ISRCTN25356068 https://doi.org/10.1186/ISRCTN25356068

Evaluating the impact of community based sociotherapy on social dignity in post-conflict contexts: two-arm cluster randomized controlled trial

Submission date
22/12/2025

Recruitment status
No longer recruiting

Registration date
23/12/2025

Overall study status
Ongoing

Last Edited
22/12/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Severe conflicts in the Great Lakes Region have inflicted profound psychological and social scars across multiple countries. In Rwanda, the 1994 genocide against the Tutsi unleashed extreme violence with lasting consequences, forcing survivors and perpetrators to coexist in many communities after genocide-related prisoners were released. Similarly, Northern Uganda, particularly among the Acholi in Gulu District, endured decades of violence during the Lord's Resistance Army (LRA) conflict, marked by abductions, displacement, and severe trauma. Despite the end of active hostilities, communities continue to experience high rates of post-traumatic stress disorder (PTSD), depression, and other mental health challenges that affect individuals, families, and social cohesion. In neighboring Burundi, conflict and violence have also deeply impacted communities, especially in provinces like Buhumuza and Gitega, where unrest and political instability have led to displacement, trauma, and challenges in rebuilding social networks and trust among affected populations. Together, these conflicts highlight a regional legacy of trauma and the urgent need for healing and reconciliation initiatives.

In response, Community-Based Sociotherapy (CBS), originally developed in Rwanda, seeks to restore social fabric and mitigate trauma via participatory, community-level healing processes. Although CBS shows promise, causal evidence of its effectiveness remains limited in post-conflict settings like Northern Uganda. This cluster randomized controlled trial (CRCT) will generate rigorous, large-scale evidence on whether CBS enhances psychosocial well-being and bolsters social dignity.

This study aims:
1. To evaluate whether the CBS intervention improves social dignity
2. To evaluate whether the CBS intervention improves mental health and psychosocial well-being
3. To evaluate whether the CBS intervention improves social cohesion
4. To investigate whether CBS's impact on social dignity mediates changes in mental health, psychosocial well-being, and social cohesion

Who can participate?
Participants are recruited through CBS facilitators. The participants should be 18 years old and above, residing in the selected districts of Rwanda where the Community-Based Sociotherapy (CBS) is currently implemented. Both men and women are eligible, regardless of their socio-economic status. Individuals must be willing to provide informed consent and commit to attending the CBS meetings over the 15-week intervention period. The study population spans various demographic characteristics, including different marital statuses, locations, educational backgrounds, and occupations. Those unable to provide informed consent, or those presenting with severe cognitive impairment or acute mental health conditions that would prevent meaningful engagement in the sessions will be excluded. Additionally, individuals already participating in other structured psychosocial or clinical intervention studies are ineligible. To minimize contamination effects, individuals participating in different randomized groups will be recruited from non-neighboring cells.

What does the study involve?
This study is a cluster randomized controlled trial (CRCT) conducted in three countries: Rwanda, Uganda and Burundi. The groups of participants (clusters) are randomly assigned to receive Community-Based Sociotherapy (CBS) or to serve as control groups. CBS is a group-based program in which participants meet weekly for 15 sessions to build trust, respect, care, and shared problem-solving skills together in a safe group setting. In Uganda and Burundi, the trial uses a two-arm design, with clusters randomly allocated either to the intervention arm (receiving CBS) or to a control arm that serves as a benchmark for natural changes over time. In Rwanda, the same CBS intervention and control condition are implemented, but an additional third arm is included: one control arm receives baseline and follow-up assessments, while another control arm does not complete baseline assessments. This extra arm in Rwanda is designed to test whether taking part in baseline interviews alone has a therapeutic or measurement effect (for example, by increasing self-awareness or expectancy) that could influence outcomes. Data are collected at four time points—before the intervention begins (baseline), immediately after the 15-week intervention, six months later, and twelve months later—to capture both short-term and longer-term effects of CBS across all sites.

