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Project Shikamana: community empowerment-based combination HIV prevention significantly impacts HIV incidence and care continuum outcomes among female sex workers in Iringa, Tanzania

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Abstract

Objective: Determine the impact of a community empowerment model of combination HIV prevention (Project Shikamana) among female sex workers (FSW) in Iringa, Tanzania.

Methods: We conducted a two-community randomized trial. Intervention elements included: 1) community drop-in-center; 2) venue-based peer education, condom distribution and HIV testing; 3) peer service navigation; 4) provider sensitivity trainings; and 5) SMS reminders. We utilized time-location-sampling to enroll 496 FSW and conducted a survey and blood draws to screen for HIV and assess viral load at 0 and 18 months. We conducted an intent-to-treat analysis using logistic and Poisson regression and inverse probability weighting for primary outcomes.

Results: The analysis included 171 HIV-positive and 216 HIV-negative FSW who completed both the baseline and 18-month study visits. Participants in the intervention were significantly less likely to become infected with HIV at 18-month follow-up (RR 0.38; p=0.047), with an HIV incidence of 5.0% in the intervention vs. 10.4% control. Decreases in inconsistent condom use over time were significantly greater in the intervention (72.0% to 43.6%) vs. control (68.8% to 54.0%; RR 0.81, p=0.042). At follow-up, we observed significant differences in behavioral HIV care continuum outcomes, and positive, but non-significant, increases in viral suppression (40.0% to 50.6%) in the intervention vs. control (35.9% to 47.4%). There was a strong association of between higher intervention exposure and HIV outcomes including viral suppression.

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Conclusions: Project Shikamana is the first trial of community empowerment-based combination prevention among FSW in Africa to show a significant reduction in HIV incidence warranting its broader implementation and evaluation.

Trial registration: Clinicaltrials.gov # NCT02281578.

Keywords

Female sex workers; HIV; community empowerment; combination prevention; incidence; viral suppression

INTRODUCTION

Female sex workers (FSW) are among those women most disproportionately impacted by HIV, with an estimated global HIV prevalence of 10.4%.[1] HIV prevalence is the highest among FSW in sub-Saharan Africa.[1,2] A systematic review of epidemiologic studies conducted between 2006 and 2017 found a 33.3% HIV prevalence among FSW in Eastern and Southern Africa.[1] In Tanzania, we found a baseline HIV prevalence of 40.9% among the Shikamana cohort of venue-based FSW in the Iringa region, located in the Southwest of the country.[3] Mathematical modeling has shown that FSW and their sexual partners are estimated to account for 23% of all new HIV infections in Tanzania, demonstrating their importance in overall transmission.[4] FSW also have worse HIV care and treatment outcomes compared to other women, including lower access and adherence to antiretroviral therapy (ART).[5] Globally, only 38% of FSW are estimated to have access to ART and among those, 57% are estimated to be virally suppressed.[6]

Socio-structural factors have been found to be associated with the disproportionate HIV risk and sub-optimal care and treatment outcomes of FSW.[7–12] FSW may experience multiple intersecting forms of stigma, discrimination and violence related to their occupation, gender, and/or HIV status which constrain their ability to engage in protective behaviors and access health services.[12,13] Previous reviews have found that between 32–55% of FSW experienced workplace violence in the past year.[14] In our prior work among FSW in both Tanzania and the Dominican Republic (DR) we found that stigma and discrimination related to sex work and HIV,[15–17] and gender-based violence (GBV) were associated with increased HIV-related risk behaviors, as well as suboptimal HIV care continuum outcomes.[18,19]

Community empowerment approaches that seek to address socio-structural constraints associated with the higher risk for HIV infection experienced by FSW have been shown to be effective, and cost-effective, in this key population.[20,21] Such approaches are set within a broader health and human rights framework and are tailored to the needs and priorities of a given community. Among FSW, these strategies have often focused on first creating safe spaces and opportunities for social cohesion through the use of community-led drop-in-centers, where community mobilization activities to address socio-structural constraints, such as stigma, discrimination, violence and financial insecurity, can be planned and take place.[22,23] These models generally also include peer education, condom distribution, HIV/STI testing and linkage to care.

