexual sensation seeking: scale development and predicting AIDS-risk behavior among homosexually active men. *J Pers Assess*. 1994; 62:385–97. [PubMed: 8027907]
65. Ware J Jr, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care*. 1996; 34:220–33. [PubMed: 8628042]
66. Robins LN, Wing J, Wittchen HU, Helzer JE, Babor TF, Burke J, et al. The Composite International Diagnostic Interview: an epidemiologic instrument suitable for use in conjunction with different diagnostic systems and in different cultures. *Arch Gen Psychiatry*. 1988; 45:1069–77. [PubMed: 2848472]
67. Kessler RC, Andrews G, Mroczek D, Ustun B, Wittchen H. The World Health Organization composite international diagnostic interview short-form (CIDI-SF). *International Journal of Methods in Psychiatric Research*. 1998; 7:171–85.
68. Straus MA, Hamby SL, Boney-McCoy S, Sugarman DB. The revised conflict tactics scales (CTS2): development and preliminary psychometric data. *Journal of Family Issues*. 1996; 17:283–316. <http://jfi.sagepub.com/content/17/3/283.abstract>.
69. Liebschutz J, Saitz R, Brower V, Keane TM, Lloyd-Travaglini C, Averbuch T, et al. PTSD in urban primary care: high prevalence and low physician recognition. *J Gen Intern Med*. 2007; 22:719–26. [PubMed: 17503105]
70. Navaline HA, Snider EC, Petro CJ, Tobin D, Metzger D, Alterman AI, et al. Preparations for AIDS vaccine trials. An automated version of the Risk Assessment Battery (RAB): enhancing the assessment of risk behaviors. *AIDS Res Hum Retroviruses*. 1994; 10:S281–3. [PubMed: 7865319]
71. Beck, AT. Beck Depression Inventory - Second Edition. Copyright 1996 Aaron T. Beck. Russian translation, Copyright 2007, Aaron T. Beck. Pearson Education, Inc.;
72. Samet JH, Horton NJ, Meli S, Dukes K, Tripps T, Sullivan L, et al. A randomized controlled trial to enhance antiretroviral therapy adherence in patients with a history of alcohol problems. *Antivir Ther*. 2005; 10:83–93. [PubMed: 15751766]
73. Parsons JT, Golub SA, Rosof E, Holder C. Motivational interviewing and cognitive-behavioral intervention to improve HIV medication adherence among hazardous drinkers: a randomized controlled trial. *J Acquir Immune Defic Syndr*. 2007; 46:443–50. [PubMed: 18077833]
74. Leon DA, Shkolnikov VM, McKee M. Alcohol and Russian mortality: a continuing crisis. *Addiction*. 2009; 104:1630–6. [PubMed: 19681805]
75. Razvodovsky YE. Alcohol-attributable fraction of ischemic heart disease mortality in Russia. *ISRN Cardiol*. 2013; 2013:287869. [PubMed: 23956877]
76. Scott-Sheldon LA, Huedo-Medina TB, Warren MR, Johnson BT, Carey MP. Efficacy of behavioral interventions to increase condom use and reduce sexually transmitted infections: a meta-analysis, 1991 to 2010. *J Acquir Immune Defic Syndr*. 2011; 58:489–98. [PubMed: 22083038]
77. Champion JD, Collins JL. Comparison of a theory-based (AIDS Risk Reduction Model) cognitive behavioral intervention versus enhanced counseling for abused ethnic minority adolescent women

- on infection with sexually transmitted infection: results of a randomized controlled trial. *Int J Nurs Stud.* 2012; 49:138–50. [PubMed: 21937041]
78. Fisher HH, Patel-Larson A, Green K, Shapatava E, Uhl G, Kalayil EJ, et al. Evaluation of an HIV prevention intervention for African Americans and Hispanics: findings from the VOICES/VOCES Community-based Organization Behavioral Outcomes Project. *AIDS Behav.* 2011; 15:1691–706. [PubMed: 21573724]

Figure 1. HERMITAGE Study CONSORT Diagram

Table 1
Baseline Characteristics of HIV-infected Russian Heavy Drinkers (n=700)

