

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

Submission date 19/02/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 22/02/2018	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/12/2023	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

One in three women in India have survived physical or sexual violence, making it a major public health burden. Reviews recommend community mobilisation to address violence, but evidence is limited. The aim of this study is to test the effects of community mobilisation through groups and individual volunteers on the prevalence of violence against women and girls in informal settlements in Mumbai.

Who can participate?

Residents of informal settlements in Mumbai

What does the study involve?

Participating areas are randomly allocated to the control group or the intervention group. Residents in control group areas receive unrestricted access to services provided by the implementing organisation: crisis intervention, counselling, police liaison, medical attention, mental health intervention, family interventions, and legal recourse. Residents in intervention group areas receive the same services as the control group, with the addition of community mobilisation activities with groups of women, men, and adolescents, and with individual women volunteers. A salaried community mobiliser convenes three women's groups, one men's group, and one mixed-sex adolescent group monthly, following manuals over three years. Community mobilisers and group members organise local campaigns and events. Group members who show leadership are trained and supported to undertake identification of survivors of violence, crisis intervention and preliminary counseling, referral, and collective community campaigns. These community mobilisation activities are assessed through a follow-up survey after three years. Prevalence of domestic physical or sexual violence, and prevalence of domestic emotional or economic violence, control or neglect, are both measured by survey interview at 3 years after the start of intervention, along with disclosure of violence to support services, community attitudes to violence, bystander intervention, gender equality, common mental disorders, and prevalence of non-partner sexual violence.

What are the possible benefits and risks of participating?

Benefits to participants in interviews include information on support services, confidential disclosure, and access to crisis counselling and support services, including medical care, police intervention, and legal support. Participants in community activities have access to the same services, and benefit from joining support groups of women and men. Minimised by confidentiality procedures and response protocols, a woman's disclosure of violence may lead to family tensions and possible escalation, or denial of access to support services. There is a small possibility of resistance from community members. Protocols are in place for response to disclosure, crisis, and threat.

Where is the study run from?

1. UCL Institute for Global Health (UK)
2. SNEHA (Society for Nutrition, Education and Health Action) (India)

When is the study starting and how long is it expected to run for?

July 2017 to March 2024

Who is funding the study?

Wellcome Trust (UK)

Who is the main contact?

1. Prof. David Osrin
d.osrin@ucl.ac.uk
2. Dr Nayreen Daruwalla
nayreen@snehamumbai.org

Study website

<https://www.ucl.ac.uk/global-health/research/z-research/sneha-tara-trial>

Contact information

Type(s)

Scientific

Contact name

Prof David Osrin

ORCID ID

<http://orcid.org/0000-0001-9691-9684>

Contact details

Institute for Global Health
30 Guilford Street
London
United Kingdom
WC1N 1EH
+44 (0)2079052122
d.osrin@ucl.ac.uk

Type(s)

Scientific

Contact name

Dr Nayreen Daruwalla

ORCID ID

<http://orcid.org/0000-0002-5716-1281>

Contact details

SNEHA, Urban Health Centre
Room 310, 60 Feet Road, Dharavi
Mumbai
India
400017
+91 (0)224040045
nayreen@snehamumbai.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CTRI/2018/02/012047, Wellcome 206417/Z/17/Z

Study information**Scientific Title**

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

Acronym

SNEHA-TARA

Study objectives

Over and above a package of crisis intervention, counselling, and support services, a community mobilisation intervention delivered in informal settlements for three 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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. UCL Research Ethics Committee, 27/09/2017, ref: 3546/003
2. PUKAR (Partners for Urban Knowledge, Action, and Research) Institutional Ethics Committee, 25/12/2017

Study design

Single-centre parallel-group phased analyst-masked cluster randomised controlled superiority trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Violence against women and girls

Interventions

Computer pseudorandomised 1:1 allocation of 48 clusters blocked in 4 phases of 12 each. 24 areas receive support services, community group, and volunteer activities, and 24 areas receive support services only.

Intervention: as control, with the addition of community mobilisation activities with groups of women, men, and adolescents, and with individual women volunteers.

1. In each cluster, a salaried community mobiliser will convene three women's groups, one men's group, and one mixed-sex adolescent group monthly, following manuals over three years.
2. Community mobilisers and group members will organise local campaigns and events.
3. Group members who show leadership will be trained and supported to undertake identification of survivors of violence, crisis intervention and preliminary counseling, referral, and collective community campaigns.

Control: unrestricted access to services provided by the implementing organisation: crisis intervention, counselling, police liaison, medical attention, mental health intervention, family interventions, and legal recourse.

These community mobilisation activities will be evaluated through a follow-up survey after three years.

Intervention Type

Behavioural

Primary outcome measure

Measured by survey interview at 3 years after the start of intervention:

1. Prevalence of physical or sexual domestic violence against women 15-49 years in the preceding 12 months, based on Demographic and Health Survey (DHS) and WHO perpetration

modules

2. Prevalence of emotional or economic domestic violence or gender-based household maltreatment of women 15-49 years in the preceding 12 months, based on DHS and WHO modules and the new Indian Family Violence and Control scale

Secondary outcome measures

Measured by survey interview at 3 years after the start of intervention:

1. Disclosure of violence against women and girls to support services (non government organisations, police, healthcare, government programmes)
2. Community attitudes to violence against women and girls, based on the National Community Attitudes towards Violence Against Women Survey
3. Bystander intervention, based on the Mentors in Violence Prevention Efficacy Scale
4. Gender equality, based on WHO modules
5. Prevalence of non-partner sexual violence in preceding 12 months, based on DHS and WHO modules
6. Prevalence of anxiety (GAD-7) and depression (PHQ-9)

Overall study start date

01/07/2017

Completion date

31/03/2024

Eligibility

Key inclusion criteria

Any resident of an intervention cluster may participate in the intervention

Survey 1 after 3 years of intervention:

200 women aged 18-49 in each of 48 clusters of 500 households will be asked about their health, wellbeing, common mental disorder, household decision-making, household power and control, neglect, experience of economic, emotional, physical, and sexual violence, disclosure and support (9600 participants)

Survey 2 after 3 years of intervention:

100 women and men aged 18-65 in each of 48 clusters, in different households from respondents to Survey 1, will be asked about gender roles, gender equality, ambivalent sexism, violence in their locality, attitudes to and justifiability of violence against women, bystander intervention, and potential sources of support (4800 participants)

Participant type(s)

All

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

48 clusters of 300 evaluation participants (9600 women for Survey 1)

Total final enrolment

9600

Key exclusion criteria

1. Aged under 18 or over 65
2. Unwilling to give consent for interview

Date of first enrolment

05/03/2018

Date of final enrolment

31/03/2024

Locations

Countries of recruitment

England

India

United Kingdom

Study participating centre

UCL Institute for Global Health

30 Guilford Street

London

United Kingdom

WC1N 1EH

Study participating centre

SNEHA (Society for Nutrition, Education and Health Action)

Urban Health Centre, 60 Feet Road, Dharavi

Mumbai

India

400017

Sponsor information

Organisation

UCL Institute for Global Health

Sponsor details

30 Guilford Street
London
England
United Kingdom
WC1N 1EH

Sponsor type

University/education

Website

<http://www.ucl.ac.uk/igh>

ROR

<https://ror.org/02jx3x895>

Funder(s)**Funder type**

Charity

Funder Name

Wellcome Trust

Alternative Name(s)**Funding Body Type**

Private sector organisation

Funding Body Subtype

International organizations

Location

United Kingdom

Results and Publications**Publication and dissemination plan**

1. Protocol to be published in 2018, analysis plan to be finalised at the third meeting of the Trial Steering Committee

2. Theory of change to be published in 2018
3. Planned trial publication in a high-impact open-access peer-reviewed journal in 2022

Added 11/02/2021:

1. The research will produce protocols for community interventions which will be made available through the project and organisational websites.
2. Resources to support data sharing will be provided by UCL. Open access publication will be supported by Wellcome.

IP the research will generate:

1. Datasets from cross-sectional surveys on domestic violence survivorship and associated community attitudes: pre-intervention, midpoint, and post-intervention
2. Qualitative data collected during process evaluation: interviews with key informants and beneficiaries
3. Protocols for community interventions

How IP will be protected:

Background and foreground IP will be protected according to UCL policies. No pecuniary advantage will be sought from foreground IP.

How IP will be used to achieve health benefits:

Sharing of data and protocols will help other individuals and organisations to develop the evidence base for work to prevent violence against women and girls

Intention to publish date

30/06/2024

Individual participant data (IPD) sharing plan

The data and software outputs the research will generate and/or re-use:

1. Datasets from cross-sectional surveys on domestic violence survivorship and associated community attitudes: pre-intervention, midpoint, and post-intervention.
2. Qualitative data collected during process evaluation: interviews with key informants and beneficiaries.
3. The metadata and documentation that will accompany the outputs
 - 3.1. Data will be discoverable through MeSH terms and keywords applied to open access publications
 - 3.2. Codebooks for datasets
 - 3.3. Indices and descriptions of qualitative data

Data will be available at the time of publication. Supporting data will be available on acceptance of each research paper, in sets that enable replication of published analyses. For example, unlinked data will accompany publications describing the prevalence of domestic violence from the pre-intervention survey.

Where the data and software will be made available: Open Science Framework (OSF)

How the data and software will be accessible to others:

1. Unlinked data will be available after being made public and registered in the Open Science Framework
2. Datasets will be discoverable through articles published with CC BY licences and DOIs

Whether limits to data and software sharing are required:

Participants will give written consent for sharing of unlinked data. No data will include identifiers of an individual or geographic nature. There will be no restrictions to access under CC BY licences.

How datasets and software will be preserved:

Data will be preserved for a minimum of 10 years, initially on Open Science Framework and subsequently with the UCL Research Data Storage Service (<https://www.ucl.ac.uk/isd/services/research-it/research-data-storage-service>)

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/12/2019	19/12/2019	Yes	No
Results article	cross-sectional survey results	16/12/2020	18/12/2020	Yes	No
Statistical Analysis Plan	version 9	13/12/2022	04/01/2023	No	No