PROJECT SHIKAMANA

Good Evidence – Medication Adherence Evidence-Based Structural Intervention

INTERVENTION DESCRIPTION

Goals of Intervention

- Improve HIV-related outcomes, including:
 - o Condom use
 - o HIV incidence
 - o Engagement in HIV care
 - o Antiretroviral therapy (ART) uptake
 - o ART adherence
 - Viral suppression
- Improve overall health and human rights

Intended Population

Female sex workers (FSW)

Brief Description

Project Shikamana ("Let's Stick Together" in Swahili) is a community empowerment HIV prevention intervention for female sex workers in Tanzania. The intervention is comprised of (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 intervention engagement, and reminder messages to promote care engagement and ART adherence among HIV-positive women. Workshops are held at the drop-in center and focus on the following topics: stigma, discrimination, genderbased violence, family planning, HIV/STD prevention, ART adherence, financial security, and sex worker rights and community mobilization strategies. In the peer education component that is held monthly, peer educators distribute condoms and health materials developed by participants and a local artist. Mobile HIV testing and counseling is offered twice during the intervention period. Provider sensitivity trainings take place on a quarterly basis with a group of HIV clinical care providers, in coordination with peer navigators, to promote respectful quality health services tailored to FSW needs. Additional intervention activities are ongoing and are based on community priorities such as cervical cancer screenings, community health education fairs, and a workshop with local police and justice sector officials regarding support in accessing gender-based violence services and justice.

Theoretical Basis

• Principles of Community Empowerment

Intervention Duration

• The intervention was implemented from October 2015 to December 2017. Community-based intervention activities are still ongoing through the Shikamana women's group.

Intervention Settings

- Community-led drop-in center
- Sex work venues

- Clinics
- Phone

Deliverer

- Health care worker
- Peer educator

- Peer navigator
- Shikamana staff

Delivery Methods

- Community events
- Printed health materials
- Risk reduction supplies

- Sensitivity trainings
- · Skills building
- Text messages

Structural Components

- Access Condoms, HIV testing, HIV health care
 - o Provided 81,463 condoms to FSW in sex work venues
 - o Offered mobile HIV counseling and testing at all sex work venues
 - o Offered linkage to HIV care to all, and linkage to HIV care to FSW with HIV at all sex work venues
 - o Increased access to HIV testing and linkage to HIV medical care
- Capacity Building Provider/supervisor training
 - Conducted provider sensitivity training to promote respectful quality health services tailored to FSW needs
- Community Mobilization
 - Incorporated community mobilization strategies that led to the development of a community savings group, a catering business to promote financial security and support community-led intervention activities, a violence support group, and a women's group that formally registered as a local organization
- Social Determinants of Health Acceptance and respect
 - Addressed structural constraints such as stigma, discrimination and violence in workshops by promoting social cohesion and community mobilization
 - Conducted provider sensitivity training to promote respectful quality health services tailored to FSW needs

INTERVENTION PACKAGE INFORMATION

The intervention curriculum is available upon request. Please contact Deanna Kerrigan, Department of Prevention and Community Health, Milken Institute School of Public Health, George Washington University, 950 New Hampshire Avenue NW, Washington, D.C. 20052.

Email: dkerrigan@gwu.edu for details on intervention materials.

EVALUATION STUDY AND RESULTS

Study Location Information

The original evaluation was conducted in the Ilula and Mafinga communities in Iringa, Tanzania from October 2015 to December 2017.

Key Intervention Effects

• Increased ART adherence

Study Sample*

A total of 493 women participated in the Shikamana cohort. The analytic study sample of 387 female sex workers is characterized by the following:

- Mean age of 28 years
- 71% completed less than secondary school; 29% completed secondary school or higher
- 54% married; 46% not married
- 64% responsible for two or fewer children; 36% responsible for three or more children
- Mean years in community: 13 years
- Mean years of duration of sex work: 7 years
- 52% experienced gender-based violence
- 71% reported substance use in sex work venues; 42% reported substance use during sex exchange

Recruitment Settings

Sex work venues (e.g., modern and traditional bars, guesthouses and hotels, groceries/mini-bars/pubs, and clubs).

Eligibility Criteria

Women aged 18 years or older were eligible if they reported exchanging sex for money in the last month.

Assignment Method

Two communities were randomized to 1 of 2 study arms: the Shikamana Intervention or a standard-of-care comparison. Communities were matched on population size (approximately 25,000 people each) and HIV risk characteristics (approximately 7% HIV prevalence in the overall population). Within the 2 study communities, 164 active sex work venues were identified, and 496 FSW were enrolled in the study using time-location sampling. The analytic sample size included 387 FSWs: Shikamana Intervention (n = 211) and standard-of-care comparison (n = 176).

