Protocol Samvedana Plus: Evaluating the impact on vulnerability of FSWs to HIV and intimate partner violence

As part of the STRIVE research consortium, KHPT is implementing an intervention with sex workers and intimate partners called *Samvedana Plus*. The intervention aims to reduce vulnerability among Female Sex Workers (FSWs) by reducing partner violence and increasing consistent condom use within intimate relationships.

The intervention is composed of innovations aimed at three levels: among individual FSWs and their intimate partners (IPs); through community-based organizations of female sex workers; and in the wider community where the FSWs and their partners live. At the individual level, the intervention will focus on the formation of reflection groups for FSWs and access to individual and couples-based counselling. These reflection groups are designed to enhance self-esteem, encourage critical thinking on gender, social norms, violence, and HIV risk; and build individual and collective efficacy. At the level of FSW collectives, the intervention will focus on strengthening supportive crisis management systems for FSWs experiencing intimate partner violence, improved distribution of male and female condoms, and improved referrals to clinical services for FSWs and their partners. At the larger community level, the intervention will link the FSW groups to women's organizations, identify and train male champions and folk media troops to build a community environment that encourages action against intimate partner violence (IPV). Further information on the intervention and its theory of change are available in Appendix A.

The intervention will cover over 2200 FSWs and their intimate partners living in 91 villages and 7 towns of 4 Talukas of Bagalkot and Bijapur districts in Northern Karnataka. The intervention is partly funded by United Nations Trust Fund (UNTF) to End Violence against Women, and implemented by KHPT in partnership with two community based organizations (CBO) of FSWs. The intervention has been developed and the curriculum for reflection groups and counselling sessions pre-tested and revised over the last two years, mainly in the towns. With villages in Bijapur much smaller, and in order to ensure comparability between intervention and control clusters, it was decided to restrict the evaluation to villages in Bagalkot only, among an estimated 800 FSWs.

This document details the protocol for evaluating Samvedana Plus intervention conducted in partnership with the community-based organization (CBO) *Chaitanya Mahila Sangha* (CMS) in Bagalkot district, Karnataka Health Promotion Trust (KHPT), and the London School of Hygiene and Tropical Medicine (LSHTM). A separate document details the qualitative component of this study, looking more in-depth at relationship change between the participating FSWs and their intimate partners. It uses a longitudinal case study method and in-depth interviews with sex workers, their intimate partners and the counsellors who lead the reflection groups and provide individual and couple-based counselling. Ethics approval for this qualitative component has already been provisionally approved (Review Reference PR/1447/1447).

Existing literature on intimate partner violence and HIV risks among FSW

Gender-based violence stems from the low social status of women and girls, undermining their safety and well-being. In the context of India, as in many low and middle-income countries, gender-based violence includes child marriage, sexual violence and intimate partner violence (IPV). A WHO multi-country study[1] of domestic violence and women's health found that partner violence is the most common form of violence. Data from the National Family Health Survey (NFHS)-3[2] indicates the extent of gender-based domestic violence in India – 35% ever married women aged 15-49 years experienced spousal physical or sexual violence while in Karnataka it is 20%. The prevalence of violence is much higher among rural women than urban women; among women belonging to the Scheduled Castes and Scheduled Tribes (SC/ST) than women from the general category, thereby increasing the risk and vulnerability of rural and SC/ST women.

Northern Karnataka is home to one of the most marginalized SC/ST communities in its rural areas – the Devadasi sex workers, through a tradition in which young girls are initiated as Devadasis, which provides them cultural sanction to engage in sex work. Their situation makes them vulnerable to violence from clients (56%), intimate partners (23%), police (7%), and "rowdies" (7%).[3] In a participatory assessment workshop (2012) that KHPT conducted, FSWs identified key triggers of intimate partner violence as insistence on condom use, influence of alcohol, refusal to give status of wife to FSW, to have children with her, or accept her children. However, most of the interventions to address violence against sex workers are targeted to clients and the police. Addressing intimate partner violence is a challenging programmatic gap since the woman and her partner may be in more than one intimate relationship.[4] The FSW-intimate partner relationships are complex with 98% FSWs reporting economic and non-economic support from their main intimate partners, including emotional support, social status, and protection from other men[5].

FSWs reported low condom use at last sex with their main intimate partner at 38 percent. As per the Polling Booth Survey (PBS), 2009, 27% FSWs in Karnataka reported that they could not use the condom because either of the partners was under the influence of alcohol.[6] Data from NFHS-3 indicates that women whose husbands drink alcohol experience significantly higher rates of violence than women whose husbands do not drink at all. A paper by Beattie et al (2010)7 shows significant linkage between women who reported violence, low condom usage, and reduced likelihood of accessing HIV services. Gurnani et al (2011)[8] cite findings indicating the possibility of addressing the broader structural factors of violence as part of HIV prevention programs.

