Annexure 1

Data Analysis Plan (Samvedana Plus)
The group should prepare the data analysis plan and share

Proposed title	The effectiveness of a multi-level intervention to reduce violence and increase condom use in intimate partnerships of sex workers in Karnataka: findings from a clustered randomised controlled trial
Journal options Note journal, impact factor and word limit	1. Lancet Global Health (17.7) 2. American Journal of Public Health (3.86) 3. Social Science Medicine (2.8)
Proposed lead authorship Define lead authors names, organisations and role in authorship (i.e. who will conduct analyses, who will write first draft)	**First joint author:** Shajy Isac and Lucy Platt will conduct the analysis and prepare the draft together **Second:** Prakash Javalkar will support the analysis and partial draft write-up **Last:** Lori will review the analysis and the first draft of manuscript
Potential additional authors (who may be invited to join) Name/Organisation	Co-authors from KHPT, LSHTM, and UoM to be decided. Sequencing will be decided based on the contribution of the co-authors. Rachel Jewkes to be invited as co-author
Proposed Research Question Note if this is a primary or secondary study question	What is the effect of the Samvedena Plus intervention on reducing violence and increasing condom use within intimate partner relationships among female sex workers in Karnataka?
Define data to be used in the analysis • Quantitative data plans should detail all dependent and independent variables (including categorisation of variables) • Qualitative data plans should detail data themes	Quantitative data collected through face-to-face interview with female sex workers would be used to analyze the above-stated research questions. The table below summarises the definitions of indicators, the questions to be used for analysis and the source of information.

Table. Indicators, analytical variables and data source for primary and secondary outcomes

Research question #	Indicator(s)	Variable	Source of information	Survey data round	Analysis
1. Primary outcome					
What is the effect of the	1. Proportion of FSWs who	**Q901(e to m):** *How often experienced*	Individual FTFI	End-line data	Comparison of responses

Samvedena Plus intervention on reducing violence and increasing condom use within intimate partner relationships among female sex workers in Karnataka?	report physical or sexual violence from intimate partners in the past 6 months.	*each act of violence in last 6 months from intimate partner-1* (coded >0 in any of violence act from e to m)	(Responses for IP1 that is most significant partner)		between intervention and control arms
	2. Proportion of FSWs experienced severe physical and/or sexual violence from intimate partners in the past 6 months	**Q901 (e to m):** *How often experienced each act of violence in last 6 months from intimate partner-1* (Coded as 3 in any of e to f **and/or** coded>0 in any of g to m)	Individual FTFI (Responses for IP1 that is most significant partner)	End-line data	Same as above
	3. Proportion of FSWs who report consistent condom use in their intimate relationship, within the past 30 days	**Q605 ():** *Usually, how often are condoms (either male or female) used while having sexual intercourse with this partner? Would you say every time, most of the time, sometimes or never (coded 1-Everytime)?* **and** **Q606:** *Did you have an instance in the last 30 days where you did NOT use condom with this IP (coded 0-No)?* ***Consistency checks:*** CHECK 601 number who reported not having sex in last 30 days and conduct	Individual FTFI (Responses for IP1 that is most significant partner)	End-line data	Same as above

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		sensitivity analysis removing any individuals not reporting sex in the last 30 days from the analysis.			
2. Secondary outcomes					
	4. Reduced acceptance of violence by their IPs	*Increase in % of FSWs who said all of the following actions were not acceptable or justified (composite variable) :* **Q801:** *Do you think it is acceptable if a man beats his lover if she has done nothing wrong?* **Q802:** *Is a man justified if he beats her if she does not prepare his food well or on time?* **Q803**: *Is a man justified to beat her if she continues to see clients when he has asked her not to?* **Q804:** *Is a man justified to beat her if she refuses to have sex with him on a particular night?* **Q805:** *Is a man justified to beat her if she goes out without his permission?* **Q807:** *Is a man justified in beating his lover if he fails to provide for her financially?*	Individual FTFI	Endline	Comparison of responses between intervention and control arms

		Q808: *Is a man justified in beating his lover if he has multiple lovers?*			
	5. Increased disclosure of IPV	*Increase in % of FSWS reporting incidence of violence to the following individuals:* **Q903 (a to x**): *Who, if anyone, have you told about the violence you experienced from you IP?* (Denominator = those who've experienced any sexual/physical violence in last 6 months (response y); Numerator = responses a to x)	Individual FTFI	Endline	Comparison of responses between intervention and control arms
	6. Increased knowledge of self-protection strategies	*Increase in % FSWs who have reported protection strategies: a) identifying allies; or b) identifying individual counter measures.* **Q1223**: *Have you ever developed a safety plan to prevent violence from your intimate partner?*	Individual FTFI	Endline	Same as above
	7. Increased self-efficacy to negotiate condom use with IP	*Increase in % FSWs reporting fully confident (response 3) to* **Q712:** *How confident are you that you can persuade your intimate partner(s)*	Individual FTFI	Endline	Same as above

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		to use condom in future?			
	8. Increased solidarity among FSWs around issues of IPV	*Increase in % FSWs reporting always/most of times to either*: **Q1001:** *Can you confide in other sex workers if you need to talk about your problems with intimate partners?* **OR** **Q1002:** *Can you go to your fellow sex workers for help at times of intimate partner violence?*	Individual FTFI	Endline	Same as above

Data collection: BL [Jul-Aug'14]; **ML** [Aug, Oct-Dec'16]; **EL** [Jul-Sep'17]
Intervention: April 2015 to Jun-2017