Comparison Group

The community randomized to the comparison arm received standard-of-care services which included access to HIV testing and treatment provided through government services. The comparison community also received HIV-related health education, condom promotion, and HIV testing initiatives for key populations provided through nongovernmental groups.

Relevant Outcomes Measured and Assessment Time

- ART adherence was measured at 18 months post-baseline among participants with HIV at baseline and assessed using the AIDS Clinical Trails Group measure for self-reported adherence in the last 4 days.
- Viral suppression was measured at 18 months post-baseline among participants with HIV at baseline and was defined as <400 copies/mL.

Participant Retention

- Overall Study sample:
 - o 82% retained at 18 months post-baseline

Significant Findings on Relevant Outcomes

• Among participants with HIV at baseline, a significantly greater percentage of intervention participants than comparison participants were adherent to ART at 18 months post-baseline (71.4% vs 46.2%, RR = 1.54, p = 0.002).

Considerations

Additional significant positive findings on non-relevant outcomes

- Among participants who were HIV negative at baseline, a significantly smaller percentage of intervention participants than comparison participants became infected with HIV at 18 months post-baseline (5.0% vs 10.4%, RR = 0.3, p = 0.047).
- A significantly smaller percentage of intervention participants than comparison participants reported inconsistent condom use with clients at 18 months post-baseline (43.6% vs 54.0%, RR = 0.81, p = 0.042).
- Among participants with HIV at baseline, a significantly greater percentage of intervention participants than comparison participants were linked to HIV care at 18 months post-baseline (79.1% vs 55.0%, RR = 1.44, p = 0.002).
- Among participants with HIV at baseline, a significantly greater percentage of intervention participants than comparison participants were engaged in HIV care over the last 6 months at 18 months post-baseline (76.9% vs 51.2%, RR = 1.50, p = 0.001).
- Among participants with HIV at baseline, a significantly greater percentage of intervention participants than comparison participants were ever on ART at 18 months post-baseline (82.4% vs 67.5%, RR = 1.22, p = 0.029).
- Among participants with HIV at baseline, a significantly greater percentage of intervention participants than
 comparison participants were currently on ART at 18 months post-baseline (81.3% vs 63.8%, RR = 1.27, p =
 0.013).

Note: The findings on linkage to and engagement in HIV care are important, but the PRS Project does not consider self-reported linkage to and engagement in HIV care as relevant outcomes. Self-reported outcomes for linkage to and engagement in HIV care are considered relevant if verified by medical, agency or surveillance reports.

Non-significant findings on relevant outcomes

• There were no significant intervention effects on viral suppression at 18 months post-baseline.

Negative findings

None reported

Other related findings

Project Shikamana is the only randomized controlled trial in Sub-Saharan Africa to show reduced HIV
incidence among FSWs. However, this study does not meet criteria for the Risk Reduction Chapter due to the
study being conducted outside of the United States.

Implementation research-related findings

None reported

COMPENDIUM OF EVIDENCE-BASED INTERVENTIONS AND BEST PRACTICES FOR HIV PREVENTION

Process/study execution findings

- Among participants within the intervention community, 88% had some contact with the intervention at various levels of exposure:
 - \circ 47.4% attended a workshop or mobilization activity, or received services (e.g., HIV testing) or resources (e.g., condoms) at the drop-in center
 - o 38.4% participated in the community savings group
 - o 33.7% reported contact with the project's venue outreach
 - o 38.4% reported receiving condoms
 - o 49.3% reported receiving texts on intervention activities
 - o 60.4% of participants with HIV engaged with a peer navigator
- Aggregate exposure to the intervention at the highest level was significantly associated with improved HIVrelated outcomes, including:
 - o decreased inconsistent condom use
 - o decreased HIV incidence
 - o increased engagement in HIV care
 - o currently being on ART
 - o adhering to ART, and
 - o viral suppression

Adverse events

None reported

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REFERENCES AND CONTACT INFORMATION

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Kerrigan, D., Mbwambo, J., Likindikoki, S., Beckham, S., Mwampashi, A., Shembilu, C., Mantsios, A., Leddy, A., Davis, W., & Galai, N. (2017). <u>Project Shikamana: Baseline findings from a community empowerment-based combination HIV prevention trial among female sex workers in Iringa, Tanzania</u>. *JAIDS Journal of Acquired Immune Deficiency Syndromes, 74*(Suppl 1), S60–S68.

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