

Cluster randomized trial of community based trauma healing on sexual and physical violence victimization of women and perpetration by men in the Democratic Republic of Congo

Submission date 02/09/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/09/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/11/2024	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

We evaluate the impact of a Community Based Trauma Healing (CBTH) implemented in Eastern the Democratic Republic of the Congo (DRC) by Search for Common Ground (SFGC) as part of a wider program, that aims to reduce Gender-Based Violence.

The program recruited local Community Trauma Healers that were trained and supported by SFGC to organize community sessions and celebrations. During the session, the program aims to help community members heal from post-conflict trauma resulting from, among other things, death, injury, (systematic) rape, indigenous conflict, internal displacement, and inheritance conflicts. These community “detraumatisme” sessions bring together (potential) victims, perpetrators, traditional leaders, and faith-based leaders. CBTH teaches community members strategies to control emotions, and reduce risks of GBV.

We use a cluster-randomized trial to evaluate the impact of CBTH in 80 randomly selected communities in Eastern DRC using detailed baseline and follow-up surveys involving 20 respondents per community. Our core outcome of interest is reported incidence of sexual or physical Intimate Partner Violence (IPV) and sexual or physical non-partner victimization experienced by women and perpetration by men.

A primary mechanism is respondent mental health, comprising validated scales relating to depression and anxiety as well as trauma. As secondary outcomes also report impacts on individual coping and attitudes and social cohesion.

Why can participate?

All residents of selected villages

What does the study involve?

Villages are randomly allocated to either the CBTH intervention or the control group. As part of

the CBTH intervention, in each village a Trauma Healing Champions (THC) was recruited and trained which then helped organise trauma healing sessions bringing together 20-25 interested people from the village, each session span across three days, meeting for about 2-3 hours each day. Separate sessions were organized for men and women. Using the facilitation guide THC's facilitate each session to enable participants to identify incidents that affect their personality and cause them trauma. In addition, people were invited to participate in village celebrations to share experiences.

What are the possible benefits and risks of participating

Potential benefits include reduction in risk of IPV or non-partner sexual or physical victimization, a reduction of stress and anxiety, PTSD, increased take up of services, increased self efficacy, individual and community resilience, gender equitable attitudes.

This intervention does not pose a threat to participant physical or emotional wellbeing.

However, but it is possible that participants suffer loss of privacy or be stigmatized in some way due to participation. Trauma Healing Champions are trained and supervised to help mitigate distress arising from participating.

Where is the study run from?

Villages in the Democratic Republic of Congo

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

September 2018 to July 2021

Who is funding the study

United States Agency for International Development

Who is the main contact

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Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

18.08.13

Study information

Scientific Title

Impact evaluation of Community Based Trauma Healing in the Democratic Republic of Congo

Acronym

CBTH

Study objectives

Hypothesis 1A: Community Based Trauma Healing decreases past-year reported physical and sexual IPV victimization for women

Hypothesis 1B: Community Based Trauma Healing decreases reported past-year non partner physical and sexual violence victimization for women

Hypothesis 1C: Community Based Trauma Healing decreases reported past-year physical and sexual IPV perpetration by men

Hypothesis 1D: Community Based Trauma Healing decreases reported past-year non partner physical and sexual violence perpetration by men

While CBTH is expected to decrease the incidence GBV, the program may also change propensity of people to speak out about GBV. An observed shift in reported CBV may reflect both changes in incidence as well as changes in reporting about incidence. These forces may work in opposite directions. While it is impossible to fully determine what is causing the observed changes in our measures of GBV, to help interpretation, we also look at if CBTH changes respondent: reported incidence on other traumas not related to GBV, reported willingness to intervene, changes in GBV attitudes, changes in tolerance for violence.

Hypothesis 2A: Community Based Trauma Healing decreases depression and anxiety (Hopkins Symptom Depression and Anxiety Checklist)

Hypothesis 2B: Community Based Trauma Healing decreases PTSD (Harvard Trauma Scale)

Hypothesis 3: Community Based Trauma Healing increases Self Help Actions

Our secondary hypotheses are:

Hypothesis 4: Community Based Trauma Healing decreases past-year reported emotional IPV victimization for women

Hypothesis 5A: Community Based Trauma Healing increases Self Efficacy

Hypothesis 5B: Community Based Trauma Healing increases Individual Resilience

Hypothesis 6: Community Based Trauma Healing increases Gender Equitable Attitudes

Hypothesis 7: Community Based Trauma Healing increases Community Resilience

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 09/10/2018, NORC Institutional Review Board (55 East Monroe Street, Chicago, IL, USA; +1 773-256-6000; no email provided), ref: IRB00000967, Project Number 7554.059.01, IRB Protocol Number 18.08.13

Study design

Cluster randomized trial

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Reduction of sexual and physical IPV and non partner victimization

Interventions

Intervention: Community Based Trauma Healing in DRC

We evaluate the impact of Community Based Trauma Healing (CBTH), a program implemented in Eastern DRC, as a core strategy to help strengthen community capacity to support the trauma healing process and increase individual mental health, and reduce GBV in a (post)-conflict context. CBTH was part of a wider Tushinde Ujeuri programme activities that were targeting communities in Nyangezi, Katana and Walikale Health Zones in Eastern DRC. These other activities included legal support (such as a legal clinic, legal aid, working with a paralegal), medical support (such as visiting a health center, training of service providers, care and services for GBV survivors, family planning services), psychological support (such as speaking to a service provider or counselor) and economic support (village savings and loan programs or microcredit) and were available to all communities in the Health Zones.