In a prior meta-analysis led by the first author, community empowerment interventions were associated with a 32% reduction in the odds of HIV infection among FSW.[20] Yet, most of the studies included in the review were conducted in South Asia and Latin America and the Caribbean.[20] Additionally, limited rigorous evaluations of community empowerment-based combination HIV prevention interventions that included ART-based prevention strategies have been conducted to date among FSW.[24,25] As such, we sought to establish a tailored combination HIV prevention model grounded in the principles of community empowerment to improve HIV outcomes among FSW in sub-Saharan Africa. Based on formative qualitative research among sex workers and key informants such as local health officials and providers, Project *Shikamana* ("Let's Stick Together" in Swahili), a community-driven, multi-level model was developed to improve HIV outcomes, and the overall health and human rights of FSW in Iringa, Tanzania.

METHODS

Study Design and Sampling

The Shikamana study design was a prospective community-randomized trial conducted in two communities matched on population size (approximately 25,000 people each) and HIV risk characteristics (~7% HIV prevalence in the overall population) within the Iringa region of Tanzania. The study design is described in further detail in the baseline publication.[3] The Iringa region has among the highest HIV prevalence in Tanzania (11.3% in Iringa vs. 4.7% overall).[26] Its location along the Tanzanian-Zambian (TanZam) highway, a major trucking route, and its numerous agricultural plantations with large numbers of migrant seasonal workers, create a demand for female sex work.[27] Sex work in the region is generally establishment-based and occurs in venues such as modern and traditional bars, guesthouses and hotels, groceries/mini-bars/pubs, and clubs.

We identified all active sex work venues (164 total) in the two study communities (Ilula and Mafinga). We utilized time location sampling (TLS) to enroll a cohort of 496 FSW that included 203 HIV-positive and 293 HIV-negative women. Women 18 years or over who reported exchanging sex for money in the last month met inclusion criteria. The recruitment period ran from October of 2015 to April of 2016. Participants were screened for eligibility in a private place at or nearby the venue. Oral informed consent was conducted with all study participants. There were two study visits at baseline (0) and 18 months. Participants in the cohort were followed up through ongoing monthly contact conducted by the study team using both phone and personal contact to optimize retention. We achieved an 81.5% retention rate among all study participants, with retention rates of 86.8% among HIV-positive and 77.7% among HIV-negative women in the cohort. No significant differences in retention rates were observed across arms. Retention was correlated with being older, more educated, and having a mobile phone and having worked in the venue for less than 6 months was correlated with loss to follow-up.

Intervention Model

The Shikamana model included: (1) a community-led drop-in-center to stimulate social cohesion and mobilization activities; (2) venue-based peer education, condom distribution

and HIV counseling and testing; (3) peer service navigation and social support to promote HIV treatment access and adherence; (4) HIV clinical care provider and police sensitivity trainings; and (5) text messages to promote solidarity and engagement with the intervention, and reminder messages to promote care engagement and ART adherence among HIV-positive women.

During the course of the 18-month intervention period, 7 workshops were held at the drop-in-center with 324 participants on topics such as: stigma, discrimination and GBV; family planning; HIV/STI prevention including condom negotiation; ART adherence; financial security; sex worker rights and community mobilization strategies. Program participants led the formation of a community savings group that met at the drop-in-center on a weekly basis and went on to establish a catering business to promote financial security and to support community-led intervention activities. Additional groups started by the women included a violence support group. A Shikamana women's group was also formed and met monthly. During the study, the women formally registered the Shikamana women's group as a local organization. HIV counseling and testing and condoms were continuously available at the drop-in-center.

Venue-based peer education occurred on a monthly basis including a total of 1,542 contacts between peer educators and FSW. Peer educators distributed health materials developed by participants and a local artist and a total of 81,463 condoms to FSW working in venues in the intervention community. Mobile HIV counseling and testing was offered in all venues by study staff twice during the intervention period with 376 tests conducted. Linkage to care and peer navigation and support services were offered to all women living with HIV in the cohort and from venues. More than 2,635 calls and 3,550 home visits were made by peer service navigators.

Provider sensitivity trainings were conducted on a quarterly basis with a group of 22 HIV clinical care providers to promote respectful quality health services tailored to FSW needs in coordination with peer navigators. A total of 14,184 text message reminders were sent to participating FSW during the study. Additional intervention activities were developed and implemented in an ongoing manner, as driven by community priorities, such as cervical cancer screenings, community health education fairs as well as a workshop with local police and justice sector officials in response to the need for support accessing GBV services and justice.