[1] Heise, Lori L., 2011 What Works to Prevent Partner Violence? An Evidence Overview
[2] http://www.measuredhs.com/pubs/pdf/frind3/15chapter15.pdf
[3] http://www.biomedcentral.com/1471-2458/10/476/
[4] Shaw, S and Pillai, P., 2012, Understanding Risk for HIV/STI Transmission and Acquisition within Non-paying Partnerships of Female Sex Workers in Southern India, KHPT.
[5] Shaw, S and Pillai, P., 2012, Understanding Risk for HIV/STI Transmission and Acquisition within Non-paying Partnerships of Female Sex Workers in Southern India, KHPT.
[6] KHPT, 2010, HIV/AIDS Situation and Response in Karnataka: Epidemiological Appraisal Using Data Triangulation.
[7] Beattie et al, "Violence against female sex workers in Karnataka state, south India: impact on health, and reductions in violence following an intervention program", BMC Public Health 2010, 10: 476
[8] Gurnani et al, "An integrated structural intervention to reduce vulnerability to HIV and sexually transmitted infections among female sex workers in Karnataka state, south India", BMC Public Health 2011, 11:755

The intervention

The intervention is composed of innovations aimed at three levels: among individual FSWs and their intimate partners (IPs); through community-based organizations of female sex workers; and in the wider community where the FSWs and their partners live. At the level of FSW collectives, the intervention will focus on strengthening supportive crisis management systems for FSWs experiencing intimate partner violence, improved distribution of male and female condoms, and improved referrals to clinical services for FSWs and their partners.

At the individual level, the intervention will focus on the formation of reflection groups for FSWs and access to individual and couples-based counselling. The reflection groups will introduce an empowerment curriculum with specific sessions focused on:

- women's human rights,
- gender roles and norms
- violence against women,
- building solidarity between sex workers,
- analysing our relationships,
- responding to HIV-related risks,
- improving relationship skills and couples communication,
- negotiation and use of the female condom.

These groups will provide FSWs the motivation and courage to strengthen their individual resolve and introduce new mechanisms for protection such as a safety plan. The wider sex work community has implemented a crisis management system where crisis management teams (CMT) are trained to intervene in the case of abuse by clients, the police, or street criminals. The new project will encourage women to make a private arrangement with a family members, friend of neighbour, which they can call in in case of violence by a partner (or can stay with should a partner become abusive or arrive drunk).

Individual counselling sessions will provide women support for action; they will enable counsellors to understand the turning points for women – protecting their children from abuse; increased severity and frequency of abuse; increased awareness of and access to support services and resources – and use them to motivate women to seek change in their IPV situation.[9]

The project also proposes reflection with and counselling of intimate partners so as to directly engage them in the prevention of intimate partner violence.

FSWs will participate in collective action such as rallies, campaigns against domestic violence to express and seek solidarity from mainstream women's groups, positioning violence against FSWs as a significant type of gender-based violence that also puts women at risk of STI/HIV. At the larger community level, the intervention will link the FSW groups to women's organizations, identify and train male champions and folk media troops to build a community environment that encourages action against intimate partner violence (IPV).

The study will test whether the intervention can increase condom use and reduce violence within the sex workers' intimate partnerships.

[9] Chang, J. C. et al, "Understanding Turning Points in Intimate Partner Violence: Factors and Circumstances Leading Women Victims Toward Change", Journal of Women's Health (Larchmt), 2010 February; 19(2): 251–259.

Assumptions

The interventions have been developed following a set of assumptions, and the research (detailed in this and the linked qualitative research proposal) will test whether addressing these factors will lead to the desired outcomes. The assumptions are;

1. Given more immediate support will help protect FSWs from future violence
1. Reduction in violence will happen only if we work with both the victims and the perpetuators of violence and other stake holders
2. With better skills (negotiation, communication) and greater access to female condoms FSWs will be able to negotiate safe sex with IP
3. Individual and collective action against violence and/or STI/HIV transmission requires a supporting enabling environment
4. Building capacities of CBOs and linking them with women's organization will strengthen the support structure

Study questions

The study aims to assess the impact of the interventions on vulnerability of FSWs to HIV and intimate partner violence.

