ISRCTN20474555 https://doi.org/10.1186/ISRCTN20474555

Community-based Socio-therapy Adapted for Refugees: the COSTAR study.

Submission date
15/03/2019

Recruitment status
No longer recruiting

Registration date
27/03/2019

Overall study status
Completed

Last Edited
09/06/2023

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 experience of conflict can have significant impacts on social relationships within communities. Community Based Sociotherapy (CBS) is a group-based approach that aims to help communities to heal after experiences of conflict. CBS runs over 15 weekly sessions. During CBS group meetings people talk, participate in exercises and games, sing songs, and engage in other forms of cultural expressions. This helps group members to address issues that can include ongoing daily stress, difficulties from the past and threats to safety and trust within their communities. CBS has been used in post-genocide Rwanda. Conflict in neighbouring Democratic Republic of Congo have led to large numbers of refugees being forcibly displaced to both Rwanda and Uganda. The COSTAR Project aims to investigate whether an adapted form of CBS can be used to reduce the levels of depression symptoms experienced by Congolese refugees in Rwanda and Uganda.

Who can participate?
Female and male, adult Congolese refugees living in Gihembe refugee camp in Rwanda and Kyangwali refugee settlement in Uganda can participate.

What does the study involve?
The COSTAR project is a randomized controlled trial. This means that participants are assigned by chance to either participate in CBS groups or participate in group meetings that simply provide those attending with updates about life in the refugee settlement. The participants will all complete a range of questionnaires that assess levels of depression symptoms, wellbeing, social support, social relationships, trauma, and daily stress. The participants will complete these questionnaires on three occasions: at the beginning, after 18 weeks and finally after 32 weeks. The COSTAR project will also investigate whether CBS is good value for money.

What are the possible benefits and risks of participating?
Each CBS group meetings will be facilitated by two facilitators who come from the refugee communities. They will be trained by the project team. Those participating in the trial may benefit from attending group meetings. The group meetings may involve discussion of emotive topics. The facilitators and research team members will be trained in how to support participants who may become distressed.

Where is the study run from?
The COSTAR Project is a collaboration between University of Liverpool (UK), Makerere University (Uganda), University of Rwanda (Rwanda), University of Glasgow (UK) and Queen's University Belfast (UK)

When is the study starting and how long is it expected to run for?
June 2019 to September 2022

Who is funding the study?
The Economic and Social Research Council

Who is the main contact?
Prof. Ross G. White, r.white@qub.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Ross White

ORCID ID
https://orcid.org/0000-0003-4026-6439

Contact details
University of Liverpool
School of Psychology
G.10, Ground floor, Whelan Building
Quadrangle
Brownlow Hill
Liverpool
United Kingdom
L69 3GB
0151 794 5532
ross.white@liverpool.ac.uk

Type(s)
Public

Contact name
Prof Ross White

Contact details
School of Psychology
Queen's University Belfast
Room 03.528, David Keir Building
8-30 Malone Road
Belfast
United Kingdom

BT9 5BN
+44 (0)28 9097 6566
r.white@qub.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ES/S000976/1

Study information

Scientific Title
Treating depressive symptomatology in Congolese refugees in Uganda and Rwanda: Adapting and evaluating community-based socio-therapy

Acronym
COSTAR

Study objectives
1. Community based socio-therapy (CBS) intervention will be superior to enhanced care as usual (ECU) in lowering the levels of depressive symptomatology at 16- (primary endpoint) and 32-weeks (secondary endpoint) follow-up.
2. CBS will be superior to enhanced care as usual (ECU) in improving the levels of wellbeing and quality of life.
3. Refugees in the CBS intervention arm will incur lower health care costs compared to ECU group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 22/11/2018, Makerere University (School of Social Sciences Research and Ethics Committee, Makerere University College of Humanities and Social Sciences, P. O Box 7062, Kampala- Uganda; 256 41(+256) 0414 -545040; research@chs.mak.ac.ug/rresearch9@gmail.com), ref: makss rec 11.18.237
2. Approved 07/02/2019 University of Rwanda (Ministry of Health, P.O.Box 84, Kigali, Rwanda; (250) 55 10 78 84; rnec@moh.gov.rw), ref: No 065/CMHS IRB/2019
3. The application for approval is now under processing at University of Liverpool (Liverpool L69 3BX;
+44 (0)151 794 2000; ethics@liverpool.ac.uk)

