ISRCTN17659369 https://doi.org/10.1186/ISRCTN17659369

# Evaluating how the community-based social healing intervention improves Ubuntu in post genocide Rwanda

**Submission date**
29/01/2024

**Recruitment status**
No longer recruiting

**Registration date**
09/02/2024

**Overall study status**
Completed

**Last Edited**
19/11/2024

**Condition category**
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
The Community-Based Social Healing model was created and is being implemented by the Ubuntu Centre for Peace, a non-profit organization that strives to bring people living with trauma and common mental health conditions to a more flourishing life.
This study aims:
1. To adapt and psychometrically test the reliability and validity of an existing Ubuntu scale in the Rwandan context
2. To investigate whether the Community-based Social Healing model has an impact on mental health, wellbeing, social capital, resilience, intimate partner violence and psychosomatic symptoms
3. To examine whether Ubuntu mediates the impact of Community-Based Social Healing on mental health and mental wellbeing, social capital resilience, intimate partner violence and psychosomatic symptoms

Who can participate?
Everyone who is recruited by the Community Healing Assistants for eventual participation is eligible unless they are unable to communicate or less than 18 years of age. Those who have previously gone through Community-Based Social Healing intervention or similar will not be eligible. According to the target categories of the community-based social intervention, the participants will be people with trauma, depression, anxiety symptoms and those who often have family conflicts.

What does the study involve?
The participants of this study will be asked to participate in the first round of quantitative data collection in March 2024 and the second round in June 2024. They will be asked standardized questionnaires on Ubuntu, mental health, mental well-being, social capital, resilience, intimate partner violence and psychosomatic symptoms. The interviews will take about 45 minutes. After the baseline data collection, villages will be randomly allocated to either receive the intervention straight away or to be put on a waiting list.
The CBSH model includes breath-centered mind-body practices, collective narratives in a safe

place, and rituals. These sessions are provided by Community Healing Assistants (CHAs) who are recruited community members. The CHAs receive a 6-week training that covers the basic concepts of trauma and common mental conditions, breath-body-mind practices, and data collection. They are also equipped with group facilitation skills and then facilitate healing practices through therapeutic groups. The CHAs are supervised and mentored by professional psychologists. Each therapeutic group comprises 18-20 people who meet once a week for 2-3 hours, over 15 weeks. They then transition to long-term support or self-help groups and create additional socio-economic activities including lending circles, solidarity work, and business or farming cooperatives to sustain healing, health, and resilience.

What are the possible benefits and risks of participating?
There are no guaranteed direct benefits of the study. No compensation will be given to participants. The responses will contribute to advancing the understanding of the impact of the Community-Based Social Healing model on Ubuntu. The results of this study will inform the decision of health practitioners and policymakers to scale up this intervention to all Rwandans in need as well as other countries.
The researchers do not foresee any risks associated with participation in this research, but the questions asked about their personal lives might make the participants feel uneasy.

Where is the study run from?
The study will take place in villages local leaders' meeting places in the randomly selected villages in Kirehe District in the East province of Rwanda

When is the study starting and how long is it expected to run for?
November 2023 to August 2024

Who is funding the study?
Trauma Research Foundation (UK) through Ubuntu Centre for Peace

Who is the main contact?
Prof. Stefan Jansen, sjansen.ur@gmail.com

# Contact information

### Type(s)
Public, Scientific, Principal Investigator

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
Nil known

# Study information

### Scientific Title
Examining how community-based social healing improves Ubuntu in post-genocide Rwanda: a pilot cluster randomized control trial

### Acronym
ECBSHubu

### Study objectives
1. Community-based social healing (CBSH) model improves Ubuntu
2. CBSH model improves mental health and wellbeing, social capital, resilience and reduces intimate partner violence and psychosomatic symptoms
3. Ubuntu mediates the impact of CBSH on mental health and wellbeing, social capital, resilience and reduces intimate partner violence and psychosomatic symptoms

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 23/01/2024, Institutional Review Board (IRB) of the College of Medicine and Health Sciences at the University of Rwanda (PO Box 3286, Kigali, 0000, Rwanda; +250 (0)781884895; researchcenter@ur.ac.rw), ref: 111/CMHS IRB/2024

### Study design
Cluster randomized control trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Community

### Study type(s)

Quality of life, Treatment

## Participant information sheet
See study outputs table

## Health condition(s) or problem(s) studied
Improving ubuntu way of living, mental health, mental well-being, social capital, resilience and reducing intimate partner violence and psychosomatic symptoms

## Interventions
The CBSH model includes breath-centered mind-body practices, collective narratives in a safe place, and rituals. These sessions are provided by Community Healing Assistants (CHAs) who are recruited community members. The CHAs receive a 6-week training that covers the basic concepts of trauma and common mental conditions, breath-body-mind practices, and data collection. Additionally, they are equipped with group facilitation skills and then facilitate healing practices through therapeutic groups. The CHAs are supervised and mentored by professional psychologists. Each therapeutic group comprises 18-20 people who meet once a week for 2-3 hours, over 15 weeks. They then transition to long-term support or self-help groups and create additional socio-economic activities including lending circles, solidarity work, and business or farming cooperatives to sustain healing, health, and resilience.