Specifically, the research aims to:

1. Assess the impact of the intervention on consistent condom use and experience of violence in intimate relationships among female sex workers who have access to the intervention
2. Assess the impact of the intervention on consistent condom use and use of violence in intimate relationships among the partners of female sex workers who have access to the intervention
3. Explore how the intervention has affected the response to partner violence among female sex workers and the community writ large.
4. Investigate the processes and causal pathways through which positive changes occur in the following areas: enhanced sense of self-worth and individual and collective efficacy; enhanced critical thinking on gender, violence, social norms and HIV risks among sex workers and their intimate partners; improved sense of safety and well-being among female sex workers, increased appreciation among FSWs and their intimate partners of STI/HIV risks in the context of intimate partnerships; increased awareness among FSWs, their partners and other stakeholders of violence, rights and the law; and reduced acceptance of violence by intimate partners among sex workers.

Study components

This is a rigorous evaluation study that will be implemented by the Karnataka Health Promotion Trust (KHPT), based in Bangalore, Karnataka, in collaboration with the London School of Hygiene and Tropical Medicine (LSHTM. The KHPT will be the implementing agency, with the specific responsibilities of data collection, report writing and dissemination of research findings. LSHTM is responsible for quality control, contributing to the development of study tools, and study design and assistance in analysing and write-up of evaluation results.

The project uses a cluster randomized delayed intervention design to estimate the effect of the intervention and this quantitative component has four main components:

1. A quantitative survey among a random sample of female sex workers with intimate partners who are exposed to the intervention and those who are not, at baseline and following the intervention
2. A quantitative survey among the intimate partners of female sex workers who are exposed to the intervention (pre and post intervention comparison)
3. Detailed monitoring of intervention implementation by measuring exposure of each target group to various components of intervention
4. A polling booth survey to validate the responses on primary and secondary outcomes reported in face to face interviews.

Evaluation design

Indicators and target groups

The evaluation will collect the quantitative and qualitative data on the following anticipated outcomes of the intervention:

Table 1: List of indicators for each target group

	FSWs	IPs	FSW CBO	General community
Impact-level outcomes	• Increased reported consistent condom use in intimate relationships • Decreased experience of reported physical and/or sexual violence in intimate relationships	• Increased reported consistent condom use in intimate relationships • Decreased reported use of physical and/or sexual violence in intimate relationships		
Long-term outcomes	• Increased individual processes and action to reduce intimate partner violence and STI/HIV risk • Enhanced STI/HIV risk perception and skills for self protection		• Increased collective processes and action to reduce intimate partner violence and STI/HIV risk	• Improved supportive environment for dialogue and action on intimate partner violence
Medium term outcomes	• Enhanced sense of self-worth and individual efficacy • Improved sense of safety and well being • Reduced acceptance of violence by intimate partners		• Increased appreciation of STI/HIV risks in the context of intimate partnerships • Increased awareness of violence, rights and laws with respect to intimate partner violence • Reduced acceptance of violence by intimate partners	• Increased awareness of violence, rights and laws with respect to intimate partner violence • Reduced acceptance of violence by intimate partners
	• Enhanced critical thinking on gender, violence, social norms and HIV risk • Increased appreciation of STI/HIV risks in the context of intimate partnerships • Increased awareness of violence, rights and laws with respect to intimate partner violence			

Study design

Since April 2012, the intervention started with sensitization of the CBO on intimate partner violence, which has been ongoing in all areas. This entails the FSW collectives focusing on strengthening supportive crisis management systems for FSWs experiencing intimate partner violence and referral for individual and couple counselling.

The intervention will eventually cover over 2200 FSWs and their intimate partners living in 91 villages and 7 towns of 4 Talukas of Bagalkot and Bijapur districts in Northern Karnataka. The intervention has been developed and the curriculum for reflection groups and counselling sessions pre-tested and revised over the last two years, mainly in the towns. With villages in Bijapur much smaller, and in order to ensure comparability between intervention and control clusters, it was decided to restrict the evaluation to villages in Bagalkot only, among an estimated 800 FSWs.

In each of the intervention and control areas, surveys will be carried out both at baseline and after 1 year of intervention.

Site selection and cluster definition - The intervention is being implemented in 91 villages and 7 towns of 4 Talukas of Bagalkot and Bijapur districts in Northern Karnataka. Yet during the first two years, the curriculum for reflection groups and counselling sessions were developed and tested in the towns. Since the villages in Bijapur are much smaller, and in order to ensure comparability between intervention and control clusters, the evaluation was restricted to villages in Bagalkot only.