A priori confounders for primary outcomes

Individual- level
- Age *(Q301: how old are you?)*
- Literacy *(Q302: can you read and write)*
- Duration of sex work *(Q402: how old were you when you started sex work MINUS Q301: how old are you?)*
- Income other than sex work/Total income *(Q310: what is your average monthly income from any activities other than sex work? /Q310 PLUS Q311: what is your average monthly income from sex work)*
- Place of solicitation *(Q403: Where do you generally solicit/pickup most of your clients?)*
- Number of sex work clients *(Q405: How many clients do you have sexual intercourse in a typical week?)*
- Number of intimate partners -> *(Q501: How many main/intimate (regular) partners do you currently have?)*
- Intimate Partner caste -> caste difference *(Q511: what is the caste or tribe of this partner? AND Q306: what is your caste or tribe?)*
- Intimate Partner age difference? *(Q506: what is the current age of this partner? AND Q301: how old are you?)*
- Intimate Partner frequency of visit *(Q514: how often does this partner visit you?)*
- Number of children (Yes/No) – Total (with intimate partner + others) *(Q307: do you have children? If yes, how many?)*

- Membership of Community Based Organisation *(Q1204: are you member of any sex worker collective (CBO)?)*
- Alcohol use (IP, FSW) (any + during sex) *(Q533: how often does this IP come to you drunk or get drunk in your presence? <u>OR</u> Q534: during the past month, how often was this IP under the influence of alcohol when he had sex with you? <u>AND</u> Q535: during the past month, how often were you under the influence of alcohol when you had sex with this IP? <u>AND</u> Q414a: during the past month, have you consumed drinks containing alcohol? <u>AND</u> Q414b: during the past month how frequent did you get drunk?) For all these indicators we are referring to regular alcohol use (every time/often) as an indicator of heavy alcohol use for intimate partners (533, 534, 535). For FSW every day or at least once a week is heavy use. (414a and 414b)*
- Intimate partner knowing sex work status *(Q518: does this partner know about your sex work profession?)*
- Practiced sex work outside the village (*Q402c: In the last 12 months, have you ever practiced sex work anywhere other than the village where you live*?)
- Moved away from the state/district (*Q402d: Which were the different places where you had done sex work during the last 12 months?)*
- Village and FSW population size strata

Cluster-level confounders (taken from baseline dataset)

- Baseline levels of outcomes

A priori confounders for secondary outcomes.
As above

Analysis methods	
- Quantitative data plans should detail statistical analysis methods - Qualitative data plans should detail theoretical analysis methods	The primary outcome will be an adjusted, individual-level intention to treat analysis, comparing outcomes in interventions and control villages using <u>end-line survey as the primary analysis for primary outcomes</u> and secondary outcomes (see above). We will include all women surveyed at each time point (i.e. don't dismiss women who aren't captured at baseline) The analysis will be conducted in two stages: <u>Stage one: descriptive analysis (Figure 1 – Tables 1-2)</u> We will check imbalance between confounders and socio-demographic indicators (see above) between arms within baseline data using blinded datasets and reporting proportions only to avoid deductive disclosure (since we have an imbalance in clusters between arms).

This comparison is just to observe differences. We will review the tables as a critical reader to assess imbalances making judgements on the importance of imbalances depending on their association with outcomes – i.e. bigger imbalances of something not strongly related to the outcome is less important than smaller imbalances of outcomes.

We will report cluster-level summaries (mean of the cluster-level means by Trial arm for each primary and secondary outcomes as a way of double checking our analyses and since risk differences are easier to interpret than odds ratios used in the individual level analysis. This is summarised in Table 2.

Stage two: individual –level analysis with mixed effects logistic model (Table 3)

As we have more than 20 clusters, we will conduct individual-level analysis with a mixed effects logistic model. We will fit dummy variables for strata (village population size-> 1-33 percentile; 34-67 percentile; 68-100 percentile; number of FSWs <=12 FSWs; > 12 FSWs). We will adjust for confounders in the following way:

- Outcome variables are adjusted for at a cluster level using mean _baseline summaries (we need to check cluster sizes through – perhaps better to stratify if clusters are too small_)
- Other variables will be adjusted for at individual level _using endline data_– only adjust for those variables that strongly predict outcome (a priori confounders but not on causal pathway) and where we think there is variability (drawing on descriptive analysis of baseline – stage 1).

For the covariates that were not measured at baseline (i.e. alcohol or mobility) we should check if they are on the causal pathway or if they were discussed in the intervention. We will not include them in the main analysis but conduct a sensitivity analysis.

| Timelines | Draft Data analysis plan: 23th October, 2017 |
| | Final Data analysis plan: 31st October, 2017 |

Note timelines for completion of each step in the writing process (add additional steps as appropriate)	Draft unblinding protocol: 23rd October,2017 Data cleaning and basic coding: 10th November, 2017 Draft analysis: By 2nd December, 2017 Final analysis: 15th January, 2018 First draft: End February'2018 Journal submission: End March'2018
Review process If the authors request review of the data analysis plan by someone external to the writing team, note the name of the reviewer, timelines and document feedback.	Will this data analysis plan be reviewed? **YES**/NO Shajy, Mitzy, Lori, Parinita, Rachel, Tara
Changes If changes are subsequently suggested to the data analysis plan, detail the suggested changes and details of review and agreement by the authors and the reviewer (if relevant)	
Notes	