Community interventions to prevent violence against women and girls in informal settlements in Mumbai: the SNEHA-TARA pragmatic cluster randomised controlled trial

Statistical Analysis Plan (SAP)

Version 9

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List of abbreviations

CTRI	Clinical Trials Registry of India
DMC	Data Monitoring Committee
ISRCTN	International Standard Randomised Controlled Trial Number
NGO	Non-government organisation
GAD-7	Generalized Anxiety Disorder 7 item questionnaire
PHQ-9	Patient Health Questionnaire 9-item questionnaire
SAP	Statistical analysis plan
SNEHA	Society for Nutrition, Education and Health Action
SOP	Standard operating procedure
SWEMWBS	Short Warwick Edinburgh Mental Wellbeing Scale
TARA	Taking Action Reaching All
TSC	Trial Steering Committee
UCL	University College London
WHO	World Health Organization

Administrative information

Study identifiers

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Revision history

Version 9

Contributors to the statistical analysis plan

Roles and responsibilities

David Osrin is the principal investigator for UCL, was responsible for trial design and international governance and wrote the first draft of the SAP.

Nayreen Daruwalla is the lead investigator for SNEHA, was responsible for conceptualisation of the intervention and implementation of the trial and contributed to revisions of the SAP.

Andrew Copas is the trial statistician at UCL, advised on design and analysis and contributed to revisions of the SAP.

Lu Gram is the trial Senior Research Associate at UCL, contributed to design of data collection and analysis and to revisions of the SAP.

Approvals

The undersigned have reviewed this plan and approve it as final. They find it to be consistent with the requirements of the protocol as it applies to their respective areas. They confirm that this analysis plan was without knowledge of the effect of the intervention being assessed.

	Signature	Date
Prof David Osrin UCL Lead d.osrin@ucl.ac.uk		14th December 2022
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Study synopsis

Background

One in three women in India has survived physical or sexual violence, making it a major public health burden. Reviews recommend community mobilisation to address violence, but trial evidence is limited. To achieve this aim, our preventive activities—the complex intervention that the trial is testing—involve two kinds of community outreach: group education and enablement, and individual voluntarism.

Design

We are testing the effects of community mobilisation through groups and volunteers in a parallel-group, phased, cluster randomised controlled pragmatic superiority trial, with 1:1 allocation to intervention and control in a total 48 urban informal settlement clusters, each of 500 dwellings. 24 clusters were allocated randomly to receive the intervention and 24 to control. The trial has been implemented in 4 phases, each including 6 intervention and 6 control clusters. Each phase began with a pre-intervention survey. The intervention was implemented for 3 years in each phase, followed by a post-intervention survey.

Study objectives

Primary objective

We aim to help people understand the gendered nature of violence, so that survivors make decisions, potential perpetrators think again, and others believe that action is possible.

Secondary objectives

As a result of this, people will stand up against violence, individually and collectively, and community members will act to help survivors, will stop accepting violence, and will strengthen community structures that support a conviction that it is unacceptable

Population

Residents of two large informal settlement areas in Mumbai.

Inclusion criteria

Any resident of an intervention cluster could participate in the intervention. Women, men, and adolescents were eligible to participate in group activities, and women were eligible to volunteer as *sanginis*.

The pre-intervention survey of perpetration was administered to 100 women aged 18-49 years in each cluster, selected by systematic interval after random start (4800 participants).

The pre-intervention survey of community attitudes was administered to 50 women and men aged 18-65 years in each cluster, selected by systematic interval after random start (2400 participants).

The post-intervention survey of perpetration is administered to 150 women aged 18-49 years in each cluster, selected by systematic interval after random start (7200 participants).

The post-intervention survey of community attitudes is administered to 50 women and men aged 18-65 years in each cluster, selected by systematic interval after random start (2400 participants).

Exclusion criteria

For the post-intervention survey of perpetration, women aged <18 or >49 years.

For the post-intervention survey of community attitudes, women and men aged aged <18 or >65.

Outcomes

Primary outcomes

Comparing intervention and control arms, measured in cross-sectional survey after 3 years of intervention (accounting also for the pre-intervention survey)

1. Prevalence of physical or sexual domestic violence against women 15–49 years in the preceding 12 months.

2. Prevalence of emotional or economic domestic violence or gender-based household maltreatment of women 15–49 years in the preceding 12 months.