Study design
Two-arm cluster randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depressive symptomatology of Congolese refugees

Interventions
The Adapted Community Based Sociotherapy (aCBS) intervention is delivered in groups of 10 to 15 people living in the same geographic area (e.g. villages in camps). The aCBS intervention does not target specific diagnoses or symptoms. Rather attention is placed on being inclusive of all people in the community. Thus, aCBS minimises the potential stigma associated with disorder-focused interventions. Training and supervision for 24 facilitators across Rwanda and Uganda will be provided by CBS Rwanda (an organisation with 15 years' experience of delivering CBS in Rwanda). The fidelity of aCBS delivery will be monitored in a subset (10%) of randomly selected sessions using an existing checklist that is completed by field staff.

Clusters of participants (e.g. villages) in the Gihembe camps and the Kyangwali (updated 22/07 /2019, previously: Nakivale) settlement will be randomised to aCBS or ECU with a ratio of 1:1. Randomisation will be conducted independently by the Clinical Trials Research Centre (CTRC), University of Liverpool. The outcome of the randomisation will be communicated directly to the Trial Coordinator based at University of Rwanda. In the selected clusters, participants will be recruited through door-to-door approach. This approach has been used successfully in refugee camps in Uganda. Participants will be recruited prior to randomization of clusters. Informed consent will be obtained from participants. Outcome assessors will be blind to group allocation.

There is a theoretical possibility of contamination by recruiting refugees who might interact each other and therefore divulge intervention components from people in the experimental arm to those in the control condition. In order to minimize the possibility of any form of contamination, both the experimental and the control group will be asked to refrain from sharing study-related information and materials during the study. At all possible times during the trial, steps will be taken to organize the delivery of the intervention in a way that will prevent potential contamination.

Intervention Type
Behavioural

Primary outcome(s)
1. Depressive symptomatology score as measured on the PHQ-937 at 16-weeks (primary endpoint) and 32-weeks (secondary endpoint) compared between the aCBS programme and ECU.

Key secondary outcome(s))
1. Self-Reporting Questionnaire for detecting CMDs in primary health care settings.
2. Checklist for Daily Life Stressors (CDES), WHO-5 for wellbeing.
3. WHO Quality of Life BREF, Shortened and Adapted Social Capital Assessment Tool, PTSD Check List – Screener (PCL-6) and Multi-dimensional Scale of Perceived Social Support to measure social connectivity.

Outcomes will be assessed at baseline, and at 16- (primary outcome)- and 32-weeks (secondary outcome) post-baseline. The Major Depressive Episode module of the MINI will be used at baseline only.

Completion date
30/09/2022

Eligibility

Key inclusion criteria
1. Adult <18 years
2. Living in Kyangwali (updated 22/07/2019, previously: Nakivale) settlement, Uganda and Gihembe refugee camp, Rwanda
3. Identify as Congolese refugees
4. Have a self-reported good level of fluency in the languages that aCBS will be delivered in (Kinyarwanda in Rwanda / Kiswahili in Uganda).

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
1042

Key exclusion criteria
1. Current diagnosis of a complex mental disorder (e.g. psychotic disorders, PTSD, substance dependence)
2. Severe cognitive impairment (e.g. severe intellectual disability, dementia)
3. Actively express suicidal intent

Individuals that are excluded because of a diagnosis of a mental disorder or imminent risk of suicide will be referred for urgent local mental health support.

Date of first enrolment
01/06/2019

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
Rwanda

Uganda

Study participating centre
University of Rwanda
Kigali
Gikondo - Street, KK 737
PO Box 4285
Kigali
Rwanda
4285

Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Research council

Funder Name
Economic & Social Research Council (ES/S000976/1)

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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		20/01/2023	14/04/2023	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes