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Characteristics of Female Sex Workers in Southern India Willing and Unwilling to Participate in a Placebo Gel Trial

Barbara S. Mensch[1], **Barbara A. Friedland**[1], **Sharon A. Abbott**[1], **Lauren L. Katzen**[1], **Waimar Tun**[2], **Christine A. Kelly**[1], **Avina Sarna**[3], **Aylur K. Srikrishnan**[4], and **Suniti Solomon**[4]

[1]Population Council, New York, NY

[2]Population Council, Washington DC

[3]Population Council, New Delhi, India

[4]Y.R. Gaitonde Center for AIDS Research and Care (YRG CARE), Chennai, India

Abstract

Respondent-Driven Sampling was used to recruit female sex workers (FSWs) for a community survey conducted in southern India. After survey completion, participants were given a brochure describing a clinical trial that entailed daily use of a placebo vaginal gel for four months. This study assessed predictors of screening among survey respondents, predictors of enrollment among those eligible for the trial, and predictors of visit attendance and retention among those enrolled. FSWs who reported STI symptoms, engaging in sex work in the past month, and living in a subdistrict easily accessible by public transportation with a high concentration of FSWs, were more likely to screen. FSWs never before tested for HIV were more likely to enroll. This analysis suggests that the primary reason FSWs participated in the trial was a desire for health care—not other factors hypothesized to be important, e.g., HIV risk perception and poverty status.

Keywords

microbicides; willingness to participate; female sex workers; Southern India

Introduction

HIV prevention trials have not systematically addressed whether those willing to participate in microbicide trials differ from the ultimate target population, nor the implications of possible participant selectivity, both for trial results and the ability to generalize to nontrial populations. To the extent that the characteristics of those who enroll in Phase 2 or 3 microbicide trials are investigated, analyses are generally limited to a description of the socioeconomic makeup of participants and their risk behaviors.

Inclusion and exclusion criteria for microbicide trials are based almost entirely on health considerations and demonstration of a basic ability to comprehend the informed consent process. Seldom do trials explore the linkages between motivations to participate, the selectivity of those who do participate, and the implications these have for adherence, reporting of adherence, and the ability to assess product effectiveness. Understandably, meeting accrual targets is important, but not at the risk of enrolling participants who don't use the study product or who are not at risk of infection. Data from recent microbicide trials

Correspondence/Proofs: Barbara S. Mensch, Ph.D., Senior Associate, Population Council, One Dag Hammarskjold Plaza, New York, NY 10017, Tel: 212-339-0640 Fax: 212-755-6052, bmensch@popcouncil.org.

reveal that self reports of adherence are much higher than plasma blood levels of drug indicate [1, 2], suggesting that some participants who enroll in trials may be reluctant to use the product or ambivalent about doing so.

An extensive literature exists investigating willingness to participate (WTP) in HIV vaccine trials, often as a component of preparedness studies seeking to identify potential sites [3]. The primary objective of these studies, which have been conducted in the U.S., Latin America, Asia and sub-Saharan Africa, is to identify barriers to participation, and improve the recruitment and informed consent process for large trials. Participants are asked hypothetical questions about willingness to participate. Those who indicate they would potentially be interested in joining a trial are then compared with those who are reluctant to participate on numerous attributes, including demographic and behavioral characteristics, knowledge about HIV/AIDS, familiarity with vaccines, fear of side effects, attitudes about blinding, apprehension about vaccine-induced infection and sero-positivity, and concern about the social consequences of participation. While factors vary across studies, race and gender have not generally been found to be associated with willingness to participate, whereas lower educational level and older age have. Altruistic reasons (an interest in helping to end the HIV epidemic), a desire to receive medical care, HIV risk perception, and risk behaviors are also associated with a willingness to participate. Perceived risks of participation and stigma potentially associated with participation have been identified as barriers, whereas support of partners and family members has been identified as a facilitating factor [4–24]. Only a few studies explore the implications of particular characteristics for the trial, including Bartholow et al. (who found that, among men who have sex with men in the U.S., those who were older were disproportionately willing to participate; the authors concluded that an older sample could potentially undermine an efficacy trial because the risk of seroconversion in this population would likely be too low) [4].

While vaccine preparedness studies generally ask whether the participant is motivated by such factors as free and/or higher-quality health care and desire for reimbursement, few explicitly discuss the selection biases these motivators may cause and the consequence of enrolling less-than-willing participants for efficacy and for the ability to generalize trial results.

In contrast to the vaccine literature, few studies have been conducted on the willingness to participate in microbicide trials. One study investigated motivation for and barriers to participation among family planning clinic attendees in Thailand [25], another explored attitudes regarding possible participation in a rectal microbicide trial among men who have sex with men (MSM) who practiced receptive anal intercourse in the U.S. [26], a third examined reasons for nonenrollment in a diaphragm/microbicide safety and feasibility study in South Africa among women approached by study recruiters [27], and a fourth assessed willingness to participate among African-Americans in the United States [28]. Only one study, conducted in preparation for the Population Council's Phase 3 Carraguard trial among Phase 2 participants and women who were recruited but chose not to be screened for the Phase 2 trial, focused on sample selectivity and its implications for microbicide trials; results indicated that women who attended the screening were older and had a lower frequency of sex than their counterparts who did not go for screening [29].