Secondary outcomes

Comparing intervention and control arms, measured in cross-sectional survey after 3 years of intervention (accounting also for the pre-intervention survey)

1. Proportion of violence against women and girls disclosed to support services (NGOs, police, healthcare, government programmes)

2. Community tolerance of violence against women and girls:

    a. Attitudes towards domestic violence

    b. Attitudes towards gender equality

    c. Attitudes towards rape and sexual violence

    d. Bystander attitudes

3. Prevalence of non-partner sexual violence in preceding 12 months

4. Prevalence of anxiety (GAD-7) and depression (PHQ-9)

5. Subjective wellbeing (SWEMWBS)

6. Either or both of primary outcomes 1 and 2.

Safety outcomes

1. Disclosure leading to reprisal and increase in abuse
2. Vigilantism, precipitate action or punishment of uninvolved people
3. Demands for support for perpetrator rather than survivor
4. Alteration of form of domestic violence
5. Limits set to women's mobility
6. Threats to team members or families, community hostility

Intervention

Group education involves women, men, and adolescents. It aims to develop awareness and understanding of violence, knowledge of rights and recourse, individual and collective local strategies for primary and secondary prevention, and increased confidence and leadership, and to reduce community tolerance and increase bystander action. Individual intervention involves women volunteers, *sanginis*, who identify survivors of violence, provide support, connect them with crisis intervention and counselling services, and facilitate police and health service consultation.

Secondary interventions for survivors—the background activities available to both intervention and control groups in the trial—include counselling, liaison with the police, medical attention, mental health intervention, family interventions, and legal recourse. Our centres offer support from trained counsellors, clinical psychologists, municipal clinicians, visiting psychiatrists, and lawyers.

Hypotheses

We hypothesise that women and girls will be more likely to disclose violence, that communities will become less tolerant of it, and that the prevalence of intimate partner and domestic violence will diminish.

Primary hypothesis

Over and above a package of crisis intervention, counselling, and support services (the control arm exposure), a community mobilisation intervention delivered in informal settlements for 3 years and involving groups and volunteers will reduce the reported prevalence of domestic physical or sexual violence, and of domestic emotional or economic violence, control, or neglect.

Secondary hypothesis

Over and above a package of crisis intervention, counselling, and support services (the control arm exposure), a community mobilisation intervention delivered in informal settlements for 3 years and involving groups and volunteers will increase the disclosure of intimate partner or domestic violence to support services, improve indices of community attitudes towards violence against women and girls, reduce the prevalence of non-partner sexual violence, and improve women's mental health and subjective wellbeing.

Consent for participation

Ethical approval was granted by the UCL Research Ethics Committee (3546/003 27/09/2017) and by the PUKAR (Partners for Urban Knowledge, Action and Research) Institutional Ethics Committee (25/12/2017). We secured gatekeeper consent for inclusion of clusters in the trial. Informed signed consent for data collection was obtained by field investigators from all respondents after discussion of a participant information sheet.

Implementation

Allocation

Allocation was done by the UCL and SNEHA leads using computer-generated random permutation, in 4 blocks each of size 12 clusters corresponding to the 4 trial phases.

Masking

Allocation was not masked to implementation or data collection teams. Trial analysts will be masked to the allocation of clusters and the names and locations of the clusters themselves for the primary analyses (see later for details).

Data collection

Structures and homes within clusters were mapped and female interviewers visited households to enumerate residents and list possible participants. Interviewers began at a random start point and visited every second household in a random walk to enrol participants. When there was more than one potential respondent in a household, the interviewers applied an algorithm that selected the youngest woman at risk of disability, followed by the youngest married woman, followed by the youngest unmarried woman.

Perpetration questionnaire content for primary analysis

Household fabric, toilet, assets
Respondent characteristics: age, education, religion, disability, marriage, livelihood, alcohol or drug use
Partner characteristics: age, education, disability, livelihood, alcohol or drug use
SWEMWBS, GAD-7, PHQ-9, suicidal ideation
Household decision-making, justification of violence
Abuse: neglect, coercive control, economic abuse, emotional violence, physical violence, sexual violence
Disclosure and help-seeking

Awareness of the SNEHA TARA intervention
Participation in community action
Perceived impacts of the SNEHA TARA intervention

Community attitudes questionnaire content for primary analysis

Household fabric, toilet, assets
Respondent characteristics: age, sex, education, disability, religion, marital status, livelihood
Gender roles
Gender equality
Understanding of domestic violence
Attitudes to domestic violence
Male power and control
Privacy norms
Bystander attitudes and intervention
Social capital
Participation in CBOs and NGOs
Group action to address VAW
Family and neighbourhood norms
Social identity
Rape myths
Awareness of the SNEHA TARA intervention
Perceived impacts of the SNEHA TARA intervention

Data storage and management

Interviewers used electronic tablets to enter information in Hindi, Marathi or English in a database in CommCare (www. dimagi. com). To optimise accuracy, the system included field constraints, lookup tables and automated skip logic. We examined variation in prevalence rates by interviewer and discussed performance in supervisory meetings. We selected for field observation interviewers who showed signs of deviation from the group average and provided feedback where necessary. Data are stored in a MySQL database overseen by SNEHA information managers.

