

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

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| Submission date 15/03/2019 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 27/03/2019 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 09/06/2023 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 Socioterapy (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

Study website

<https://www.liverpool.ac.uk/population-health/research/groups/costar/>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Depressive symptomatology of Congolese refugees

Interventions

The Adapted Community Based Socioterapy (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 measure

1. Depressive symptomatology score as measured on the PHQ-9/37 at 16-weeks (primary endpoint) and 32-weeks (secondary endpoint) compared between the aCBS programme and ECU.

Secondary outcome measures

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.

Overall study start date

01/06/2019

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

640 (320 per study arm)

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

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Sponsor information**Organisation**

University of Liverpool

Sponsor details

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Sponsor type
University/education

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ROR
<https://ror.org/04xs57h96>

Funder(s)

Funder type
Research council

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

Results and Publications

Publication and dissemination plan

Anonymised project data will be openly available and discoverable for analysis through the UK Data Service in accordance with the ESRC research data policy. There will be a dedicated project webpage and Twitter account to provide regular updates on progress. Video presentations relating to project relevant themes (e.g. refugee mental health and wellbeing; social capital; daily stressors) will be developed to serve as educational resources (1 online resource per 4 months). These will be freely available via the project webpage. Policy briefs will be developed with the UNHCR to inform decision-making for service allocation in refugee camps. Academic papers will be submitted to high impact peer reviewed journals including but not limited to The Lancet Psychiatry, Global Mental Health, Nature reviews, Psychological Medicine etc. Members of the project team will present at academic conferences and briefing sheets will be disseminated to communicate project-related content. Implementation guidance (co-published by UNHCR and CBS Rwanda) for adapting, disseminating and evaluating aCBS for refugees in diverse settings will be developed and made available through the Institute for Community-based Socio-therapy and UNHCR web-portals. These activities will promote enhanced understanding amongst clinicians, researchers and policy makers about how to promote mental health and wellbeing in refugees at a time of unprecedented global migration.

Intention to publish date
31/12/2023

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 |