The control community received standard of care HIV services which included access to HIV testing and treatment through government services, and HIV-related health education, condom promotion and HIV testing initiatives for key populations through non-governmental groups. These services and programs were also available in the intervention community during the study.

Data Collection Procedures

A survey and blood draws were conducted with all consenting participants at each study visit. The survey assessed demographic, behavioral and socio-structural factors, as well as exposure to the intervention and utilization of HIV services. Participants were counseled and

tested for HIV following Tanzanian national guidelines, using a dual parallel algorithm of the Determine and Uni-Gold HIV-1 rapid antibody tests in the field at the time of the survey, followed by a repeat dual parallel algorithm after two weeks in case of discordant results. Viral load testing was performed at the Muhimbili University of Health and Allied Sciences (MUHAS) laboratory in Dar-es-Salaam, using Abbott m2000RT HIV-1 polymerase chain reaction (Abbott GmbH & Co, Germany) system. The study was approved by the Institutional Review Boards (IRB) of the Johns Hopkins Bloomberg School of Public Health, and MUHAS and the National Institute for Medical Research (NIMR) in Tanzania. Participants were compensated 5,000 Tanzanian Shillings (TZS) (USD $2.50) per visit. A community advisory board (CAB) comprised of 10 FSW from study communities and an advisory board (AB) comprised of FSW and government officials and service providers guided study implementation through quarterly meetings. The trial was registered at Clinicaltrials.gov: # NCT02281578.

Measures

Socio-demographic and behavioral variables measured included participants' age, education, residence, migration/mobility, marital status, number of children, number of paying and non-paying sexual partners in past month, consistent condom use per each partner type, drug and alcohol use, exposure to GBV, HIV and sex work stigma, type of sex work venue, total amount of income per month and percent derived from sex work, and length of time in sex work.

Primary study outcomes assessed after 18 months were HIV acquisition among participants who were HIV-negative at baseline, and viral suppression (<400 copies/mL) among those who were HIV-positive at baseline. Secondary prevention outcomes included HIV risk behaviors such as inconsistent condom use with new and regular clients. Secondary care and treatment outcomes include engagement in HIV care, ART use and adherence, which was assessed using the AIDS Clinical Trials Group (ACTG) measure for reported adherence in the last 4 days.[28]

Data Analysis

Women who returned to the 18-month follow-up visit were included in the analysis (n=387: 171 HIV-positive and 216 HIV-negative). The data were first explored using descriptive statistics. The impact analysis then focused on a comparison of the intervention to control communities at follow-up with an intent-to-treat approach. Logistic regression models were used for rare outcomes (e.g. cumulative HIV incidence) and for more common outcomes (e.g. condom use and HIV care continuum outcomes) we fit Poisson regression models with robust variance estimates. Only women who were found to be HIV-negative at baseline (n=216) were included in the HIV incidence outcome analysis presented here and only women who were found to be HIV-positive women at baseline (n=171) were included in the HIV care and treatment outcomes analyses. These bivariate logistic regression models included an intervention indicator as the main covariate, with a time indicator and their interaction for models comparing changes in outcomes over time between communities.

To account for potential bias due to women not returning to the follow-up visit, we applied inverse propensity score weighting for the primary biological outcomes of HIV seroconversion and viral suppression. The probability of returning to the 18-month visit was estimated with a logistic model using baseline covariates including characteristics such as age, HIV status and reported sexual risk behaviors such as consistent condom use. The weighted models were then evaluated with bootstrap estimation for the parameters of interest and standard errors.

To further explore the impact of the intervention on study outcomes we created two aggregate measures of exposure to the intervention activities, one that focused on prevention and relevant to all participants that included 6 items (e.g. participation in community drop-in-center activities (0,1,2+), peer educator contact in venue, receipt of condoms from project (y/n), receipt of project educational materials (y/n), participation in community savings group (y/n), and receipt of text messages (y/n)) and one that included those items plus 3 items relevant only to HIV-positive women (e.g. HIV support group (y/n), HIV treatment and adherence counseling (y/n), and peer service navigation visits and phone contacts (0,1–2,3+ each)). The measures were then categorized into low, medium and high levels of exposure to the intervention for each population group, based on the sum of all reported exposures. The aggregate prevention measure distribution in Ilula, the intervention community was low, 0 (17.5%), medium, 1–2 (39.8%) and high 3–6 (42.6%) among all participants with almost identical distribution among the HIV-positive and HIV-negative groups. The aggregate care measure distribution was low, 0–1 (22.0%), medium, 2–5 (46.1%) and high 6–9 (31.9%) among the HIV-positive women.