Analysis

Scope of the SAP

This SAP specifies the study results to be included in the primary analysis results paper and analyses required for monitoring the safety of the trial.

Dataset

Database lock will occur when the post-intervention survey has been completed. A frozen dataset will be created by the SNEHA TARA Trial data manager for statistical analysis.

Derivation of primary outcomes

Primary outcomes	Positive response to at least one question within module	
1. Prevalence of physical or sexual domestic violence against women 15–49 years in preceding 12 months Single composite outcome: one or more items reported. Items are binary		
Physical violence	1	Pushed, shoved, shaken, hurt
	2	Twisted arm, banged head, pulled hair
	3	Slapped, pinched, bitten
	4	Hit, punched
	5	Kicked, dragged, beaten
	6	Things thrown at, burned
	7	Attacked or threatened: sharp object
	8	Attacked or threatened: blunt object
	9	Suffocated, choked, hanged, poisoned
Sexual violence	1	Forced to have intercourse

	2	Forced to perform other degrading acts
	3	Forced to replicate pornography
	4	Partner insisted on multiple intercourse

2. Prevalence of emotional or economic domestic violence or gender-based household maltreatment of women 15–49 years in preceding 12 months
Single composite outcome: one or more items reported. Items are binary

Emotional violence	1	Insulted or made to feel bad about herself
	2	Ignored or treated indifferently
	3	Belittled or humiliated in front of others
	4	Scared or intimidated on purpose
	5	Threatened to hurt her or someone she cared about, take away her child
	6	Insulted or treated badly for not having a baby
Economic violence	1	Denied right to property
	2	Belongings taken by force
	3	Money coercively taken or account used
	4	Convinced to loan money and not repaid
	5	Pressurised to bring parental money or property
	6	Not trusted with money
	7	Kept from having enough money
	8	Forced to hand over income
Coercive control	1	Excluded from family matters
	2	Prevented from accessing healthcare
	3	Forced out of house
	4	Locked in house
	5	Prevented from attending meetings
	6	Movement monitored
	7	Prevented from seeking employment
	8	Prevented from seeking education
	9	Made to work excessively
	10	Prevented from using contraception
	11	Prevented from accessing termination of pregnancy
	12	Unable to talk freely on phone
	13	Always accompanied when out
	14	Unable to meet female friends
	15	Unable to meet natal family
Neglect	1	Allowed insufficient food
	2	Allowed insufficient sleep
	3	Health neglected
	4	Child's health neglected

Derivation of secondary outcomes

Secondary outcomes		
1. Proportion of violence against women and girls disclosed to support services (NGOs, police, healthcare, government programmes)		
Composite outcome: one or more item reported. Items are binary		
Survivor disclosed	1	To SNEHA staff
	2	To doctor or nurse
	3	To teacher
	4	To police
	5	To community leader
	6	To panchayat member
	7	To SNEHA women's group
	8	To SNEHA counsellor
	9	To other SNEHA person
	10	To other organisation
	11	To corporator or politician
	12	To religious figure
	13	To local group