The major limitation of the vaccine preparedness studies, and several of the microbicide studies, is that they investigate hypothetical willingness to participate; for the most part they conclude that a high level of willingness to participate exists (typically 50–100%). However, it is one thing to reply favorably to an interviewer who asks whether you would participate in a trial if a product were available, but quite another to volunteer to participate in an actual

study. Indeed one study comparing hypothetical and actual willingness to participate found that only 20% of those indicating they would participate actually enrolled [30].

The primary goal of this paper was to investigate how sex workers who screened and enrolled in a four-month microbicide trial of a placebo gel in southern India differed from peers who were offered the opportunity to participate but chose not to do so, and to discuss the implications these differences may have for future HIV prevention trials among high-risk populations in India.

Methods

Sample

Female sex workers (FSWs) aged 18–45 living in and around Nellore in Andhra Pradesh were recruited for a community survey and were subsequently invited to screen for enrollment into a placebo microbicide trial taking place at a local clinic. According to sentinel surveillance data collected by the National AIDS Control Organization (NACO) in 2007, of the 35 states in India, Andhra Pradesh was estimated to have the highest prevalence of HIV (1.00%) among antenatal clinic attendees (ANC), the third highest (0.97%) adult prevalence, and the third highest prevalence (9.74%) among FSWs [31]. Among the 23 districts within Andhra Pradesh, Nellore was in the top half in terms of ANC prevalence of HIV, with 2% of women testing positive in 2006 [32].

Because no sampling frame exists for FSW populations and because their behavior is so stigmatized, traditional methods of data collection such as household surveys do not generate sufficiently large or representative samples [33–35]. Thus, we used respondent-driven sampling (RDS), developed to address some of the shortcomings of survey methodologies commonly used for hard-to-reach and hidden populations [33–37]. As with snowball samples, RDS relies on peer networks to produce a sample. Research staff recruit a small group of index subjects who are referred to as “seeds.” Seeds are then given a limited number of coupons, typically three or four, with unique numbers and contact information, which they use in recruiting eligible peers (in our case, fellow FSWs). Each referred respondent is then given her own numbered coupons to distribute to peers who, in turn, refer new recruits. Participants are compensated both for completing a survey and for recruiting eligible respondents. This recruitment process continues until the composition of the sample stabilizes with respect to particular characteristics of interest (that is, additional seeds’ recruits no longer change the composition of the sample) and the desired sample size is achieved. RDS differs from snowball sampling in that the number of initial seeds is limited, the peers do not have to be identified by name (thus maintaining peer confidentiality), the participant’s social network size is obtained, and the recruitment process is documented through the numbered coupon system [33]. Limiting the number of coupons results in long recruitment chains since no one seed’s network can predominate. RDS is thought to produce relatively unbiased estimates of the outcomes of interest since the analysis adjusts for differential network sizes and homophily (recruitment of others like oneself) [36].

Local outreach workers affiliated with the organization implementing the study, Y.R. Gaitonde Centre for AIDS Research and Education (YRG CARE) in Chennai, initially identified three seeds who lived in the catchment area, had large social networks, were willing to recruit their peers for the WTP Survey, and met eligibility criteria. These three seeds, who varied with respect to age, place of residence, and primary mode of finding clients (brothel, home, street), were each asked to recruit two FSW peers. In order to enroll 250–300 participants in the trial, we initially set the target sample at 500 FSWs. While recruitment into the WTP Survey was rapid, subsequent screening and enrollment into the trial was slower than expected, resulting in the need to expand the sample size for the WTP

Survey; thus, four additional seeds were added and the number of peer recruitment coupons distributed was increased from two to three. The seven seeds and their peers distributed 1,484 coupons. It took approximately 24 weeks to recruit 730 respondents for the survey. (For more information about the RDS process, see Tun et al. 2011 [38].)

WTP Survey Eligibility Criteria

Women were eligible to complete the WTP Survey if they were between the ages of 18–45 years, had vaginal, oral, or anal sex in exchange for money, goods, or other help at least once in the past month in the catchment area, were willing and able to give informed consent, and arrived at the survey site with a valid recruitment coupon from an FSW peer who previously participated in the WTP Survey. Women were excluded if they appeared to be mentally impaired or under the influence of drugs or alcohol, appeared to have been coerced to participate in the survey, or falsely self-identified as an FSW.

WTP Survey

The WTP Survey was conducted at three sites, in Buchi, Rajupalem, and the Nellore city center, located approximately 19.5, 15.1, and 2.1 kilometers, respectively, from the trial site at the YRG CARE Community Health Clinic in Nellore. Sites selected were in areas frequented by and easily accessible to FSWs. To minimize attention from the community, study sites were not located at health clinics, nor were they identifiable as being related to activities involving female sex work or HIV/AIDS. The survey sites were specifically selected to be located at a reasonable distance from the clinical trial site since the primary purpose of the WTP was to assess participation in the clinical trial under typical circumstances. All participants received a reimbursement of Rs. 100 (approximately US $2.25) for participation in the survey and Rs. 50 (approximately US$1.10) for each peer successfully recruited into the WTP Survey.