From a list of 612 villages of Kirehe District in the East Province Rwanda, 54 villages (27 intervention group and 27 control group) calculated using the Optimal Design Software) will be randomly selected using Microsoft Excel. Selected village clusters will be randomly allocated to case and control: To minimize spillover, CBHS groups belonging to one village will altogether be allocated to either the case group (i.e., ones receiving the CBSH intervention) or to the control group (i.e., waiting for the intervention). The randomization into case or control will be done using Microsoft Excel. The random assignment of the villages to either case or control group will be done at the level of the villages after all participants have been selected. Each pair of CHAs will have selected participants in two villages, i.e., their own village and a random other village. Randomization into case and control is done for each pair of villages that are allocated to a pair of CHAs. Pairs of CHAs will be randomly allocated to a case village. Given the randomization process, CHAs will have equal chances of serving their own village or another village for whom they selected the participants. No placebo treatment is offered to the control group.

## Intervention Type
Behavioural

## Primary outcome measure
Ubuntu is measured using Ubuntu measurement scale developed by Itayi Mutsonziwa's yet-to-be-published PhD thesis and the Ubuntu scale by Terblanche-Greeff and Nel for convergent validity. Ubuntu will be measured at baseline data collection (before the intervention), endline 1 (after 15 weeks of intervention) and at endline 2 (after 12 months of the intervention).

## Secondary outcome measures
Measured at baseline data collection (before the intervention), endline 1 (after 15 weeks of intervention) and at endline 2 (after 12 months of the intervention):
1. Socio-demographic characteristics measured using the sociodemographic questionnaire (age, sex, marital status, profession and location)
2. Mental health assessed using:
2.1. The Patient Health Questionnaire (PHQ-9) for depression

2.2. The Generalized Anxiety Disorder (GAD-7) assessment for anxiety
2.3. The Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5) for posttraumatic stress disorder
3. Mental wellbeing assessed using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWS)
4. Social capital measured using the Adapted Social Capital Assessment Tool (SASCAT)
5. Resilience assessed using the 10 items Connor-Davidson Resilience scale (CD-RISK-10)
6. Intimate partner violence assessed using the Revised Conflict Tactics Scale short form (CTS2S SHORT FORM)
7. Psychosomatic symptoms assessed using the Patient Health Questionnaire 15-item Somatic Symptom Severity Scale (PHQ-15)

### Overall study start date
01/11/2023

### Completion date
31/08/2024

## Eligibility

### Key inclusion criteria
1. 18 years and older
2. Recruited by the Community Healing Assistants
3. Residing in Kirehe district during the study period

### Participant type(s)
Population

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Given the limited available data of the effect size of the intervention on the primary outcomes, the current study aims to detect a medium effect size (Cohen's d = 0.35). Building from insights from similar community-based interventions, an estimated Intraclass Correlation of Rho = 0.15 has been identified. Drawing from previous experience, it has been noted that, on average, 3 out of 20 participants within a group discontinue the intervention before fulfilling the requirement of 15 sessions. Employing a standard Alpha = 0.05, a priori power calculations conducted using the Optimal Design Software for Multilevel and Longitudinal Research indicate that a total of 54 groups (27 control and 27 intervention), each consisting of 20 participants, would yield the desired standard power of 0.80 (Raudenbush, 1997). In anticipation of potential attrition-related challenges, each of the initially recruited 20 participants will undergo an interview process, ultimately aiming to achieve a final sample size of up to 1080 participants. This estimation

accounts for an anticipated response rate of 96%. The sample size of 1080 will also suffice for other planned analyses including structural equation modeling and the linear mixed effect model analyses.

### Key exclusion criteria
1. Candidates who are unable to communicate, with hearing and speech disability with no translator
2. Candidates who are mentally and intellectually incapacitated and are unable to understand and respond to the questions
3. People who have already participated in CBSH intervention or similar

### Date of first enrolment
05/02/2024

### Date of final enrolment
20/02/2024

## Locations

### Countries of recruitment
Rwanda

### Study participating centre
**Community centers in 54 randomly selected villages in Kirehe District in the East province of Rwanda**
Kirehe
Rwanda
-

## Sponsor information

### Organisation
University of Rwanda

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### Sponsor type
University/education

**Website**
https://ur.ac.rw/

**ROR**
https://ror.org/00286hs46

# Funder(s)

**Funder type**
Charity

**Funder Name**
Trauma Research Foundation

# Results and Publications

**Publication and dissemination plan**
Publications in high-impact peer-reviewed journals are planned. The researchers will also disseminate locally at the community and policy levels.

**Intention to publish date**
31/08/2025

**Individual participant data (IPD) sharing plan**
The data-sharing plans for the current study are unknown and will be made available at a later date

**IPD sharing plan summary**
Data sharing statement to be made available at a later date

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | English | | 31/01/2024 | No | Yes |
| Participant information sheet | Kinyarwanda | | 31/01/2024 | No | Yes |
| Protocol article | | 16/11/2024 | 19/11/2024 | Yes | No |