RESULTS

Socio-demographic and behavioral characteristics of the Shikamana sample

Socio-demographic and behavioral characteristics of women participating in the Shikamana cohort that were interviewed at both baseline and follow-up study visits are presented in Table 1. Participants were generally of child bearing age (average age of 27.8 years old) with more than one child (average number of children of 2.2). Most had low levels of formal education, with only 29.2% having attended any secondary school. Participants' average monthly income was US$ 52.2, with an average of US$ 21.7 from sex work. On average, participants had been exchanging sex for money for 7.2 years and had an average of 2.8 clients per week. The average amount charged per client date was US$ 6.5. Most (70.7%) participants reported substance use (drugs or alcohol) in the venue(s) where they worked and met clients, with alcohol being the more common substance. More than half (62.6%) scored high (>8) on the AUDIT score (Alcohol Use Disorder Identification Test). GBV was common in the sample with just over half (51.7%) reporting having previously experienced either physical or sexual violence from a sexual partner.

Several characteristics varied significantly between HIV-negative and HIV-positive participants at baseline including: age, education, marital status, years in sex work, travel, venue type, employment status and substance use overall and during sex exchange. HIV-positive women were more likely to be older, less educated, previously married, less likely

to travel, more likely to be self-employed and earn less compared to women who were HIV-negative.

HIV incidence at follow-up and inconsistent condom use between baseline and follow-up

Examining the primary study outcome for HIV-negative participants (Table 2), we found that participants in the intervention community were significantly less likely to become infected with HIV at the 18-month follow-up study visit (OR 0.38; p=0.047), with a cumulative HIV incidence of 5.0% in the intervention community vs. 10.4% in the control community. Decreases in inconsistent condom use with clients (having reported inconsistent condom use with either a new or regular client in the last month) among all participants occurred in both arms from baseline to follow-up. However, we detected significantly lower rates of inconsistent condom use in the intervention arm (72.0% to 43.6%) vs. the control arm (68.8% to 54.0%) at follow-up, with an RR of 0.81, p=0.042.

HIV care continuum outcomes including viral suppression between baseline and follow-up

In our analysis of study outcomes relevant for participants living with HIV (Table 3), we observed significant improvements in multiple behavioral indicators along the HIV care continuum between baseline and follow-up in both study arms. However, again we observed significant differences in the levels of these HIV care continuum outcomes at follow-up between the intervention and control communities. At follow-up, 79.1% of participants in the intervention arm were linked to care versus 55.0% in the control arm (RR 1.44; p=0.002) and 81.3% were on ART at follow-up in the intervention arm vs. 63.8% in the control arm (RR 1.27; p=0.013). Reported adherence to ART in the last 4 days was also significantly higher at follow-up in the intervention (71.4%) vs. the control (46.2%) arm (RR 1.54; p=0.002). Positive, but non-significant increases in viral suppression occurred during the follow-up period, with levels of suppression increasing from 40.0% to 50.6% in the intervention vs. 35.9% to 47.4% the control (RR 1.05 at follow-up, p=0.7).

Dose-response analysis per levels of aggregate measures of exposure to the intervention

Overall, 88.0% of participants in Ilula, the intervention community, had some contact with the intervention. The level of exposure to the intervention among participants in the intervention community varied per type of activity. For example, approximately half (47.4%) of the women in the intervention community had come to a workshop or mobilization activity or received services (e.g. HIV testing) or resources (e.g. condoms) at the drop-in-center and 38.4% had participated in the community savings group. A third, 33.7%, reported having contact with the project's venue outreach. Another 38.4% reported receiving condoms from the project. Nearly half of all participants, 49.3%, reported receiving texts about Shikamana intervention activities. Among HIV-positive participants, 60.4% reported having engaged with a peer navigator.