The survey elicited information on demographic characteristics, socioeconomic status, drug and alcohol use, sexual practices with paying and nonpaying partners, experiences of sexual and physical abuse, types of sex work (home-based, brothel-based, street-based), self-reported symptoms of sexually transmitted infections (STIs), and answers to a series of questions about reasons one might hypothetically be willing or unwilling to participate in an HIV prevention trial. Demographic and nonsensitive questions and questions about reasons one might or might not be willing to participate in a microbicide trial were administered by trained interviewers, while questions related to sexual and substance-use behaviors were administered through audio computer-assisted self-interviews (ACASI) on Lenovo tablet-based computers with customized software developed by the Population Council. The ACASI application made use of graphics and color to facilitate comprehension among nonliterate participants. The survey data were saved to Secure Digital (SD) cards. At the end of each day, the data from the SD cards were merged onto a data manager computer with access to the internet and compressed and encrypted for security.

After completion of the WTP Survey, participants were issued uniquely numbered recruitment coupons. Study staff explained to participants that they should keep one half of each recruitment coupon and give the other half to a peer. A participant’s recruit was required to come to the WTP Survey site with the coupon given to her by her recruiter. In order for the recruiter to receive compensation for recruiting her peers, she was asked to bring back to the survey site the retained portion of each coupon she distributed. Surveyed FSWs were then given a brochure and a description of the microbicide trial, which mentioned that a participant screening for the trial would meet with a doctor to discuss her health, that a pelvic exam would be conducted, and that her blood would be taken and tested for HIV and other STDs. The brochure also indicated that study participation included daily

insertion of a placebo gel that did not prevent HIV/STDs. Study participants were then referred to the clinic to learn more about the trial and for screening.

No other advertising about the trial or recruitment was conducted in the community. Because the study was designed to identify factors associated with willingness to participate in the trial, outreach staff were instructed not to contact respondents between completion of the survey and the screening visit.

Clinical trial

Only women who participated in the WTP Survey, agreed to be tested for HIV, and were willing to give study staff contact information, were screened for the trial. Clinical eligibility criteria mirrored those required for a clinical trial of an active microbicide product. (For further information on eligibility criteria, see Abbott et al. 2011 [39].) Women were invited to return to the clinic two weeks after their screening visit to receive their STI and Pap smear results and enroll in the trial if eligible and interested. When clinically indicated, participants were treated for STIs, and either rescreened after completing treatment, or simultaneously treated and enrolled. In part because of a concern that women might falsely identify as FSWs in order to enroll in the study, at screening, potential participants worked with counselors to diagram their sexual networks and risk behaviors. Ultimately, eight WTP respondents were not considered eligible for the clinical trial because it was thought that they were not currently sex workers.

The clinical trial entailed daily use of hydroxyethylcellulose (HEC), a placebo gel distributed in prepackaged single-dose Microlax-type applicators, for four months and included experiments with different methodologies and techniques to improve behavioral data collection [39]. Participants completed screening, enrollment, and four monthly follow-up (FU) visits. Physical and pelvic exams were conducted at screening and at the final visit; RTI/STI testing—HIV, HSV-2, trichimoniasis, syphilis, gonorrhea and chlamydia—was done at screening and the final visit, and, as clinically indicated at other visits for all infections except HIV. Pregnancy testing was conducted at each visit and a swab specimen for rapid stain identification of human semen (RSID), which detects unprotected sex in the prior 48 hours, was also taken at the screening visit and each FU visit. Women were instructed to bring back all applicators dispensed at each visit.

Statistical Analyses

For the descriptive analysis (Table 1), sample proportions produced from STATA and RDS-adjusted population proportions produced from RDS Analysis tool (RDSAT) version 5.60 (www.respondentdrivensampling.org) are reported. RDSAT adjusts for recruitment homophily and differential network sizes of participants. Specifically, the analysis in RDSAT adjusts the sample proportions downward in cases of larger than average personal network sizes and higher homophily, and upward in cases of smaller personal network sizes and lower homophily. Weighted logistic regression was conducted using STATA to assess whether, among the FSWs who were interviewed for the WTP Survey, those who came to the clinic to screen for the trial differed significantly from those who did not screen. The weights were derived from the RDSAT software. We also assessed, again using logistic regression: 1) whether, among women who were eligible for the trial, those who enrolled differed from those who did not enroll; and 2) whether those who came to the clinic for all four follow-up visits differed from those who missed at least one visit, and; 3) whether those who were lost to follow-up differed from those who completed the study or completed a final visit. These latter analyses were not weighted because we were not generalizing to the larger population of FSWs, but simply investigating those who enrolled in the trial. Adjusted models include all variables from the unadjusted models that were significant at $p<0.10$. We

assessed the significance of the multivariate models using the likelihood ratio chi square test comparing each model to an intercept-only model. A p-value less than .05 indicates that the model as a whole is statistically significant, in other words that the coefficients are jointly significantly different from zero. For the enrollment and screening analyses, we also examined, using z tests for the equality of proportions, whether the hypothetical reasons women reported in the WTP Survey for participating or not participating in an HIV prevention trial differed by screening and enrollment status.

Ethical Approval

The study was approved by the Institutional Review Boards of the Population Council, New York, and YRG CARE, Chennai, India. All participants gave informed consent in accordance with established guidelines and ethical standards for research involving human subjects.