What are the possible benefits and risks of participating?
Possible Benefits: The CBS sessions provide participants with opportunities to strengthen their interpersonal and intrapersonal life skills, develop trust, and practice constructive ways of engaging with others, which is expected to enhance resilience and community cohesion. The study aims to directly improve social cohesion, dignity, and mental well-being in communities affected by trauma and social fragmentation.
Possible Risks: There is no known adverse event or harm directly associated with participating in the study itself. However, given the post-genocide context and the sensitive nature of the questions asked during interviews, participants may experience emotional distress.
Risk Management: To manage this potential distress, specific protocols have been developed:
• An Adverse Event (AE) Reporting Protocol.
• A Distress Management Protocol to guide staff in recognizing and responding to discomfort during interviews or CBS sessions.
• A Re-traumatization Management and Reporting Protocol.
A dedicated team of mental health experts located at the nearest health facility will be available to provide timely psychological support or referral if necessary.

Where is the study run from?
The trial is conducted in three East African countries: Rwanda, Uganda, and Burundi.
- Rwanda: The community centres within seven districts: Rwamagana, Gasabo, Ruhango, Rutsiro,

Nyamasheke, Gatsibo and Burera.
- Uganda: Residents of Bulalo, Awach, Owalo, Bongatira, and Owoo Sub Counties in Gulu District
- Burundi: 1. Province Buhumuza: commune Butihinda, Muyinga, 2. Province Gitega: commune Gitega, Giheta, Bugendana

When is the study starting and how long is it expected to run for?
The trial in Rwanda is scheduled to be conducted from October 2025 to March 2027. The CBS intervention itself consists of 15 weekly sociotherapy sessions. Data collection will be conducted at 4 different time points including baseline assessment before intervention, endline 1 to be conducted immediately after CBS intervention, endline 2 to assess short term impact at 6months post intervention and endline 3 to assess longterm effect at 12 months post intervention.

Who is funding the study?
Embassy of the Kingdom of the Netherlands in Kigali, Rwanda

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
Evaluating the impact of community based sociotherapy on social dignity in post-conflict contexts: two-arm cluster randomized controlled trial

Acronym
CBSRCT

Study objectives

1. To evaluate whether the CBS intervention improves social dignity
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Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 08/10/2025, Rwanda National Ethics Committee (RNEC) (KN 3 RD, Kicukiro, Kigali, +250, Rwanda; +250 788592004; info@rnecrwanda.org), ref: RNEC953/2025

2. Submitted 04/12/2025, Lira University Research Ethics Committee (LUREC) (Gulu, Gulu, +25, Uganda; +256 702065885; research@uncst.go.ug), ref: LUREC-2025-481

Primary study design
Interventional

Study design
Interventional cluster randomized controlled trial

Study type(s)
Quality of life, Treatment

Health condition(s) or problem(s) studied
Improving social dignity, mental health, and social cohesion.

Interventions
Community-based sociotherapy (CBS) is one of the programs implemented in the post-genocide Rwandan social landscape to contribute to this recovery (Dekker, 2018; Ingabire et al., 2017; Jansen et al., 2015; Richters et al., 2008). Over the past 20 years, CBS has been meticulously adapted to the Rwandan context based on observations of its practice and findings of ongoing qualitative research, allowing it to resonate deeply with local cultural and social nuances (Ingabire et al., 2022).

CBS operates in geographically defined places, primarily neighborhoods where people live together. It is practiced in sociotherapy groups (socio-groups) of, on average, ten to fifteen people. Groups meet weekly for approximately three hours over a period of fifteen weeks in a location within the participants' direct living environment that they experience as safe.

Group members are identified and invited by facilitators who originate from the communities where CBS is applied. The presumption is that they have a profound understanding of the social dynamics and cultural sensitivities in the area where they facilitate groups. The approach builds on local capacity available in the setting of its implementation. This implies, for instance, having trained prisoners in prisons, refugees in refugee settings, and students and staff in a university to facilitate the socio-groups in that specific setting. These facilitators know the living conditions of their fellow community members, are aware of who is in need of psychosocial support, and are often familiar with the historical events that took place in a community or someone's life. Facilitators are progressively trained—basic, intermediate, and advanced—to build their capacity to facilitate socio-groups and serve their living environment in general.

