

# Evaluation of the impact of Community-Based Sociotherapy on social dignity among beneficiaries dealing with the consequences of genocide in Rwanda

<b>Submission date</b> 02/04/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 13/05/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/03/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English Summary

### Background and study aims

The Community Based Sociotherapy (CBS) program is one of the programs initiated in Rwanda to help people deal with the consequences of the 1994 genocide against the Tutsi.

Main aim: To evaluate whether CBS improves social dignity, mental health and psychosocial wellbeing among beneficiaries.

### Who can participate?

Everyone who is recruited by the sociotherapist for eventual participation is eligible unless they are unable to communicate. Those who have gone through Community-Based Sociotherapy in previous programs will not be eligible. According to target categories in sociotherapy program, the selected respondents will either be a genocide survivor, perpetrator, bystanders, their descendants, and leaders in districts where sociotherapy is being implemented.

### What does the study involve?

The participants in this study will be asked for two rounds of quantitative data collection (in July and November 2022). In addition to standardized questionnaires on mental health and psychosocial wellbeing, a number of questions will be asked related to everyday life like trust, care, respect, safety, perceived social support, traumatic events, reconciliation, family and social relationships. The interviews will take about 45 minutes. Half of the participants will be randomly allocated to the intervention group, i.e. they will receive Community-Based Sociotherapy treatment; the other half will be allocated to the control group who receive no treatment.

### What are the possible benefits and risks of participating?

There is no compensation associated with participating in this study. The answers will contribute to advancing the understanding of the impact of Community Based Social Therapy on social dignity among Rwandans. Based on the answers, the results of this study will inform the decision of practitioners and policy makers to scale up this intervention to more participants and beyond.

This can also inform decision makers in designing adequate services that respond to the real need felt by people. There is no risk associated with participating in this study except perhaps some discomfort that may be felt as they share about their personal lives.

Where is the study run from?

The study will be carried out in meeting places in the community in ten districts of Rwanda: Gasabo, Karongi, Rubavu, Rulindo, Burera, Gatsibo, Gicumbi, Nyanza, Muhanga, Nyamagabe.

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

March 2022 to November 2022

Who is funding the study?

Community-Based Sociotherapy (Rwanda)

Who is the main contact?

Prof. Stefan Jansen, [sjansen.ur@gmail.com](mailto:sjansen.ur@gmail.com)

## Contact information

### Type(s)

Principal Investigator

### Contact name

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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**

A cluster randomized controlled trial evaluating the impact of Community-Based Sociotherapy on social dignity among beneficiaries dealing with the consequences of genocide in Rwanda

## **Acronym**

ECoSoDi

## **Study hypothesis**

1. Community-Based Sociotherapy improves social dignity among beneficiaries
2. Community-Based Sociotherapy improves mental health and psychosocial wellbeing among beneficiaries.
3. Community-Based Sociotherapy impact on social dignity is mediated by the improvement of mental health and psychosocial wellbeing.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 14/04/2022, Institutional Review Board (IRB) of the College of Medicine and Health Sciences at the University of Rwanda (PO Box 3286, Kigali, Rwanda; no telephone number provided; researchcenter@ur.ac.rw), ref: 269/CMHS IRB/2022

## **Study design**

Two-level cluster randomized controlled trial

## **Primary study design**

Interventional

## **Secondary study design**

Cluster randomised trial

## **Study setting(s)**

Community

## **Study type(s)**

Treatment

## **Participant information sheet**

See additional files

## **Condition**

Mental health and psychosocial wellbeing

## **Interventions**

This study uses a two-level cluster randomized controlled trial design with person-level outcomes and treatment delivered at the cluster level. It will be a two-arm study. The allocation fraction will be 1:1 intervention and control. One arm will serve as a control (control) while the other will receive the Community-Based Sociotherapy (CBS) treatment (case). Recruitment of participants will be performed by CBS facilitators. Out of the total number of groups that are recruited by CBS facilitators, eighty groups will be randomly selected following a computer-

generated random sequence. The eighty groups will then be randomly allocated to case or control. Data will be collected just before and after the intervention. The data collectors will not be blinded on allocation to case and control, and neither will the study participants, as in reality study participants become aware to which group they belong and they typically share this with the data collectors.