Results

Table 1 provides background data on the 730 women interviewed for the WTP Survey. The mean age was 30.8 years, with approximately 18% of women under age 25 and 13% 40 years old or over. Nearly two-thirds of women had not attended school. Over two-thirds were Hindu. About 70% of the sample reported being currently married and over 90% had at least one child. Socio-economic status (SES) was derived from reported access to 14 household goods or services, including toilet facilities, electricity, and television. Using principal component analysis, a composite asset score was generated [40], which reflected the relative value of participants' assets; the higher the value, the higher the implied SES. Nearly 90% reported that they did not have enough money to support themselves and those who depended on them. A large proportion of FSWs engaged in high-risk behaviors, over half reporting anal sex with a paying client in the last month, and more than one in five reporting never using a condom with a paying client. Moreover, about half reported an STI symptom in the past month—abdominal pain, abnormal genital bleeding, white discharge, foul-smelling discharge, burning or pain on urination, genital ulcers/sores, swelling/ tenderness in groin/glandular area, or genital itching. About one-half had been tested for HIV, and a similar fraction reported not worrying about becoming infected with HIV.

Table 2 presents results from logistic regression analyses comparing those who screened (N=551) with those who did not come for screening (N=179) among the WTP participants. The unadjusted models indicate several variables that distinguish those who came for screening from those who did not. FSWs who were older, not married, did not have children under 12 living at home, reported engaging in sex work in the past month, reported STI symptoms, and lived in Gudur—a subdistrict that is over 40 kilometers from Nellore but easily accessible by public transportation and known as having a high concentration of FSWs—were more likely to attend screening. These same variables, with the exception of age and children living at home, remained significant at $p < 0.10$ in the multivariate model. STI symptoms were the most significant factor associated with likelihood of screening; FSWs who reported one or two symptoms were two times as likely to screen for the trial (odds ratio = 2.01, 95% CI 1.30–3.10) and those who reported three or more symptoms were over two and one-half times as likely to screen (odds ratio = 2.62, 95% CI 1.36–5.04) as those not reporting any STI symptoms.

Table 3 presents results from logistic regression analyses comparing those who enrolled in the trial (N=267) with those who were eligible but did not enroll (N=99). Four variables were significant at $p<0.10$ in the unadjusted models, currently married, sex work in the past month,[1] anal sex with a paying client in the last month, and ever having tested for HIV. Only ever having tested for HIV remained significant in the multivariate model; those who

reported never being tested for HIV or not knowing if they were tested were significantly more likely to enroll (odds ratio = 1.74, 95% CI 1.08–2.83).

Table 4 examines reasons women indicated for participating or not participating in an HIV prevention trial by screening and enrollment status. Of all the reasons included in the WTP survey, only two—"family member would not allow it" and "worry about contracting HIV"—were significant in distinguishing those who enrolled in the trial from those who did not. That is, women who were eligible but did not enroll in the trial were significantly more likely to indicate that they thought 1) a family member would not permit their participation and 2) participation might result in HIV infection. Moreover, while few women indicated that the conditions for participating in a trial were a concern, women who enrolled reported being slightly more willing to take time off from work ($p<0.05$) and childcare ($p<0.02$), and stay in Nellore ($p<0.05$) than those who were eligible but did not enroll.

Table 5 presents results from logistic regression analyses comparing those who attended all four monthly visits (N=145) with those who missed at least one visit (N=122). While four variables were significant in the unadjusted models—education, SES score, sex work in the past month, and condom use with a paying client—only one remained significant at $p<0.05$ in the multivariate model; those who had engaged in sex work in the month prior to the WTP survey (odds ratio = 0.45 95% CI 0.22–0.91) were less likely to attend all four visits. Table 6 presents results from logistic regression analyses comparing those who attended their month 4 exit visit (N=218) with those who were lost to follow-up (N=49). Three variables were significant at $p<0.10$ in the unadjusted models—age, having at least one child, and sex work in the past month. None of these was significant at $p<0.05$ in the multivariate models.

Discussion

The review of the literature revealed that there is much more to be learned about the selectivity of those who participate in microbicide trials in developing countries. Few studies have compared those who enroll in microbicide trials with those who are informed about a trial but do not screen and enroll. Do women participate because they are in need of money and the reimbursement makes it worth the investment of time? Do they participate because they are eager to access decent-quality health care? Do they participate because they perceive themselves to be at risk of HIV and/or STIs and believe enrolling in a trial will protect them [41]? And why do women who learn about a microbicide trial choose not to participate? Is it because they are burdened by childcare responsibilities or because family members object? Is it because they do not want to test a product or undergo medical procedures? Or, for some, is life so chaotic or unpredictable that they are unable to visit a clinic regularly?

This analysis of a representative sample of FSWs in Southern India suggests that the primary reason these women participated is a desire for health care. FSWs who reported STI symptoms were much more likely to come to the clinic for screening. Moreover, those who had never been tested for HIV were more likely to enroll. Interestingly, the STI symptom variable, while significant in the screening analysis, was not significant in distinguishing those who enrolled from those who did not enroll. Note that there was no difference in eligibility status on basis of reported STI symptoms, suggesting that once women received health care at screening, STI symptoms were no longer a motivation to enroll, presumably

[1]While women who did not perform sex in the past month were considered ineligible both for the WTP survey and the trial, many women reported no sex work in the past month in ACASI for the WTP survey. At the screening visit, most of these women who reported no sex work in the past month at the time of the WTP survey were discovered to have engaged in sex work during this period.