	All Participants (n=700)	Intervention (n=350)	Control (n=350)
Male	415 (59.3%)	207 (59.1%)	208 (59.4%)
Mean Age (SD)	30.1 (5.2)	30.6(5.6)	29.6 (4.7)
Married/living with partner	251 (35.9%)	130 (37.2%)	121 (34.6%)
< 9 Grades education	156(22.3%)	62 (17.7%)	94 (26.9%)
Mean CD4 Cell Count (SD)	413.3 (285.4)	445.8 (296.5)	382.8 (271.7)
CD4 < 350	237(33.9%)	100 (28.6%)	137 (39.1%)
Ever taken ART	167 (23.9%)	89 (25.4%)	78 (22.3%)
Alcohol dependent	446 (63.7%)	225 (64.3%)	221 (63.1%)
Heavy alcohol use, past 30-days	570 (81.4%)	283 (80.9%)	287 (82.0%)
IDU, past year	423 (60.4%)	212 (60.6%)	211 (60.3%)
Any needle sharing, past 30-days	164 (23.5%)	76 (21.7%)	88 (25.2%)
Distributive needle sharing, past 30-days	115 (16.5%)	51 (14.6%)	64(18.3%)
Multiple sex partners	189 (27.0%)	89 (25.4%)	100 (28.6%)
Any STI (by biologic test)	105 (15.4%)	56 (16.5%)	49 (14.2%)
Median number of unprotected sex acts, past 3-months (IQR)	5(1,18)	4(1,16)	5(1,18)
No/mild depressive symptoms (BDI-II: 0-19)	406 (58.0%)	202 (57.7%)	204 (58.3%)
Moderate/severe depressive symptoms (BDI-II: 29-63)	294 (42.0%)	148 (42.2%)	146 (41.7%)
Enrolled at primary recruitment site	388 (55.4%)	192 (54.9%)	196 (56.0%)

Table 2
Effect of the HERMITAGE risk reduction intervention on STIs, unprotected sex, needle sharing, and alcohol use

	Intervention			Attention Control			Intervention vs. Attention Control: Unadjusted		Intervention vs. Attention Control: Adjusted*	
	Baseline N=350	6-months N=264	12-months N=252	Baseline N=350	6-months N=259	12-months N=240	OR (95% CI)	P value	AOR (95% CI)	P value
Primary Outcome										
STIs by biological test	56 (16.5%)	†	20 (8.1%)	49 (14.2%)	†	28 (12.0%)	0.65 (0.35, 1.19)	0.16	0.63 (0.34, 1.18)	0.15
Secondary Outcomes										
Change in unprotected sex acts (% with decrease since baseline) [^]	--	149 (56.4%)	151 (59.9%)	--	156 (60.7%)	143 (60.1%)	0.91 (0.69, 1.20)	0.50	0.91 (0.69, 1.20)	0.51
Any needle sharing	76 (21.7%)	37 (14.1%)	46(18.3%)	88 (25.2%)	36 (14.0%)	37(15.4%)	1.12 (0.75, 1.69)	0.58	1.13 (0.74, 1.73)	0.56
Distributive needle sharing	51 (14.6%)	31 (11.8%)	35 (13.9%)	64 (18.3%)	31 (12.1%)	25 (10.4%)	1.18 (0.75, 1.86)	0.47	1.20 (0.76, 1.91)	0.43
STIs by self-report	141 (40.3%)	--	27(11.9%)	145 (41.4%)	--	21 (9.4%)	1.30 (0.71, 2.38)	0.16	1.33 (0.72, 2.44)	0.36
Average drinks per day Median (25 th , 75 th percentiles)	2(1.3)	0 (0, 1)	0 (0, 2)	2(1.4)	0 (0, 1)	0 (0, 1)	1.05 (0.77, 1.43) [‡]	0.76	1.04 (0.77, 1.40) [‡]	0.80
Number of heavy drinking days Median (25 th , 75 th percentiles)	2(1.9)	0 (0, 2)	0 (0, 2)	3(1.10)	0 (0, 2)	0 (0, 3)	1.00 (0.72, 1.40) [‡]	0.98	1.00 (0.72, 1.39) [‡]	1.00

* Controlling for gender, injection drug use, and recruitment site (stratification factors used in randomization)

† Labs only completed at baseline and 12-months

‡ Incidence rate ratio

[^] Analyzed using proportional odds model; descriptives are % with decrease since baseline and represent the top 2 of 5 ordered categories used for the analysis. Odds ratio is for a 1-category improvement in unsafe sex, thus the AOR of 0.91, 95%CI: 0.69, 1.20, suggests the intervention group had a lower odds of decreasing unprotected sex acts at follow-up compared controls, although the difference was not statistically significant.