Sociotherapy facilitators take the group through a sociotherapy journey of six phases: safety, trust, care, respect, new life orientations, and processing emotional memories. These phases create a safe space that allows people to explore and share their feelings about day-to-day experiences. The focus is on helping each other find authentic and culturally appropriate ways of interacting with (or relating to) their families and neighbors. In the first few weekly sessions, confrontation with painful memories about the past is not encouraged. The focus is primarily on actual daily life problems—including poverty issues, family conflicts, health issues, mistrust among neighbors, and practically reengaging with everyday life. It is usually only after some group sessions, when an atmosphere of safety, trust, and mutual respect has been established, that painful memories of the past are shared.

The CBS methodology is further grounded in seven guiding principles: interest, equality, democracy, here and now, responsibility, participation, and learning by doing. These principles are actively embodied in each session to promote meaningful engagement, enhance group dynamics, and foster mutual understanding. Through its integrative approach, CBS functions as a platform for rebuilding dignity, trust, and shared humanity in post-genocide Rwanda, aligned with the main goal of CBS as formulated at its inception in Rwanda in 2005: “to restore people’s dignity and create connectedness” (Richters et al., 2008, p. 109).

Intervention Type
Behavioural

Primary outcome(s)
Social dignity is measured using the psychometrically validated Social Dignity Scale_35 items at the baseline data collection (before the intervention), endline 1 (immediately post-intervention), endline 2 (6-month post- intervention) and endline 3 (12-month post- intervention).

Key secondary outcome(s)
Measured at the baseline data collection (before the intervention), endline 1 (immediately post-intervention), endline 2 (6-month post- intervention) and endline 3 (12-month post-intervention):
1. Personal well-being: WHO-5 Well-Being Index
2. PTSD symptoms: PTSD Checklist for DSM-5 (PCL-5) with the Life Events Checklist (LEC)
3. Alcohol use: Alcohol Use Disorders Identification Test (AUDIT)
4. Psychosomatic symptom burden: Somatic Symptom Scale-8 (SSS-8)
5. Depressive symptoms: Patient Health Questionnaire (PHQ-9)
6. Psychological resilience: Connor–Davidson Resilience Scale and Adult Resilience Measure (ARM)
7. Ubuntu: Ubuntu measurement scale by Itayi Mutsonziwa
8. Anxiety: Generalized Anxiety Disorder 7-item scale (GAD-7)
9. Social cohesion: 16-item Perceived Neighborhood Social Cohesion brief questionnaire
10. Family relationships: Brief Family Relationship Scale (BFRS)

Completion date
30/04/2027

Eligibility

Key inclusion criteria

1. Adults aged 18 years and above
2. Residents of the selected villages where Community-Based Sociotherapy (CBS) is implemented
3. Willingness to participate in CBS group sessions and data collection activities

Participant type(s)
Population

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Inability to provide informed consent

Date of first enrolment
27/10/2025

Date of final enrolment
27/02/2026

Locations

Countries of recruitment
Burundi

Rwanda

Uganda

Study participating centre
Community centres in selected districts (Rwamagana, Gasabo, Ruhango, Rutsiro, Nyamasheke, Gatsibo, and Burera)
The study is being conducted at different community centres of seven districts of Rwanda: Rwamagana, Gasabo, Ruhango, Rutsiro, Nyamasheke, Gatsibo and Burera

Districts: Rwamagana, Gasabo, Ruhango, Rutsiro, Nyamasheke, Gatsibo and Burera
Rwanda
+250

Study participating centre
Bulalo, Awach, Owalo, Bongatira, and Owoo Sub Counties in Gulu District.
The trial will be conducted in Gulu District, Northern Uganda. Specifically, the study communities are within the selected sub-counties of Bulalo, Awach, Owalo, Bongatira, and Owoo in Gulu District
Gulu District
Uganda
+256

Study participating centre
1. Province Buhumuza: commune Butihinda, Muyinga, 2. Province Gitega: commune Gitega, Giheta, Bugendana
Bujumbura
Bujumbura
Burundi
+257

Sponsor information

Organisation
University of Rwanda

ROR
https://ror.org/00286hs46

Funder(s)

Funder type
Not defined

Funder Name
Embassy of the Kingdom of the Netherlands in Kigali, Rwanda

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date