because their symptoms were addressed at the screening visit. Two other variables were predictive of screening. Women who lived in Gudur, a subdistrict known as a hot spot for sex workers with good transportation to Nellore, were more likely to come for screening, as were those who engaged in sex work in the past month. What is also noteworthy are two factors that were not predictive of screening or enrollment, namely HIV risk perception and not having enough money to support oneself or others. Even though this was a placebo study, one might have thought those who perceived themselves at higher risk of infection would be more likely to participate because the trial included testing for HIV. With regard to poverty status, while we thought it plausible that the poorest women in our survey would be more willing to screen and enroll, the reality is that all of these women are impoverished and nearly 90 percent indicated they had insufficient means to support themselves. As for attendance at follow-up visits, although reported sex work in the past month is predictive of screening, women who reported engaging in sex work in the past month were less likely to return to the clinic for all four visits.

This study had several limitations. 1) While RDS assumes that peers recruit randomly from among their networks, the sample of FSWs may still be selective of all FSWs in Nellore. Selectivity bias resulting from nonresponse among those given coupons who did not show up for the WTP survey likely has a minimal effect on descriptive estimates and weighted regression analyses because, as we indicated earlier, RDSAT adjusts for recruitment patterns, in particular, homophily. As for the nonweighted regression analyses, because we are not generalizing to the larger FSW population, but rather to the sample of FSWs who enrolled in the trial, selectivity bias is less of a concern. 2) The models investigating attendance at all four monthly visits and participants lost to follow-up were not very illuminating, aside from demonstrating that those who reported engaging in sex work in the past month—three-quarters of our sample—were less likely to comply with the visit schedule. It appears that for this sample of FSWs the questions we included in the WTP Survey did not distinguish those who were more adherent to the protocol from those who were not. 3) Women were asked to screen for a trial that used a placebo gel rather than a product with an active ingredient. While there is precedence for conducting placebo studies to examine product acceptability and feasibility [42, 43] it could be that the factors distinguishing those willing to participate in a trial with an actual product are different from those observed for a placebo trial since there is no possibility that a placebo prevents HIV. However, compared with the Phase 3 Carraguard trial [44], a follow-up placebo-only trial in the same sites [45] showed little difference in the screen:enroll ratio (1.55 Phase 3 versus 1.66 placebo only) suggesting, perhaps, that willingness to participate and use of the study product in the India trial were not affected by the absence of an active product. Moreover, no HIV prevention trial had ever taken place at the Nellore clinic. A study requiring use of a nonmedicated gel that is conducted in a trial naïve community is likely to be viewed differently than a study conducted in a community where HIV prevention trials are common and where HIV prevalence is higher. Women in settings with many microbicide trials might find use of a nonactive product to be more problematic than women in Nellore.

The results from the screening and enrollment analyses may have implications for future HIV prevention trials that might be conducted among FSWs in India. Our multivariate findings suggest that those who reported engaging in the highest risk behaviors—including drug use, anal sex, forced sex, and unprotected sex with clients—and who might be at highest risk of acquiring HIV, were not more likely to come to the clinic for a screening visit. Inability to recruit those at highest risk of infection has implications for Phase 2b and Phase 3 microbicide trials, which need a certain number of endpoints in order to have sufficient power to estimate effectiveness.

To determine the selectivity of those who ultimately screen and enroll, future HIV prevention trials would benefit from the collection of data from those who are recruited but choose not to participate. Indeed, one explanation for the conflicting findings from recent PrEP trials of tenofovir may be the particular characteristics of trial participants and the way those characteristics affect adherence to product use and study protocols [46–49].

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Table 1

Descriptive characteristics of women who completed the WTP survey (N=712–730)[a]

Characteristic	Sample Proportion	Population-based estimate (95% C.I.)
Age (mean)	30.8	—[b]
Education		
None	66.4	65.6 (61.2 – 69.5)
Some	33.6	34.4 (30.5 – 38.8)
Religion		
Hindu	68.1	70.7 (66.2 – 74.9)
Muslim	19.5	17.5 (14.3 – 20.8)
Christian/other	12.5	11.9 (8.6 – 15.5)
Currently married		
No [c]	30.1	28.8 (24.9 – 32.8)
Yes	69.9	71.2 (67.2 – 75.1)
Children ever born		
None	7.8	8.6 (6.3 – 11.2)
One or more	92.2	91.4 (88.8 – 93.7)
Children <12 living at home		
No or N/A	39.3	37.4 (33.1 – 41.7)
Yes	60.7	62.6 (58.3 – 66.9)
Socioeconomic status score (mean=0)	0[d]	—[b]
Not enough money to support self/others		
Disagree	12.7	12.2 (9.4 – 15.2)
Agree	87.3	87.7 (84.8 – 90.6)
Anal sex with paying client past month		
No	43.8	43.5 (39.0 – 47.8)
Yes	56.2	56.5 (52.2 – 61.0)
Sex work past month		
No	23.4	23.3 (19.6 – 27.1)
Yes	76.6	76.7 (72.9 – 80.4)
Condom use with paying client		
Never	22.3	23.1 (19.2 – 27.0)
Ever	77.7	76.9 (73.0 – 80.8)
Forced sex past year		
No	52.5	53.5 (49.1 – 57.8)
Yes	47.6	46.5 (42.2 – 50.9)
Number of STI symptoms past month [e]		
0	48.6	51.7 (47.2 – 56.1)
1–2	39.0	36.7 (32.7 – 40.9)
3+	12.3	11.5 (8.9 – 14.5)
Ever tested for HIV		
No/don’t know	50.3	53.9 (49.3 – 58.4)