As seen in Table 4, which depicts findings from the dose-response analysis conducted among participants in the intervention community, we found that aggregate exposure to the intervention at the highest level was significantly associated with decreased inconsistent condom use (RR 0.64; 95% CI 0.42–0.96). For all the care continuum outcomes we observed significant and increasing effects on the outcomes with increasing level of

exposure to the intervention components. For example, at the medium and highest level of exposure respectively, we observed association with: engagement in HIV care in the last 6 months (RR 1.85; 95% CI 1.12–3.07) and (RR 2.15; 95% CI 1.31–3.51), currently being on ART (RR 1.71; 95% CI 1.08–2.71) and (RR 1.93; 95% CI 1.24–3.02), as well as reported adherence to ART within the last 4 days (RR 1.84; 95% CI 1.04–3.26) and (RR 2.24; 95% CI 1.29–3.90). There was a significant association of the highest level of exposure with viral suppression (RR 2.30; 95% CI 1.12–4.71).

DISCUSSION

To our knowledge, Project Shikamana is the first trial of a community empowerment-based model of combination HIV prevention to show a significant impact on HIV incidence among FSW in sub-Saharan Africa. Given the sustained burden of HIV risk among this key population in the region,[1] and their importance in ongoing transmission dynamics,[29] this finding is of high public health importance. These gains appear to be primarily achieved through the intervention's ability to reduce inconsistent condom use among HIV-negative participants in the community empowerment-based combination prevention arm. Future mediation analyses should explore the potential role of addressing GBV in the intervention community in terms of the significant reductions in incident HIV infections observed, given the high levels of GBV exposure.

Levels of viral suppression among HIV-positive participants showed positive, but non-significant, improvements in the intervention vs. the control arm but, encouragingly, were significantly associated with the highest level of exposure to the intervention. A number of behavioral HIV care continuum outcomes were significantly higher in the intervention vs. the control arm at follow-up, indicating positive trends resulting from the intervention. Additionally, we observed a dose-response relationship whereby participants with increasing levels of exposure to the intervention being more likely to have better HIV-outcomes at follow-up. These findings indicate the importance of sustained engagement and implementation over time as well as the impact of employing multiple intervention modalities within a combination package.

The challenges observed in increasing viral suppression among FSW living with HIV mirror findings from both our prior intervention research in the DR,[30] and a randomized trial of a targeted combination HIV prevention intervention among FSW in Zimbabwe.[31] In both cases, improvements in reported HIV care continuum outcomes were documented, but biomarkers of viral suppression did not significantly improve over the course of the respective interventions.[30,31] Such findings indicate the need to further assess socio-structural and clinical barriers to viral suppression among FSW, examine long-term adherence to ART and to investigate the possibility of HIV drug resistance as a possible impediment to achieving viral suppression in this key population.

Pre-exposure prophylaxis (PrEP) was not available through government-run health clinics during the study period and in turn was not offered to Shikamana study participants, given our focus on complementing and supporting existing government-run health services. The Government of Tanzania is currently in the process of rolling out access to PrEP for key

populations. Given the promising results of Project Shikamana in reducing HIV risk behavior and improving ART adherence, the introduction of PrEP should be strategically integrated into a community empowerment-based model of combination HIV prevention to optimize its potential impact.

This study has several limitations, including the limited number of study communities and sample size, limiting our ability to draw inferences regarding the impact of the intervention at-scale and to detect potentially significant differences in a number of HIV outcomes across study arms over time. Given the positive results observed in behavioral HIV outcomes across both intervention and control groups over time, the study may be limited by a "cohort effect," as we utilized a longitudinal design and had monthly contact with all study participants to ensure retention. However, the dose-response effects observed in the intervention community strengthen the confidence in the potential impact of this community-empowerment approach to combination HIV prevention on critical HIV outcomes in this population of venue-based FSW in the region.

Despite these limitations, Project Shikamana represents an important advance by demonstrating that a community empowerment-based approach to HIV prevention is both feasible and highly effective in sub-Saharan Africa, where such approaches have been less commonly implemented and rigorously evaluated. [20,21] Expansion of community empowerment-based models of combination HIV prevention that include attention to socio-structural constraints to the health and human rights of FSW may significantly reduce the risk of HIV in this underserved group of women that have faced a sustained and disproportionate burden of the HIV epidemic globally.