2. Community tolerance of violence against women and girls. Five outcomes in total, two from a, then b-d		
a. Attitudes towards domestic violence Items adapted from Australian National Community Attitudes Survey.		Two scores Both scored by summing items using binary coding 'generally agree'/'yes' = 1 and 'generally disagree'/'no' = 0. Higher scores indicate more tolerant attitudes towards DV.
		Can domestic violence be excused? Community attitudes questionnaire – male and female respondents
	1	Domestic violence/abuse can be excused if the violent person is under a lot of stress in their lives.
	2	Domestic violence can be excused if, afterwards, the violent person genuinely regrets what they have done.
	3	Domestic violence or abuse can be excused if it results from people getting so angry that they temporarily lose control.
	4	Domestic violence or abuse can be excused if the offender is heavily affected by alcohol.
	5	Domestic violence or abuse can be excused if the violent person is pressured by his parents to be violent.
		Can domestic violence be justified? Perpetration questionnaire – female respondents only Now I am going to read some situations. In your opinion, is a husband justified in hitting or beating his wife in the following situations. Is it ok to beat his wife…
	1	If she neglects the house or the children?
	2	If she does not complete her household work to her husband's satisfaction?
	3	If she doesn't cook properly or burns the food?
	4	If she argues with her husband or parents?
	5	If she disobeys her husband or parents?
	6	If her husband or parents suspect her of being unfaithful?
	7	If she shows disrespect or neglects in-laws/parents/husband?
	8	If she asks her husband whether he has another girlfriend?
	9	If she goes out without telling her husband?
	10	If she refuses to have sex with her husband?
	11	If her husband's parents ask him to beat her?
b. Attitudes towards gender equality Items adapted from the Australian National Community Attitudes Survey.		Score Community attitudes questionnaire – male and female respondents Scored by summing items using binary coding 'generally agree' = 1 and 'generally disagree' = 0 (except for reverse coded items). Higher scores indicate more <u>unequal</u> attitudes
	1	A good wife obeys her husband even if she disagrees.
	2	It is important for a man to show his wife/partner who is the boss.
	3	A woman should be able to choose her own friends even if her husband disapproves. (Reverse coded)
	4	It's a wife's obligation to have sex with her husband even if she doesn't feel like it.
	5	If a man mistreats his wife, others outside of the family should intervene. (Reverse coded)
	6	On the whole, men make better political leaders than women.
	7	When jobs are scarce men should have more right to a job than women.
	8	A woman has to have children to be fulfilled.
	9	Men should take control in relationships and be the head of the household.
	10	Women prefer a man to be in-charge of the relationship.
	11	Only some types of work are appropriate for both men and women.

	12	Women will cheat in a relationship if they are not watched all the time.
	13	It's good for a woman to be a little afraid of her partner.
c. Attitudes towards rape and sexual violence Items adapted from Rape Myths scale.		Score Community attitudes questionnaire – male and female respondents Scored by summing items with binary codes 'generally agree' = 1 and 'generally disagree' = 0 (except for reverse coded items). Higher scores indicate greater endorsement of rape myths.
	1	If a woman goes out alone with a man, it is her fault if she is raped.
	2	If a woman doesn't physically resist –even if protesting verbally – then it isn't really rape.
	3	Rape results from men not being able to control their need for sex.
	4	A woman cannot be raped by someone she is in a sexual relationship with.
	5	A man is less responsible for rape if he is drunk or affected by drugs at the time.
	6	Women often say 'no' when they mean 'yes' for sex
	7	Women ALMOST NEVER make false claims of being raped. (reverse coded)
d. Bystander attitudes Items adapted from Mentors in Violence Prevention (MVP) efficacy scale.		Score Community attitudes questionnaire – male and female respondents Scored by summing items with binary codes 'generally agree' = 1 and 'generally disagree' = 0 (except for reverse coded items). Higher scores indicate more supportive attitudes for bystander action.
	1	You can help prevent violence against women in your community.
	2	It is intimidating to think about trying to stop a man from hitting his wife (reverse coded).
	3	A group of men would listen to you if you confronted them about their sexist or vulgar behavior.
	4	You have the skills to support someone suffering violence or abuse from their husband or partner.
	5	The fear of being laughed at would prevent you from telling a group of men it was disrespectful to whistle/ make comments/ sing vulger songs at women (reverse coded).
	6	You don't think you could stop a group of men who are harassing a woman in a public place (reverse coded).
	7	You would be comfortable telling your friend to stop calling his wife names.
	8	You believe your peers will listen to you if you speak out against sexual violence.
	9	You have the confidence to say something to a man who is acting inappropriately.
	10	You believe violence against women comes from behaviors and habits that can be changed.
	11	It would be too hard for you to confront a stranger who was being abusive toward a woman (reverse coded).
	12	You feel that your personal efforts can make a difference in reducing violence against women.
	13	Violence against women doesn't affect me (reverse coded).