The village is the unit of randomization, and is stratified by the number of female sex workers with intimate partners in the village (above or below 12), and then by village size (1-33rd percentile; 34-67th percentile; 68-100the percentile). This produced 8-10 villages per stratum so that 4-5 villages can be allocated to the intervention in each. In total 47 villages will be included in the trial. The randomization was performed using STATA and allocated 24 villages to the intervention arm for year 1 and the balance 23 villages to the wait-list to receive intervention in year 2.

Sampling of sex workers - The project indicators for reduced vulnerability will be measured in a base-line and follow-up survey after a year. The 47 villages have 800 female sex works with intimate partners (average 17 per village). A 'line-list' of female sex workers and their intimate partner statuses is maintained regularly by the CBO, and this will be used to identify female sex workers for baseline and endline surveys. All women who engage in commercial sex work, are aged over 18, and have an intimate partner or had an intimate partner within the last 6 months will be included in the surveys. The surveys will be face-to-face and will include questions on primary and secondary outcomes, as well as programme exposure variables.

Sampling of intimate partners - it has been recognized that it may not be feasible to reach a sample size large enough to measure statistically significant changes among intimate partners, as pretesting showed issues with recruiting. Therefore to increase the response rate among intimate partners, men will be recruited from a line-list of intimate partners and initially contacted by peer educators from the CBOs rather than directly by the research team. Changes in condom use and violence reported by intimate partners will therefore not be considered as primary outcomes, but a pre-post intervention design will still provide useful information on what change can/cannot be affected by the intervention.

The sample-size calculation was performed by analyzing simulated data arising from the 800 women, distributed according to empirical data from the line-listing. The analysis was a t-test of the cluster-level proportions of women having experienced intimate partner violence in the last year between intervention and control arms. The simulations were performed 1500 times, with a control proportion of 47%, for different levels of k (the intracluster coefficient of variation), an alpha of 0.05, and a narrow range of feasible effect sizes. The trial will have over 80% power to detect a risk ratio of 0.77 if k is between 0.15 and 0.25. This risk ratio corresponds to a risk difference of 11%, or 44 women who would have experienced intimate partner violence were it not for the intervention.

Polling pooth survey

A sub-sample of 260 FSWs will be invited to take part in a polling booth survey in December 2016, coinciding with the end of mid-line data collection and before endline. Participants will be recruited randomly from the selected villages (Mudhol and Jamakhandi Talukas in Bagalkot). In total, we will conduct 26 PBS sessions involving 10-12 FSWs in each session. These 26 sessions will be distributed equally across the two talukas (13 sessions each in two talukas). Out of 47 villages we have selected 26 villages randomly having 10 or more FSWs with an intimate partner. So from each of the selected villages, we will be doing one PBS session. FSWs will be selected randomly using the most updated line list of FSWs. There will not be any selection of respondents in those villages where we have only 10 FSWs. Participants will be asked a series of 25 questions by an interviewer who will post their answers into a closed box. No identifying information will be recorded. Answers will be analysed at a group level. Informed consent will be obtained from all participants.

Intervention monitoring

A robust monitoring system has been developed to monitor the activities at group and individual/couple levels. The intervention will facilitate the CBOs to form and support group sessions, provide individual/couple counselling, and in addressing IPV. Detailed monitoring tools will be developed to track the individual FSWs and IPs through their contact with the intervention.

Data entry and analysis

The quantitative survey data will be double entered and cleaned using CSPro. At project completion, we will assess whether, at follow up, there are significant differences between the intervention and control FSWs/IPs in the key indicators of consistent condom use and violence in intimate relationships. The final analysis will also assess whether the intervention and control sites significantly differ in terms of the long-term and medium-term outcomes.

Assessing baseline balance

While randomization is conducted to ensure that the arms of cluster-randomised trials are not systematically imbalanced, it is possible that imbalances will arise due to chance. We expect that the arms of this trial will be suitably balanced for the following reasons. First, this trial has a relatively large number of clusters and individual respondents. Second, the villages included in the design have similar characteristics in terms of sex work and relationships between sex workers and their intimate partners, the norms that govern such relationships. Third, we stratified the randomization by the number of female sex workers with intimate partners in the village, and then by village size. Therefore, we expect that the trial will be largely balanced. We will assess the extent of imbalance in terms of measurable variables as the first step in the analysis. Any variables for which there is indication of imbalance will be adjusted for in the primary analysis of effect.