CBS is a group therapeutic approach and involves genocide survivors, perpetrators, bystanders, their descendants, and leaders. In this approach, sociotherapy groups of fifteen people that live in the same neighborhood meet weekly for approximately three hours over a period of fifteen weeks guided by CBS facilitators. In sociotherapy groups people speak primarily about problems in present-day everyday life. When these problems mirror the past, the past may also be addressed. The case group will receive the full CBS treatment. The control group will receive no treatment whatsoever (but will be put on a waiting list). Allocation in case and control will be done on a cluster level and will be computer-generated.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Social dignity as measured by a total score of Social Dignity Scale before and after the CBS intervention (baseline and 15 weeks)

### **Secondary outcome measures**

Measured before and after the CBS intervention (baseline and 15 weeks):

1. Sociodemographic characteristics measured using a sociodemographic questionnaire
2. Personal wellbeing measured using the WHO (Five) Well-Being Index
3. Perceived social support measured using the Multidimensional Scale of Perceived Social Support
4. Traumatic events measured using the Life Events Trauma Questionnaire
5. PTSD symptoms measured using the PTSD Checklist for DSM-5
6. Mental disorders measured using the Self-reporting Questionnaire (SRQ-20)
7. RECONCILIATION measured using a self-designed reconciliation scale

### **Overall study start date**

09/03/2022

### **Overall study end date**

11/11/2022

## **Eligibility**

### **Participant inclusion criteria**

According to target categories in sociotherapy program, the selected respondents will either be a genocide survivor, perpetrator, bystanders, their descendants, and leaders in districts where sociotherapy is being implemented. The evaluation will include both male and female respondents and respondents of all ages above 18 years old.

### **Participant type(s)**

Other

### **Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

An a priori sample size calculation revealed that 80 groups (40 control and 40 intervention) of 12 participants each would make it possible to achieve the standard power of .80 while detecting a small Cohen's d effect size of .3 with an intraclass correlation of  $Rho=0.15$ . To provide a buffer against potential attrition-related problems, each of the 15 recruited participants will be interviewed making the final sample size to recruit up to 1200 participants, assuming a response rate of 96%.

**Participant exclusion criteria**

Everyone who is recruited by the sociotherapist for eventual participation is eligible unless they are unable to communicate.

In addition, those who have gone through Community-Based Sociotherapy in previous programs will not be eligible.

**Recruitment start date**

01/06/2022

**Recruitment end date**

30/06/2022

## Locations

**Countries of recruitment**

Rwanda

**Study participating centre**

The study will be carried out in community centers in ten districts: Gasabo, Karongi, Rubavu, Rulindo, Burera, Gatsibo, Gicumbi, Nyanza, Muhanga, Nyamagabe.

Kigali

Rwanda

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## Sponsor information

**Organisation**

University of Rwanda

## Sponsor details

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## Sponsor type

University/education

## Website

<https://ur.ac.rw/>

## ROR

<https://ror.org/00286hs46>

## Funder(s)

### Funder type

Other

### Funder Name

Community Based Sociotherapy Rwanda

## Results and Publications

### Publication and dissemination plan

Planned publications in high-impact peer-reviewed journals. We will also disseminate locally at community and policy levels. And we provide detailed feedback to CBS.

### Intention to publish date

06/05/2023

### 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?
<a href="#">Participant information sheet</a>	English version		28/04/2022	No	Yes

<a href="#">Participant information sheet</a>	Kinyarwanda version	28/04/2022	No	Yes	
<a href="#">Protocol article</a>		20/12/2022	30/03/2023	Yes	No