Characteristic	Sample Proportion	Population-based estimate (95% C.I.)
Yes	49.7	46.1 (41.6 – 50.7)
Worried about getting HIV		
No	47.4	50.0 (45.6 – 54.2)
Yes	52.6	50.0 (45.8 – 54.4)
Current alcohol use		
No	44.8	48.8 (44.1 – 53.6)
Yes	42.3	38.5 (33.9 – 43.1)
Missing	12.9	12.7 (10.1 – 15.5)
Drug use past year [f]		
No	69.3	70.7 (66.8 – 74.7)
Yes	30.7	29.3 (25.3 – 33.2)
Subdistrict		
Gudur	30.3	29.2 (22.4 – 36.3)
Other subdistrict	69.7	70.8 (63.7 – 77.7)

[a] Sample sizes vary because of missing values.

[b] RDSAT does not provide population-based estimates for continuous variables.

[c] Comprises widowed, separated, never married, and married no *guana* performed.

[d] The SES score incorporates ownership of or access to 14 household assets or utility services — main water source, toilet, electricity, gas connection, pressure cooker, cot/bed, electric fan, radio, TV, refrigerator, scooter, bicycle, car, cell phone. SES scores were derived from a principal component analysis, using the first principal component as a summary indicator of long-run SES (following Filmer and Pritchett [40]. The mean of the score was set at zero and the standard deviation was 1.7.

[e] Comprises abdominal pain, abnormal genital bleeding, white discharge, foul-smelling discharge, burning or pain on urination, genital ulcers/sores, swelling/tenderness in groin/glandular area, genital itching.

[f] Comprises marijuana and/or heroin use.

Table 2

Predictors of screening among those who were surveyed (weighted models)

	Unadjusted (N=712–730) [a]				Adjusted (N=717)			
Characteristic	**OR**	**p-value**	**95% CI**		**OR**	**p-value**	**95% CI**	
Age	1.03	0.06	1.00	1.06	1.02	0.19	0.99	1.06
Education (ref=None)								
Some	0.94	0.78	0.62	1.43				
Religion (ref=Muslim)								
Hindu	0.98	0.93	0.60	1.59				
Christian/other	0.74	0.39	0.38	1.46				
Currently married (ref=No)	0.61	0.03	0.39	0.94	0.67	0.08	0.43	1.06
Children ever born (ref=None)	1.05	0.89	0.53	2.10				
Children <12 living at home (ref= No or N/A)	0.69	0.07	0.47	1.03	0.93	0.76	0.60	1.45
Socioeconomic status score	0.99	0.78	0.89	1.09				
Not enough money to support self/others (ref=Disagree)	1.21	0.50	0.70	2.11				
Anal sex with paying client past month (ref=No)	1.28	0.23	0.86	1.90				
Sex work past month (ref=No)	2.04	<0.01	1.32	3.15	1.67	0.03	1.06	2.62
Condom use with paying client (ref=Never)	1.42	0.13	0.90	2.25				
Forced sex past year (ref=No)	1.05	0.82	0.71	1.55				
Number of STI symptoms past month (ref=0)								
1–2	2.27	<0.01	1.47	3.49	2.01	<0.01	1.30	3.10
3+	3.02	<0.01	1.58	5.75	2.62	<0.01	1.36	5.04
Ever tested for HIV (ref=Yes)								
No/Don’t know	1.22	0.33	0.82	1.80				
Worried about getting HIV (ref=No)	1.03	0.87	0.70	1.53				
Current alcohol use (ref= No)								
Yes	0.78	0.25	0.51	1.19				
Missing	0.44	0.01	0.25	0.79				
Drug use past year (ref=No)	1.25	0.31	0.81	1.91				
Subdistrict (ref=Other subdistrict)								
Gudur	2.74	<0.01	1.72	4.37	2.34	<0.01	1.45	3.76

	Unadjusted (N=712–730) [a]			Adjusted (N=717)		
Characteristic	**OR**	**p-value**	**95% CI**	**OR**	**p-value**	**95% CI**
Wald chi2 (7) =						39.37
Prob>chi2 =						<0.001
Pseudo R2 =						0.0719

[a] Sample sizes vary because of missing values.