3. Prevalence of non-partner sexual violence in preceding 12 months
   Items are binary

Sexual violence	By anyone except intimate partner

4. Prevalence of anxiety (GAD-7) and depression (PHQ-9) (both binary, two outcomes)

GAD-7 questions	Proportion of respondents with score >=10
PHQ-9 questions	Proportion of respondents with score >=10

5. Subjective wellbeing (SWEMWBS)

SWEMWBS questions	Mean score

6. Either or both of primary outcomes 1 and 2
Items are binary

	Positive response to any question in primary outcome 1 or 2

Derivation of safety outcomes

Safety outcomes	Collected in intervention clusters	
1. Disclosure leading to reprisal and increase in abuse		
Quantitative and qualitative outcome.		
Field reports	1	Incidents recorded
Counselling records	2	Incidents recorded
2. Vigilantism, precipitate action or punishment of uninvolved people		
Quantitative and qualitative outcome.		
Field reports	1	Incidents recorded
3. Demands for support for perpetrator rather than survivor		
Quantitative and qualitative outcome		
Field reports	1	Incidents recorded
4. Alteration of form of domestic violence		
Quantitative and qualitative outcome		
Counselling records	2	Incidents recorded
5. Limits set to women's mobility.		
Proportion of survivors of violence (either of primary outcomes) (composite outcome: one or more item reported. Items are binary)		
Coercive control	1	Prevented from seeking healthcare
	2	Locked in house
	3	Prevented from attending meetings
	4	Movement monitored
	5	Prevented from employment
	6	Accompanied when out
	7	Prevented from going out in evening
	8	Prevented from meeting female friends
	9	Prevented from meeting natal family
6. Threats to team members or families, community hostility		
Field reports		Incidents recorded. Quantitative and qualitative outcome.

Design and contextual covariates for adjustment

Characteristic	Derivation
Trial phase (cluster level)	1-4
Asset score (household level)	Score derived from first principal component of assets Mattress, chair, sofa, bed, table, clock, fan, cooler, television, basic mobile phone, smartphone, refrigerator, mixer, washing machine, sewing machine, water pump, scooter or motorbike, tap drinking water, own home, robust housing fabric, private toilet
Age (individual level)	Years
Education (individual level)	None, Primary, Secondary, Higher Secondary, Higher
Religion (individual level)	Hindu, Muslim, Buddhist, other

Sample size calculation

Cross-sectional samples of 100 women in each of 48 clusters at baseline and 150 at follow-up provide more than 80% power at 5% significance level to detect a minimum difference of 6% between arms in 12-month prevalence of domestic violence, reflected in either primary outcome. Our power estimates were based on a range of intracluster correlation coefficients (ICCs) around 0.02 assumed to apply at both baseline and follow-up, for values of cluster autocorrelation ranging from conservative (0.5) to realistic (0.8), and a range of prevalence values for the control arm at follow-up around 15% for physical or sexual violence in the preceding 12 months and 80% for emotional or economic domestic violence, control, or

neglect. Preliminary analysis of baseline data confirmed that our assumptions of ICC values and prevalence were reasonable.

Primary analysis

Our primary analysis will be by intention-to-treat according to cluster allocation, jointly modelling baseline and follow-up data. All the primary and secondary outcomes listed are collected at both baseline and follow-up. Data from a midpoint monitoring survey will not be included. All confidence intervals will be 95% and two-sided. Statistical tests will be two-tailed and applied at the 5% significance level. The significance level for primary and secondary outcomes will not be adjusted for multiple testing and we will interpret both primary outcomes together.

'Baseline' comparability

Demographic characteristics of respondents in both the baseline and follow-up surveys will be summarised by allocation; likewise primary and secondary outcomes of respondents in the baseline survey, without statistical testing.

Populations for analysis

Denominators for primary outcomes will be all respondents to the perpetration questionnaire.

Denominators for secondary outcome 1 (disclosure) will be respondents to the perpetration questionnaire who report primary outcomes 1 or 2.

Denominators for secondary outcome 2 a-d (community tolerance of violence) will be all respondents to the community attitudes questionnaire.

Denominators for secondary outcome 3, 4, 5 and 6 (non-partner sexual violence, mental health, either primary outcome) will be all respondents to the perpetration questionnaire.

Adjustment for design and contextual factors

We will account for the structure of the data with random effects (two correlated intercept terms, one for baseline and one for follow-up) for each trial cluster. Analyses will be conducted and reported with and without adjustment for predictors of the primary outcomes listed earlier and the covariate-adjusted effect measure will be considered primary. Asset score will be included in regression models as both linear and quadratic terms. The adjustment (fixed effects) and random effects structure will be the same for all primary and secondary outcomes.

