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A randomized controlled trial on alcohol misuse and associated adversities among conflict-affected populations

Submission date
25/01/2023

Recruitment status
No longer recruiting

Registration date
30/01/2023

Overall study status
Completed

Last Edited
13/08/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The CHANGE project seeks to develop and implement a mental healthcare intervention among refugees in Uganda. Populations affected by armed conflict are at higher risk for mental health problems, and preliminary evidence shows that this might be the case for alcohol use problems as well. Although psychological interventions for mental health problems exist, there are no open-access evidence-based mental health and psychosocial interventions available that also target co-morbid alcohol misuse among populations living in humanitarian settings. To address this gap, the CHANGE project seeks to build on PM+ (an evidence-based WHO brief psychological intervention) by developing a new brief psychological intervention that can address both psychological distress and alcohol misuse. The CHANGE intervention will be evaluated amongst South Sudanese refugees residing in the Rhino refugee settlement in northern Uganda.

Who can participate?
South Sudanese men (aged over 18 years) with refugee status living in the Rhino settlement in Northern Uganda

What does the study involve?
Participants are randomly allocated to the treatment group or the control group.
The treatment group will receive enhanced usual care, as well as the CHANGE intervention. The CHANGE intervention is based on PM+. PM+ is a brief, psychological intervention based on cognitive behavioural therapy (CBT) techniques that are empirically supported and formally recommended by the WHO. The CHANGE intervention is based on PM+ strategies to treat underlying symptoms of common mental disorders and has an additional psychological component that addresses alcohol misuse. The CHANGE intervention is composed of three phases each of which includes two individual face-to-face sessions (about 90 minutes each). As such, participants in the intervention group will receive five to six individual sessions of the CHANGE intervention.
Participants in the control group will receive only enhanced usual care, which includes consultation with a community health care worker and participants will be given an information

pamphlet detailing available resources and information on reducing alcohol intake and managing psychological distress. The information sheet will be explained to participants in the intervention and the control arm by community health workers in the setting after they have completed the baseline outcome assessment.
Outcome assessments will be done at the start of the study and after 3 and 12 months.

What are the possible benefits and risks of participating?
The possible benefits of participating include experiencing a reduction in symptoms of depression, anxiety, PTSD, and alcohol misuse. Secondly, substance use is recognised as a key development issue and ensuring access to prevention and treatment of alcohol and other substance use disorders is listed as one of the Sustainable Development Goals. Problematic alcohol use can have negative social and economic impacts on the individual (e.g., loss of work, social isolation, reduced productivity, and income) and is therefore strongly linked with poverty. The aim of the CHANGE intervention is to reduce drinking levels, and will therefore potentially have a positive impact on participants' social and economic lives as well. The risks associated with participation are estimated to be minimal for the participant since the PM+ intervention reduced psychological distress in previous studies in Pakistan, Kenya, the Netherlands, and Nepal. The CHANGE intervention is based on evidence-based therapeutic techniques that have been found to be safe for use in a range of populations. Therefore it is unlikely that participation in the programme will cause distress of any sort.

Where is the study run from?
NIHR–Wellcome Partnership for Global Health Research (UK)

When is the study starting and how long is it expected to run for?
November 2022 to November 2024

Who is funding the study?
NIHR–Wellcome Partnership for Global Health Research (UK)

Who is the main contact?
Prof. Daniela Fuhr, fuhr@leibniz-bips.de

Study website
https://www.lshtm.ac.uk/research/centres-projects-groups/change

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
219468/Z/19/Z

Study information

Scientific Title
A randomized controlled trial of a psychological intervention for alcohol misuse and mental health comorbidities in conflict-affected populations in Uganda

Acronym
CHANGE

Study objectives
Aim: to evaluate the effectiveness and cost-effectiveness of the CHANGE intervention for male South Sudanese refugees in resettlement areas in northern Uganda.

Objective 1: evaluate the effectiveness and cost-effectiveness of the CHANGE intervention at reducing the percentage of days drinking at 3 and 12 months (CHANGE intervention and Enhanced Usual Care (EUC) vs EUC)

Objective 2: explore implementation processes and identify mechanisms that promote or inhibit the uptake of the CHANGE intervention amongst providers and participants

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 03/03/2023, London School of Hygiene and Tropical Medicine Research Ethics Committee (Keppel Street, London WC1E 7 HT, UK; +44(0)20 76368636; ethics@lshtm.ac.uk), ref: 28373
2. Approved 27/04/2023, Mildmay Uganda Research and Ethics Committee (MUREC, 12 Km Entebbe Road, Naziba Hill, Lweza, Kampala - Uganda; +256 312 210 200; mailbox@mildmay.or.ug), ref: 0401-2023

Study design
Parallel-arm single-blind definitive individual randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled 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
Mental health comorbidities (alcohol misuse, depression, anxiety and post-traumatic stress disorders)

Interventions
South Sudanese refugee men living in Rhino settlement in Northern Uganda will be recruited from households within previously identified villages. A total of 500 participants will be randomised. Randomization will be stratified by village. Within villages, participants will be individually randomized 1:1 to both arms of the trial after an initial baseline assessment is done. Randomization will be carried out using sealed envelopes.

The treatment group will receive enhanced usual care (EUC), as well as the CHANGE intervention. The CHANGE intervention is based on PM+. PM+ is a brief, psychological intervention based on cognitive behavioural therapy (CBT) techniques that are empirically supported and formally recommended by the WHO. The CHANGE intervention is based on PM+ strategies to treat underlying symptoms of common mental disorders and has an additional psychological component that addresses alcohol misuse. The CHANGE intervention is composed of three phases each of which includes two individual face-to-face sessions (approximately 90

minutes each). As such, participants in the intervention arm will receive five to six individual sessions of the CHANGE intervention (n = 250).

Participants in the control arm will receive only EUC (n = 250). EUC includes consultation with a community health care worker and participants will be given an information pamphlet detailing available resources and information on reducing alcohol intake and managing psychological distress. The information sheet will be explained to participants in the intervention and the control arm by community health workers in the setting after they have completed the baseline outcome assessment.

Outcome assessments will be done at baseline, 3 and 12 months after randomization. The research assistants conducting the outcome assessments will remain blind to the treatment condition of the participant throughout the trial. The cost-effectiveness of the intervention will be assessed through the incremental cost per disability-adjusted life years (DALY) averted and cost per quality-adjusted life year (QALY) gained of the CHANGE intervention compared to EUC from a societal perspective over a lifetime horizon.

Intervention Type
Behavioural

Primary outcome measure
Percentage days abstinent at the 3 months' outcome assessment, measured through the timeline follow-back assessment (TLFB) at baseline, 3 and 12 months

Secondary outcome measures
Measured at the 3- and 12-month follow-up:
1. Alcohol misuse/remission measured using the Alcohol Use Disorders Identification Test (AUDIT); Alcohol, Smoking and Substance Involvement Screening Tool (ASSIST); and the TLFB assessment at baseline, 3 and 12 months
2. Psychological distress measured using the Kessler Psychological Distress Scale (K10) at baseline, 3 and 12 months
3. Depression measured using the Patient Health Questionnaire-9 (PHQ-9) at baseline, 3 and 12 months
4. Anxiety measured using the Hopkins Symptom Checklist (HSCL-A) at baseline, 3 and 12 months
5. Post-traumatic stress disorder (PTSD) measured using PTSD Checklist (PCL-6) at baseline, 3 and 12 months
6. Functional disability measured using WHO Disability Assessment Schedule (WHODAS 2.0), 12-item, interviewer-administered version at baseline, 3 and 12 months
7. Perpetration of intimate partner violence by drinker, measured using the United Nations Multi-Country Study instrument at baseline, 3 and 12 months
8. Quality of life measured using the EQ-5D-5L and the Oxford CAPabilities questionnaire-Mental Health (OxCAP-MH) at baseline, 3 and 12 months

Other outcomes study:
1. Demographic data collected during participant screening
2. Trauma exposure measured using the Harvard Trauma Questionnaire at baseline, 3 and 12 months
3. Use of local substances measured using ASSIST at baseline, 3 and 12 months
4. Subjective wellbeing measured using Organisation for Economic Co-operation and Development (OECD) guidelines at baseline, 3 and 12 months
5. Treatment fidelity measured using audio recordings and checklists at the end of the

intervention delivery
6. Methodological trial procedures using administrative data collected via participant tracking sheets throughout the trial
7. Feasibility measured using qualitative interviews at 3 months
8. Acceptability measured using qualitative interviews at 3 months
9. Appropriateness and dose, measured using administrative data collected via participant tracking during the baseline, 3 and 12 months
10. Competence measured using ENACT as part of the EQUIP platform collected before and after intervention facilitator training
11. Information on supervision measured using administrative data collected via logbooks throughout the trial

Overall study start date
01/11/2022

Completion date
11/11/2024

Eligibility

Key inclusion criteria
1. Adult south Sudanese men (>18 years) with a refugee status
2. Alcohol Use Disorder Identification Test (AUDIT score) between 8 and 20 (Saunders, Aasland, Babor, de la Fuente, et al., 1993)
3. Elevated levels of psychological distress (Kessler Psychological Distress Scale (10-item version) (K10>20) (Kessler et al., 2010)
4. Speak English and/or Juba Arabic

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
500

Total final enrolment
504

Key exclusion criteria
Current exclusion criteria as of 26/05/2023:

1. Adult south Sudanese men (>18 years) with a refugee status
2. Alcohol Use Disorder Identification Test (AUDIT score <20) or no alcohol dependence (AUDIT score <8) (Saunders, Aasland, Babor, de la Fuente, et al., 1993)
3. Elevated levels of psychological distress (Kessler Psychological Distress Scale (10-item version) (K10>20) (Kessler et al., 2010)
4. Speak English and/or Juba Arabic
5. Have previously received PM+.
6. Have been in the camp for less than three months, given that new arrivals take 2 to 3 months to relocate (i.e. receive land and refugee determination status), and the first three months are more likely to be in acute stages of distress.

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Previous exclusion criteria as of 25/04/2023:

1. Men with possible alcohol dependence (AUDIT score ≥20).
2. Imminent risk of suicide/other life-threatening risk, acute medical conditions assessed through three questions related to suicide (i.e., 'in the past month, have you had serious thoughts or a plan to end your life?', what actions have you taken to end your life? And do you plan to end your life in the next 2 weeks?). These participants will be referred to a psychiatric community officer (PCO).
3. Signs of severe mental disorders such as psychosis and/or severed cognitive impairment (e.g. severe intellectual disability or dementia). This will be assessed using a checklist with lists of observable signs of severe mental disorders or severe cognitive impairment such as participant not understanding questions, presenting with confused speech, appearing extremely fidgety or nervous, limited communication skills, etc).
4. Men who have previously received the PM+ intervention.

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Previous exclusion criteria:

1. Men with possible alcohol dependence (AUDIT score ≥20). A validation study of the K10 in Uganda is currently being finalised, so the cut-off score may be slightly adjusted depending on the findings.
2. Imminent risk of suicide/other life-threatening risk, acute medical conditions assessed through three questions related to suicide (i.e., 'in the past month, have you had serious thoughts or a plan to end your life?', what actions have you taken to end your life? And do you plan to end your life in the next 2 weeks?). These participants will be referred to a psychiatric community officer (PCO).
3. Signs of severe mental disorders such as psychosis and/or severed cognitive impairment (e.g. severe intellectual disability or dementia). This will be assessed using a checklist with lists of observable signs of severe mental disorders or severe cognitive impairment such as participant not understanding questions, presenting with confused speech, appearing extremely fidgety or nervous, limited communication skills, etc)

Date of first enrolment
04/08/2023

Date of final enrolment
20/11/2023

Locations

Countries of recruitment
Uganda

Study participating centre
Rhino refugee settlement
X9CW+JJM, Rhino Camp
Arua
Uganda
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Sponsor information

Organisation
NIHR–Wellcome Partnership for Global Health Research

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Sponsor type
Charity

Website
https://wellcome.org

Funder(s)

Funder type
Charity

Funder Name
NIHR–Wellcome Partnership for Global Health Research

Results and Publications

Publication and dissemination plan
The results of this study will be submitted for publication in international, peer-reviewed journals.

Findings will also be shared with key stakeholders (e.g., Ministries of Health, heath clusters, NGOs, community organisations) through individual country reports and briefs. Other outputs will include peer-reviewed academic publications and presentations at relevant conferences and workshops.

Furthermore, a number of meetings will be arranged within the community to communicate the results to the community and to local stakeholders and receive feedback.

Results from these studies will also be circulated in the humanitarian community on platform used by humanitarian workers (e.g., MHPSS.net and MHIN).

Intention to publish date
01/07/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository, LSHTM Data Compass (https://datacompass.lshtm.ac.uk). The data stored will be anonymised participant data that excludes information classed as internal, confidential, or highly confidential.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		27/02/2024	28/02/2024	Yes	No
Statistical Analysis Plan			12/08/2025	No	No