Table 3

Predictors of enrollment among those who were eligible

	Unadjusted (N=360–366) [a]				Adjusted (N= 359)			
Characteristic	**OR**	**p-value**	**95% CI**		**OR**	**p-value**	**95% CI**	
Age	1.01	0.57	0.98	1.05				
Education (ref=None)								
Some	1.15	0.58	0.70	1.89				
Religion (ref=Muslim)								
Hindu	1.06	0.84	0.60	1.87				
Christian/other	2.08	0.13	0.80	5.38				
Currently married (ref=No)	0.63	0.09	0.37	1.07	0.63	0.10	0.36	1.09
Children (ref=None)	0.94	0.89	0.38	2.30				
Children <12 living at home (ref=No or N/A)	1.31	0.26	0.82	2.10				
Socioeconomic status score	0.97	0.71	0.85	1.12				
Not enough money to support self/others (ref=Disagree)	0.80	0.55	0.39	1.65				
Anal sex with paying client past month (ref=No)	1.50	0.09	0.94	2.41	1.26	0.35	0.77	2.07
Sex work past month (ref=No)	1.67	0.07	0.96	2.91	1.61	0.11	0.89	2.88
Condom use with paying client (ref=Never)	1.02	0.96	0.55	1.88				
Forced sex past year (ref=No)	0.72	0.17	0.45	1.15				
Number of STI symptoms past month (ref=0)								
1–2	1.35	0.24	0.82	2.21				
3+	1.30	0.48	0.62	2.71				
Ever tested for HIV (ref=Yes)								
No/don’t know	1.73	0.02	1.09	2.76	1.74	0.02	1.08	2.83
Worried about getting HIV (ref=No)	0.91	0.71	0.58	1.45				
Current alcohol use (ref=No)								
Yes	1.05	0.83	0.65	1.71				
Missing	1.30	0.53	0.57	2.95				
Drug use past year (ref=No)	1.31	0.30	0.79	2.19				
Subdistrict (ref=Other subdistrict)								
Gudur	1.09	0.71	0.68	1.75				

	Unadjusted (N=360–366) [a]			Adjusted (N= 359)		
Characteristic	**OR**	**p-value**	**95% CI**	**OR**	**p-value**	**95% CI**
LR =chi2 (4)						12.37
Prob>chi2						0.0148
Pseudo R2						0.0295

[a]Sample sizes vary because of missing values.

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Table 4

Comparison by screening and enrollment status of reasons for participating and not participating in an HIV prevention trial and conditions for participation [a]

	Screened (N=551) %	Not screened (N=179) %	Test Statistic	Enrolled (N=267) %	Not enrolled, if eligible (N=99) %	Test Statistic
Reasons for participating in HIV prevention research						
Financial reimbursement	33.0	36.3	$z = 0.81$ p = 0.42	37.8	30.3	$z = -1.33$ p = 0.18
Free health care during research	98.9	97.8	$z = -1.15$ p = 0.25	99.3	100.0	$z = 0.86$ p = 0.39
HIV testing	99.3	98.9	$z = -0.50$ p = 0.61	99.6	99.0	$z = -0.73$ p = 0.46
STI testing and treatment	98.9	97.8	$z = -1.15$ p = 0.25	100.0	99.0	$z = -1.64$ p = 0.10
Information about HIV prevention	98.4	97.2	$z = -0.98$ p = 0.33	98.9	99.0	$z = 0.09$ p = 0.93
Free family planning method	74.4	75.4	$z = 0.27$ p = 0.79	77.5	82.8	$z = 1.11$ p = 0.27
Free condoms	94.7	95.5	$z = 0.42$ p = 0.67	96.3	93.9	$z = -0.96$ p = 0.34
Help test a product for HIV prevention	97.3	97.8	$z = 0.36$ p = 0.72	98.9	97.0	$z = -1.28$ p = 0.20
Partner referral for HIV/STI testing and/or treatment	57.3	59.8	$z = 0.59$ p = 0.56	59.8	58.6	$z = -0.21$ p = 0.84
Reasons for nonparticipation						
Husband/partner would not allow it	22.9	29.1	$z = 1.67$ p = 0.09	16.9	24.2	$z = 1.61$ p = 0.11
Family member(s) would not allow it	24.5	27.9	$z = 0.92$ p = 0.36	18.7	28.3	$z = 1.98$ p = 0.05
Fear of doctors, nurses, other health professionals	15.8	18.4	$z = 0.83$ p = 0.41	15.0	19.2	$z = 0.97$ p = 0.33
Worry about contracting HIV	14.2	12.9	$z = -0.44$ p = 0.66	9.7	17.2	$z = 1.96$ p = 0.05
Fear of trouble with the police	34.5	29.6	$z = -1.20$ p = 0.23	36.3	33.3	$z = -0.53$ p = 0.60
Worry that community may assume HIV infection	12.3	12.3	$z = -0.02$ p = 0.99	8.6	11.1	$z = 0.73$ p = 0.47
Fear of harmful effects of HIV prevention product	6.5	7.3	$z = 0.34$ p = 0.73	5.6	6.1	$z = 0.16$ p = 0.87
Conditions for participating in HIV prevention clinical trial: Respondent would agree to …						
visit a health clinic monthly	94.6	92.7	$z = -0.90$ p = 0.37	98.5	97.0	$z = -0.95$ p = 0.34
have blood drawn for HIV and STI tests	94.4	93.3	$z = -0.53$ p = 0.60	98.5	96.0	$z = -1.48$ p = 0.14
have vaginal exam and STI tests	94.4	92.7	$z = -0.80$ p = 0.42	98.5	97.0	$z = -0.95$ p = 0.34
being asked questions about sexual behavior	94.4	94.4	$z = 0.02$ p = 0.98	98.5	96.0	$z = -1.48$ p = 0.14
use a FP method during research	79.1	78.2	$z = -0.26$ p = 0.79	80.5	83.8	$z = 0.72$ p = 0.47
use condoms for all sexual partners	93.3	93.3	$z = 0.01$ p = 1.00	97.8	93.9	$z = -1.82$ p = 0.07
take time off from work	94.2	91.6	$z = -1.22$ p = 0.22	98.5	95.0	$z = -1.95$ p = 0.05

	Screened (N=551) %	Not screened (N=179) %	Test Statistic	Enrolled (N=267) %	Not enrolled, if eligible (N=99) %	Test Statistic
take time off from caring for children/household	94.9	91.6	$z = -1.63$ p = 0.10	98.9	95.0	$z = -2.28$ p = 0.02
stay in Nellore for up to one year	94.6	93.3	$z = -0.62$ p = 0.53	98.5	95.0	$z = -1.95$ p = 0.05

[a]Tests for difference of proportions by screening and enrollment status.