Missing data

We do not expect non-trivial levels of missing data in our outcomes or covariates. For score outcomes such as attitudes, however, the proportion of participants omitting one or more item could be of some concern. We propose to use single (rather than multiple) imputation provided that levels are low (<5% missing one or more items in a score). For items with missing values, we will base the single imputation on prediction from a logistic regression model (binary item) or other model as appropriate, with predictors to include other items from the same scoring system and random effects for cluster. The models will be fitted separately by allocation arm and by time (baseline versus follow-up). We will report the levels of missing data.

Regression approach and measures of effect

Analysis of the primary and other binary outcomes will be based on modelling both baseline and follow-up data using logistic regression with random effects for clustering (two correlated intercepts for baseline and follow-up, normally distributed). Beside design and contextual factors, the model will include time (baseline versus follow-up) and an 'intervention indicator' coded zero for baseline (both trial arms) and one for the intervention arm at follow-up. The odds ratio for this intervention indicator is the intervention effect. This approach is known as a 'constrained baseline' analysis because there is no fixed effect for a difference between

arms at baseline (due to randomisation). For binary outcomes, intervention effect estimates will also be presented as difference in proportions and 95% CI (generated using the Wald method) through marginalisation (no additional statistical testing).

Analysis of secondary outcomes will follow a similar methodology. We will use linear regression for secondary outcomes based on scores, except in the case of an extreme distribution—for example, where almost all respondents fall into two narrow ranges—in which case we will treat them as binary (see later). Some of the distributional assumptions of linear regression will inevitably be violated when analysing scores that have a finite range and we will use robust standard errors.

Because the number of clusters in the trial is moderate at 48, we will not implement small sample size corrections to our regression models.

Ancillary analysis

We will conduct

1. Subgroup analysis: intervention effect on primary outcomes 1 and 2 in phases 1 and 2 compared with phases 3 and 4. This subgroup analysis is selected because the communities are in different areas of the city and differ in a number of characteristics.
2. Per protocol analysis: 'dose-response' analysis of intervention effect on primary outcomes 1 and 2, in four groups of participants: (a) participants who were not resident for the whole intervention period and did not attend a women's group or attended only 1 session, (b) participants who were resident for the whole intervention period and did not attend a women's group or attended only 1 session, (c) participants who were not resident for the whole intervention period and attended 2 or more women's group meetings, and (d) participants who were resident for the whole intervention period and attended 2 or more women's group meetings.

Testing for a different intervention effect 'by subgroup' will be based on an interaction term between subgroup factor and allocation. In the per-protocol analysis we will report summary statistics and odds ratios comparing each of the four 'dose' groups with the control arm. Outcomes between dose groups will be compared only informally.

Reporting details

A CONSORT flow chart will be produced. We will report parameters of intervention delivery in line with the published theory of change.

Analysis software

Analyses will be conducted using Stata V16.

Blinding and checking

As allocation is unblinded, preliminary analysis will be conducted using a dataset with randomly generated cluster identifiers and a 'fake' trial arm indicator generated at random. Using the dataset, the analyst will be able to assess the distribution of score outcomes, judge whether linear regression is suitable, and assess whether covariates can be included as intended or not in the analysis of all outcomes (this may not be possible, for example, if there are zero cells or strong collinearity between predictors). The approach to missing data (e.g. any imputation) can also be finalised. Once these decisions have been documented, the analyst will perform the analysis of primary and secondary outcomes with the real trial arm indicator (note that this may involve repeating any imputation as this is done separately by trial arm).

The code used to derive the primary outcomes and all adjustment factors in the primary analysis of the primary outcomes will be checked by a second analyst.

Regression diagnostics

We will check for model stability primarily through examination of standard errors for covariates, with large standard error or convergence problems indicating a problem of model instability.

Interim analyses

There are no planned interim analyses of intervention effectiveness.

Regular reports to TSC-DMC

Reports to the TSC-DMC during the trial will be limited to baseline comparison of characteristics between arms, recruitment rates by arm and reporting of possible harms (the safety outcomes listed earlier) associated with the intervention.

Tables and Figures for the primary publication

Table 1. Household and respondent characteristics in the follow-up survey, by allocation

Table 2. Primary outcome indicators before the intervention, by allocation

Table 3. Primary and secondary outcome indicators after the intervention, by allocation

Table 4. Outcomes according to programme theory, for intervention arm

Table 5. Subgroup and per-protocol analysis of primary outcomes

Figure 1. Trial design

Figure 2. CONSORT profile

Supplementary tables

Table S1. Household and respondent characteristics in the baseline survey, by allocation

Table S2. Recording of potential harms relating to the intervention