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Table 1:

Shikamana cohort characteristics and factors associated with HIV status at baseline among FSW who completed both the baseline (BL) and the 18-month follow-up (FU) surveys (n=387)

Variable or Measure n (%) or Mean (SD)	Total Completing BL and FU (n= 387)	HIV-Negative (n=216)	HIV-Positive (n=171)	P-Value
Sociodemographic				
Community				0.646
Ilula (intervention)	211 (54.5)	120 (55.6)	91 (53.2)	
Mafinga (control)	176 (45.4)	96 (44.4)	80 (46.8)	
Age in years, mean (SD)	27.80 (6.8)	25.90 (5.8)	30.20 (7.2)	**<0.001**
Education				**0.004**
< Secondary school	274 (70.8)	140 (64.8)	134 (78.4)	
≥ Secondary school	113 (29.20	76 (35.2)	37 (21.6)	
Marital Status- Single				**<0.001**
No	208 (53.8)	97 (44.9)	111 (64.9)	
Yes	179 (46.2)	119 (55.1)	60 (35.1)	
Number children responsible for				**0.004**
≤ 2	246 (63.6)	151 (69.9)	95 (55.6)	
≥ 3	141 (36.4)	65 (30.1)	76 (44.4)	
Mean (SD)	2.15 (1.5)	2.00 (1.5)	2.34 (1.4)	**0.024**
Migration (years in community)				0.072
≤ 0.5	77 (19.9)	50 (23.2)	27 (15.8)	
> 0.5	310 (80.1)	166 (76.9)	144 (84.2)	
Mean (SD)	13.49 (12.9)	11.63 (11.7)	15.84 (13.8)	**0.001**
Mobility (last 6 months)				
No travel outside Iringa	220 (56.9)	112 (51.8)	108 (63.2)	**0.026**
Travel outside Iringa	167 (43.2)	104 (48.2)	63 (36.8)	
Average overall income, TZS				0.081
≤ 120000 (=US$ 52.2)	198 (51.2)	102 (47.2)	96 (56.1)	
> 120000	189 (48.8)	114 (52.8)	75 (43.9)	

Variable or Measure n (%) or Mean (SD)	Total Completing BL and FU (n= 387)	HIV-Negative (n=216)	HIV-Positive (n=171)	P-Value
Mean (SD)	190,773 (242,371)	195,426 (180,440)	184,895 (303,5501)	**0.057**
Average sex work income, TZS				0.216
≤ 50,000 (=US$ 21.8)	231 (59.7)	123 (56.9)	108 (63.2)	
> 50,000	156 (40.3)	93 (43.1)	63 (36.8)	
Mean (SD)	83,187 (97,598)	91,061 (10,1677)	73,240 (91,517)	**0.049**
Average income per sex encounter, TZS				**<0.001**
≤ 15,000 (=US$ 6.5)	243 (63.1)	119 (55.4)	124 (73.0)	
> 15,000	142 (36.9)	96 (44.7)	46 (27.1)	
Mean (SD)	16,482 (17,954)	18,621 (20,366)	13,777 (13,928)	**<0.001**
Sex Work				
Ave number of clients per week				0.935
< 4	304 (78.6)	170 (78.7)	134 (78.4)	
≥ 4	83 (21.5)	46 (21.3)	37 (21.6)	
Mean (SD)	2.67 (2.8)	2.76 (3.4)	2.55 (1.9)	0.472
Duration of sex work in years				
< 7	226 (58.6)	151 (70.2)	75 (43.9)	**<0.001**
≥ 7	160 (41.5)	64 (29.8)	96 (56.1)	
Mean (SD)	7.16 (6.2)	5.42 (4.9)	9.36 (6.9)	**<0.001**
Sex work venue type				**0.001**
Modern bar	145 (37.5)	97 (44.9)	48 (28.1)	
Other venues/independent	242 (62.5)	119 (55.09)	123 (71.9)	
Employed/steady salary				**0.008**
Full-time/ Part-time	213 (55.2)	132 (61.1)	81 (47.7)	
Self-Employed/ Other	173 (44.8)	84 (38.9)	89 (52.3)	
Gender-based Violence				
Gender-based violence ever				0.590
No	187 (48.8)	107 (49.5)	80 (46.8)	
Yes	200 (51.7)	109 (50.5)	91 (53.2)	

Variable or Measure n (%) or Mean (SD)	Total Completing BL and FU (n= 387)	HIV-Negative (n=216)	HIV-Positive (n=171)	P-Value
Substance Use				
In venue				**0.007**
Never	113 (29.4)	75 (34.9)	38 (22.4)	
Any	272 (70.7)	140 (65.1)	132 (77.7)	
During sex exchange				**0.024**
Never	221 (57.6)	134 (62.6)	87 (51.2)	
Any	163 (42.5)	80 (37.4)	83 (48.8)	
AUDIT score				0.879
≤ 8	141 (37.4)	80 (37.7)	61 (37.0)	
> 8	236 (62.6)	132 (62.3)	104 (63.0)	
Mean (SD)	9.58 (7.2)	9.15 (7.1)	10.12 (7.3)	0.194