Table 5

Predictors of attending all four monthly visits among those who were enrolled

	Unadjusted (N=262–267) [a]				Adjusted (N= 263)			
Characteristic	**OR**	**p-value**	**95% CI**		**OR**	**p-value**	**95% CI**	
Age	1.03	0.13	0.99	1.07				
Education (ref=None)								
Some	0.53	0.02	0.33	0.89	0.62	0.09	0.36	1.08
Religion (ref=Muslim)								
Hindu	1.06	0.86	0.57	1.95				
Christian/other	1.19	0.69	0.50	2.81				
Currently married (ref=No)	0.95	0.84	0.57	1.59				
Children ever born (ref=None)	1.87	0.19	0.74	4.73				
Children <12 living at home (ref=No or N/A)	0.83	0.46	0.50	1.37				
Socioeconomic status score	0.83	0.02	0.71	0.97	0.88	0.13	0.75	1.04
Not enough money to support self/others (ref=Disagree)	0.72	0.38	0.35	1.49				
Anal sex with paying client past month (ref=No)	0.91	0.71	0.55	1.51				
Sex work past month (ref=No)	0.41	0.01	0.20	0.82	0.45	0.03	0.22	0.91
Condom use with paying client (ref=Never)	1.77	0.08	0.93	3.39	1.51	0.24	0.76	3.00
Forced sex past year (ref=No)	0.77	0.30	0.48	1.26				
Number of STI symptoms past month (ref=0)								
1–2	1.08	0.77	0.64	1.82				
3+	0.66	0.28	0.31	1.40				
Ever tested for HIV (ref=Yes)								
No/don’t know	1.29	0.30	0.79	2.09				
Worried about getting HIV (ref=No)								
Current alcohol use (ref=No)	1.17	0.52	0.72	1.89				
Yes	0.98	0.94	0.59	1.64				
Missing	1.10	0.81	0.49	2.47				
Drug use past year (ref=No)	1.25	0.40	0.74	2.09				
Subdistrict (ref=Other subdistrict)								
Gudur	0.92	0.75	0.57	1.51				

	Unadjusted (N=262–267) [a]			Adjusted (N= 263)		
Characteristic	**OR**	**p-value**	**95% CI**	**OR**	**p-value**	**95% CI**
LR chi2 (4)						16.35
Prob>chi2						0.0026
Pseudo R2						0.0451

[a] Sample sizes vary because of missing values.

Table 6

Predictors of attending exit visit among those who were enrolled

	Unadjusted (N=262–267) [a]				Adjusted (N= 264)			
Characteristic	**OR**	**p-value**	**95% CI**		**OR**	**p-value**	**95% CI**	
Age	1.06	0.02	1.01	1.11	1.05	0.07	1.00	1.10
Education (ref=None)								
Some	0.67	0.22	0.36	1.27				
Religion (ref=Muslim)								
Hindu	1.51	0.28	0.71	3.22				
Christian/other	0.99	0.98	0.36	2.73				
Currently married (ref=No)	1.00	0.99	0.52	1.94				
Children ever born (ref=None)	2.63	0.05	0.99	6.98	2.10	0.17	0.73	6.06
Children <12 living at home (ref=No or N/A)	1.04	0.90	0.55	1.98				
Socioeconomic status score	0.89	0.20	0.75	1.06				
Not enough money to support self/others (ref=Disagree)	0.52	0.24	0.17	1.54				
Anal sex with paying client past month (ref=No)	0.65	0.21	0.33	1.28				
Sex work past month (ref=No)	0.38	0.08	0.13	1.11	0.38	0.08	0.13	1.14
Condom use with paying client (ref=Never)	1.35	0.45	0.62	2.97				
Forced sex past year (ref=No)	0.72	0.30	0.38	1.34				
Number of STI symptoms past month (ref=0)								
1–2	1.18	0.62	0.61	2.31				
3+	1.00	1.00	0.39	2.58				
Ever tested for HIV (ref=Yes)								
No/don’t know	0.81	0.52	0.43	1.53				
Worried about getting HIV (ref=No)	1.12	0.72	0.60	2.08				
Current alcohol use (ref=No)								
Yes	1.43	0.30	0.73	2.81				
Missing	0.84	0.72	0.32	2.19				
Drug use past year (ref=No)	1.45	0.29	0.73	2.91				
Subdistrict (ref=Other subdistrict)								
Gudur	0.77	0.40	0.41	1.43				

	Unadjusted (N=262–267) [a]			Adjusted (N= 264)		
Characteristic	**OR**	**p-value**	**95% CI**	**OR**	**p-value**	**95% CI**
LR chi2 (3)						10.96
Prob>chi2						0.012
Pseudo R2						0.0433

[a]Sample sizes vary because of missing values.