### Title

HERMITAGE: HIV prevention RCT in Russia




### Journal

Addiction, 110(1)

### ISSN

0965-2140



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### Publication Date

2015

### DOI

10.1111/add.12716

Peer reviewed

Published in final edited form as:
*Addiction*. 2015 January ; 110(1): 80–90. doi:10.1111/add.12716.

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

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## Abstract

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Declarations of interest: The authors have no conflicts of interest to declare.

Clinical trial registration details: This study was registered with ClinicalTrials.gov through the National Institutes of Health (Project HERMITAGE: HIV Prevention in Hospitalized Russian Drinkers, NCT00483483).

**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/μl. 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, **H**IV's **E**volution in **R**ussia - **M**itigating **I**nfection **T**ransmission and **A**lcoholism in a **G**rowing **E**pidemic (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 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.

## Acknowledgements

The authors would like to thank Drs. Robert Booth and Seth Kalichman for serving as consultants in the development and quality control of the intervention, and Marlene C. Lira for providing editorial assistance in the preparation of this manuscript.

The project described was supported by grants R01AA016059, U24AA020778, U24AA020779, and K24AA015674 from the National Institute on Alcohol Abuse and Alcoholism. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute on Alcohol Abuse and Alcoholism or the National Institutes of Health.

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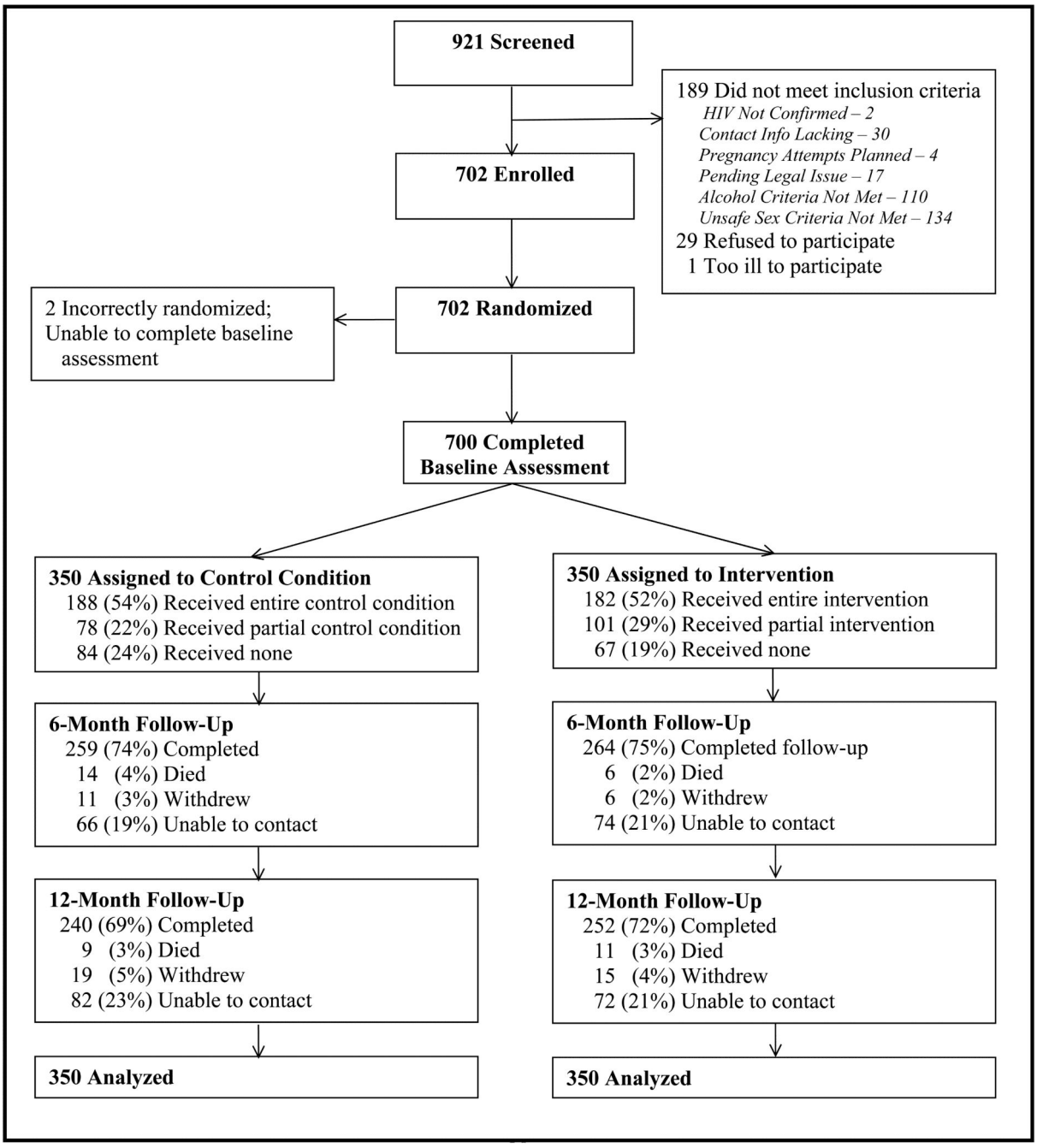


**Figure 1. HERMITAGE Study CONsolidated Standards of Reporting Trials (CONSORT) Diagram**

## 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.