ISRCTN11199072 https://doi.org/10.1186/ISRCTN11199072

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

Submission date
02/04/2022

Recruitment status
No longer recruiting

Registration date
13/05/2022

Overall study status
Completed

Last Edited
30/03/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
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

Contact information

Type(s)
Principal investigator

Contact name
Prof Stefan Jansen

ORCID ID
https://orcid.org/0000-0001-5293-1673

Contact details
University of Rwanda
Kigali
Rwanda
-
+250 784575900
s.jansen@ur.ac.rw

Additional identifiers

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 objectives
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

Primary study design
Interventional

Study design
Two-level cluster randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
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(s)

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

Key secondary outcome(s)
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

Completion date
11/11/2022

Eligibility

Key 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key 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.

Date of first enrolment
01/06/2022

Date of final enrolment
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
-

Sponsor information

Organisation
University of Rwanda

ROR
https://ror.org/00286hs46

Funder(s)

Funder type
Other

Funder Name
Community Based Sociotherapy Rwanda

Results and Publications

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?
Protocol article		20/12/2022	30/03/2023	Yes	No
Participant information sheet	English version		28/04/2022	No	Yes
Participant information sheet	Kinyarwanda version		28/04/2022	No	Yes