Analysis of primary outcomes

At project completion, we will assess whether, at follow up, there are significant differences between the intervention and control sex workers in the key indicators of condom use and violence within their intimate relationships. We will perform appropriate analysis for stratified trials on the cluster mean-summaries, using the t-statistic, to assess the significance of and differences observed between the arms. Adjustment for baseline measures of the outcomes and variables that appear to be imbalanced at baseline will be conducted using the 'two step method' that is recommended in Hayes and Moulton *Cluster Randomised Trials.* While this analysis will give a valid estimate of effect, and is robust, it may not be statistically optimal given the variation in the size of the clusters. Therefore, we will also perform an individual analysis with random effects to account for clustering. Both of these analyses will be reported, and any discrepancies will be explored.

Stata 11 will be used for all analyses.

Similar methods will be used to compare key indicators, short- and medium-term outcomes.

Addressing potential biases

The cluster randomised design will reduce problems associated with confounding factors and selection bias, and there is sufficient geographic dispersion of the villages to minimize spill-over effects. The similarity of the intervention and control samples will be assessed at baseline, and any differences controlled for in the final analysis. Impact heterogeneity will be addressed by examining the intensity of exposure to the intervention among sex workers.

Potential biases (selection, interviewer and recall biases) will be assessed and addressed in the trial as follows:

Selection bias will be largely addressed as a result of the careful process of randomization and selection of subjects. There are chances of selective loss to follow-up which can lead to a bias. There will be triangulation with the results of the qualitative longitudinal case studies looking at reasons why sex workers or their partners may drop out of the intervention. The self-selection bias with sex workers refusing to participate is planned to be countered by the trust created by a careful informed consent process and the longstanding relationship that the implementation teams have established with sex workers.

Interviewer biases will be addressed to a large extent by rigorous training of the research investigators. The training will include both class room sessions and field practices and will help ensure uniform understanding among all the interviewers and reduce variation between interviewers as far as their understanding of questions, questioning and recording of questions and responses are concerned. It will not be possible to mask the interviewers.

Ethical Framework

Conducting a study around intimate partner violence and condom use requires careful consideration of the potential benefits and harms that may be caused for those involved in the research. Extensive discussions between members of the CBO, KHPT programme implementers and LSHTM were held to identify strategies to protect the safety of participants and researchers and thus minimize any social harms resulting from the research.

Informed consent

Interviews will be conducted in private settings in a sensitive and non-judgmental manner. The purpose of the study will be introduced and the respondent will be administered an informed consent form before the interview for collecting written or witnessed consent. The Kannada/English version of the consent/assent form will be given out to read to the participants and also read out and explained before the beginning of the interviews. Written informed consent will be sought prior to conducting the interviews. For women or men who cannot read or write, we will seek oral consent witnessed by a friend or family member of the respondent's choosing. As part of the consenting procedure, participants will be assured that their participation is voluntary, and their decision to participate will not affect any benefits they receive from the intervention.

Strategies to maintain confidentiality

In the context of partner violence research, confidentiality is both a foundation for respecting participant privacy and a strategy for limiting harmful fall out that may occur if others deduce the nature of the research. Therefore training and strict guidelines will be used with the field team to emphasize the importance of confidentiality as a cornerstone of the research.

Anonymity will be maintained by using proxy names to distinguish individual participants. The identity of the participants and the information shared by them will not be revealed to anyone who does not work in the research study. At no time will any of the information given by individual participants be shared with anyone outside the research team.

All questionnaires will be stored in locked filing cabinets in the KHPT offices in Bangalore after the data has been computerised. The computer data will be password protected and only the statisticians working as part of the research teams will be authorized to open/use the data. Unique identifying numbers will be used to identify the questionnaires; no identifying names will be entered with the computer data. All data used at LSHTM will be kept on the secure server.

Ensuring participant and researcher safety

Training of interviewers will include content on gender, violence and HIV, role-play, and value clarification exercises to limit the possibility that they will communicate judgemental attitudes toward respondents, either consciously or unconsciously. They will be given extensive training on the survey instrument and how to handle potential breaches in privacy.

To limit stigma and possible retaliation from abusive partners, the study will be referred to in the community and with other family members, as a study on women and men's relationships. Respondents will be informed of the true nature of the study as part of the informed consent process. We will assume that women know best how to limit their own risk.

FSW and their intimate partners will be interviewed separately. Discussions with CBO members running the project note that the FSW live independently and have their own source of income,

making them less vulnerable to threats of retaliation than other women might be. In addition, many of the IPs' do not belong to the same village as the FSW.

During consent, access numbers to crisis response teams will be given to the women that they can call in case of any problems. The interviews will be one-on-one and there will be a code to stop talking if anyone interrupts and a plan to start the interview over at a new time or place will be decided prior to the interview if this occurs. The location for the interviews will be determined based on the comfort of the respondent.