During January 2019 - December 2020, in 80 randomly selected villages, Search for Common Ground (SFCG) implemented the CBTH program. At its core CBTH includes several steps:

1. Recruiting Trauma Healing Champions. In each community, SFCG recruited and trained local mobilizers, so called Trauma Healing Champions (THCs). Identification and training of THC occurred between January and March 2019. As eligibility criteria these should be a member of the community; are trusted by community members; have meeting facilitation skills, should be sensitive of issues related to equitable representation of the local population (for instance, ensuring that multiple tribes and religions are represented); know the conflict issues and GBV issues that affect the community welfare; be a leader for the community; should be inclusive and exert effort to include victims of: past rape, indigenous conflict, internal displacement and inheritance conflicts, traditional leaders and faith-based leaders, taking into account all sensitivities; and be able to read and write. To select candidates SFCG convened a public forum where the selection criteria were explained, and the community selected their THC. Prior to this selection forum, SFCG field assistants sensitized different people in the community to explain the approach and the purpose of the public forum so that everyone was prepared and all had a chance to participate.

2. Training local mobilizers. The local THC were then trained on trauma healing, GBV, conflict resolution and community participatory facilitation techniques, by SFCG staff using a CBTH manual. To train THCs, SFCG conducted several training workshops gathering together several

THC from nearby communities. Each training lasted several days and included extensive practice and assessment. Over the course of the project, several refresher training was organized to refreshing the skills of the THC, share experiences and update the facilitation materials if required.

3. CBTH facilitated sessions. Over the project period, THC then held trauma healing (TH) sessions about each month for a total of 12 sessions. The COVID-19 pandemic caused disruption in implementation, especially during April – August 2020. Each TH session brought together 20-25 interested persons from the community, each session span across three days, meeting for about 2-3 hours each day. Separate sessions were organized for men and women. Using the facilitation guide THCs facilitate each session to enable participants to identify incidents that affect their personality and cause them trauma. They also aimed to help participants understand the signs of trauma, think about healing and solutions, and understand psychosocial services and other forms of support that exist in the community or near the community. Discussions included gender and conflict-related issues as well as other trauma-related factors. The facilitator aimed to foster open dialogues to allow participants to feel comfortable sharing their experiences. These discussions are as engaging as possible, for example using stories telling, where facilitators drew from local myths, legends or the Bible / Quran to inspire and provide hope and relief. Participants requiring additional support were referred to medical, judicial and mediation as relevant. THC also served as local and community references and resource persons to help support other community members being confronted with trauma issues.

4. Community Celebrations. During the programming period, SFCG organized eight cultural public events for CBTH participants from several communities, organized in a central location in each Health Zone. These events take the form of a festival, traditional celebration of dances, drum, music, meal-hut, etc. SFCG engaged with the community to make sure the content reflects community preferences and is implemented as a community-led initiative. GBV and conflicts issues are integrated in an edutainment program, where the emphasis is on enjoyment and building community cohesion and engagement to surpass trauma healing issues and open safe space to survivors. During the celebrations, voluntary testimonies of former victims are encouraged.

We use the Stata Package "randomize" (Kennedy and Mann, 2017) to block assign 160 villages to either receive the CBTH intervention (treatment) or no CBTH intervention (control). We block the randomization on health area, implying we randomly assign 50% of villages in each of the 40 health areas across 3 health zones (Katana, Nyangezi, Walikale) to receive the CBTH intervention.

Intervention Type

Behavioural

Primary outcome(s)

All outcomes measured at baseline and post-intervention (1.5 years since programming started):

1. Past-year IPV physical and sexual victimization (women) measured by bespoke questionnaire
2. Past-year non-partner physical and sexual violence victimization (women) measured by bespoke questionnaire
3. Past-year physical and sexual IPV perpetration (men) measured by bespoke questionnaire
4. Past-year non-partner physical and sexual violence perpetration (men) measured by bespoke questionnaire

Key secondary outcome(s)

All outcomes measured at baseline and post-intervention (1.5 years since programming started):

1. Depression and anxiety measured using the Depression and Anxiety Scale
2. PTSD measured using the 16-item Harvard Trauma Questionnaire (HTQ-16)

3. Service uptake measured using a bespoke questionnaire
4. Emotional IPV measured using a bespoke questionnaire
5. Individual Resilience (relational) measured using a bespoke questionnaire
6. Gender equitable attitudes measured using a bespoke questionnaire
7. Community Resilience (relational) measured using a bespoke questionnaire

Completion date

01/07/2021

Eligibility

Key inclusion criteria

All residents from selected villages are eligible to participate

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

2400

Key exclusion criteria

Residents outside randomly selected 80 villages

Date of first enrolment

01/01/2019

Date of final enrolment

31/12/2020

Locations

Countries of recruitment

Congo, Democratic Republic

Study participating centre**Selected villages in Eastern DRC**

Nyangezi, Katana and Walikale Health Zones in Eastern DRC

NA
Congo, Democratic Republic
NA

Sponsor information

Organisation

University of Chicago

ROR

<https://ror.org/024mw5h28>

Funder(s)

Funder type

Government

Funder Name

United States Agency for International Development

Alternative Name(s)

U.S. Agency for International Development, Agency for International Development, USAID

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Funder report results		01/08/2022	11/11/2024	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes