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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

Registration date
22/02/2018

Overall study status
Completed

Last Edited
18/11/2025

Condition category
Other

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] 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

Contact information

Type(s)
Scientific

Contact name
Prof David Osrin

ORCID ID
https://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
https://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

Clinical Trials Registry - India (CTRI)
CTRI/2018/02/012047

Protocol serial number
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

Primary study design
Interventional

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

Study type(s)
Prevention

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(s)
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

Key secondary outcome(s)
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)

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

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
United Kingdom

England

India

Study participating centre
UCL Institute for Global Health
30 Guilford Street
London
England
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

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

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?
Results article	cross-sectional survey results	16/12/2020	18/12/2020	Yes	No
Results article			18/11/2025	Yes	No
Protocol article	version 9	17/12/2019	19/12/2019	Yes	No
Statistical Analysis Plan		13/12/2022	04/01/2023	No	No
Study website		11/11/2025	11/11/2025	No	Yes