Table 2:

Shikamana HIV prevention outcomes: overall intervention effect (N=387 total, 216 HIV-negative & 171 HIV-positive)

Prevention outcomes	Intervention community: Ilula (n=211)			Control community: Mafinga (n=176)			Compare @FU	
	BL n (%)	FU n (%)	P-Value before-after	BL n (%)	FU n (%)	P -Value before-after	RR	P -Value
Incident HIV infection (among the HIV-negative)	-	6/120 (5.0)	-	-	10/96 (10.4)	-	0.38^	**0.047**^
Inconsistent condom use with clients (among all study participants)	152 (72.0)	92 (43.6)	<0.001	121 (68.8)	95 (54.0)	0.004	0.81	**0.042**

^RR and p-value adjusted for missing outcomes

Table 3:

Shikamana HIV care and treatment outcomes: overall intervention effect (n=171 for HIV-positive participants only)

Care and treatment outcomes	Intervention community: Ilula (n=91)			Control community: Mafinga (n=80)			Compare @FU	
	BL n (%)	FU n (%)	P-Value before-after	BL n (%)	FU n (%)	P-Value before-after	RR	P-Value
Ever linked to HIV care	26 (28.6)	72 (79.1)	<0.001	15 (18.8)	44 (55.0)	<0.001	1.44	**0.002**
In care, last 6 months	19 (20.9)	70 (76.9)	<0.001	12 (15.0)	41 (51.2)	<0.001	1.50	**0.001**
ART ever	27 (28.0)	75 (82.4)	<0.001	15 (18.8)	54 (67.5)	<0.001	1.22	**0.029**
ART current	26 (28.6)	74 (81.3)	<0.001	14 (17.5)	51 (63.8)	<0.001	1.27	**0.013**
ART adherence, last 4 days	23 (25.3)	65 (71.4)	<0.001	9 (11.3)	37 (46.2)	<0.001	1.54	**0.002**
Viral suppression (<400 copies/mL)	36 (40.0)	46 (50.6)	0.154	28 (35.9)	36 (47.4)	0.149	1.05^	0.742

^RR and p-value adjusted for missing outcomes

Table 4:

Exposure to Project Shikamana elements and HIV outcomes at follow-up within the intervention arm

Prevention outcomes	**Prevention exposure level**			
(n=120 incidence; n=211 condom use in the intervention community: Ilula)	**Low (0=Ref)**	**Medium (1–2)**	**High (3–6)**	**P-Value highest exposure**
HIV incidence	2 (9.5%)	2 (4.2%)	2 (3.9%)	
RR (95% CI)	1.00	0.41 (0.05–3.18)	0.39 (0.05–3.00)	0.362
Inconsistent condom use	20 (54.1%)	41 (48.8%)	31 (34.4%)	
RR (95% CI)	1.00	0.90 (0.62–1.31)	0.64 (0.42–0.96)	**0.032**
Care and treatment outcomes	**Care and treatment exposure level**			
(n=91 for all care outcomes in the intervention community: Ilula)	**Low (0–1=Ref)**	**Medium (2–5)**	**High (6–9)**	**P-Value highest exposure**
Currently in care	9 (45.0%)	33 (78.6%)	28 (96.6%)	
RR (95% CI)	1.00	1.75 (1.05–2.91)	2.15 (1.31–3.51)	**0.002**
Currently on ART	10 (50.0%)	36 (85.7%)	28 (96.6%)	
RR (95% CI)	1.00	1.71 (1.08–2.71)	1.93 (1.24–3.02)	**0.004**
ART adherence last 4 days	8 (40.0%)	31 (73.8%)	26 (89.7%)	
RR (95% CI)	1.00	1.84 (1.04–3.26)	2.24 (1.29–3.90)	**0.004**
Viral load <400 copies/mL	6 (30.0%)	20 (47.6%)	20 (69.0%)	
RR (95% CI)	1.00	1.59 (0.75–3.34)	2.30 (1.12–4.71)	**0.023**