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

Submission date
26/05/2023

Recruitment status
No longer recruiting

Registration date
30/05/2023

Overall study status
Completed

Last Edited
15/01/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The CHANGE project seeks to develop and implement a complex mental healthcare intervention among South Sudanese male refugees in Uganda. Populations affected by armed conflict are at higher risk for mental health problems, and preliminary evidence indicates 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 further develop PM+ (an evidence-based WHO brief psychological intervention) by complementing it with psycho-social strategies addressing alcohol misuse, with the new intervention called the CHANGE intervention. The current project aims to pilot the CHANGE intervention in order to evaluate and refine the methodological procedures and measure its preliminary impact on male South Sudanese refugees in the Rhino settlement in northern Uganda.

Who can participate?
South Sudanese men (aged over 18 years) with a refugee status living in the Rhino settlement in Northern Uganda. Participants need to have good levels of English and/or Juba Arabic.

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 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 village health team worker and participants will be given an information pamphlet detailing locally 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 village health team workers in the setting after they have completed the baseline outcome assessment. Outcome assessments will be done at the start of the study (baseline) and 3 months later

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 it 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?
January 2022 to March 2023

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)
Scientific

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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 pilot randomized control 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 and refine the methodological procedures of the CHANGE intervention and measure its preliminary impact on male South Sudanese refugees in resettlement areas in northern Uganda.

Objective 1: to test and refine the procedures of recruitment, randomisation, and retention in addition to ensuring data collection methods work and can be built upon in a definitive

randomized control trial (RCT).
Objective 2: to assess that the CHANGE intervention together with enhanced usual care (EUC) is acceptable, feasible and safe.
Objective 3: to measure the preliminary impact of the CHANGE intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 22/02/2022, 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: 26617
2. Approved 13/09/2022, (MUREC, 12 Km Entebbe Road, Naziba Hill, Lweza, Kampala - Uganda, +256 (0)312 210 200; mailbox@mildmay.or.ug), ref: 0801-2022

Study design
Parallel-arm single-blind definitive individual pilot 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 including alcohol misuse, depression, anxiety and post-traumatic stress disorders

Interventions
South Sudanese refugee men living in the Rhino settlement in Northern Uganda will be recruited from households within previously selected villages on the basis that no previous HealthRight International (implementing partner) trials have been conducted there. A total of 60 participants will be individually randomised 1:1 to both arms of the trial after the baseline outcome assessment is done using sealed envelopes. The randomisation code will be generated by ODK.

The treatment group (n = 30) will receive the CHANGE intervention and enhanced usual care. The CHANGE intervention is based on PM+, which 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. It is composed of six individual face-to-face sessions

across three phases. Each session takes approximately 90 minutes and is delivered by lay healthcare workers (facilitators).

Participants in the control arm will only receive enhanced usual care only (n = 60). Enhanced usual care includes consultation with a village health team worker, who will share an information pamphlet with participants detailing available resources in the community 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 a village health team worker after they have completed the baseline outcome assessment with a research assistant.

Outcome assessments will be done at baseline and 3 months after randomization. The research assistants conducting the outcome assessments will remain masked to the treatment condition of the participant throughout the pilot study.

Intervention Type
Behavioural

Primary outcome measure
The percentage of days abstinent at the 3-month outcome assessment, measured using the timeline follow-back assessment (TLFB) at baseline and 3 months

Secondary outcome measures
Measured at the 3-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 and 3 months
2. Psychological distress measured using the Kessler Psychological Distress Scale (K10) at baseline and 3 months
3. Depression measured using the Patient Health Questionnaire-9 (PHQ-9) at baseline and 3 months
4. Anxiety measured using the Hopkins Symptom Checklist (HSCL-A) at baseline and 3 months
5. Post-traumatic stress disorder (PTSD) measured using PTSD Checklist (PCL-6) at baseline and 3 months
6. Functional disability measured using WHO Disability Assessment Schedule (WHODAS 2.0), 12-item, interviewer-administered version at baseline and 3 months
7. Perpetration of intimate partner violence by drinker, measured using the United Nations Multi-Country Study instrument at baseline and 3 months
8. Quality of life measured using the EQ-5D-5L and the Oxford CAPabilities questionnaire-Mental Health (OxCAP-MH) at baseline and 3 months

Other outcomes:
1. Demographic data collected during participant screening
2. Trauma exposure measured using the Harvard Trauma Questionnaire at baseline and 3 months
3. Use of local substances measured using ASSIST at baseline and 3 months
4. Subjective wellbeing measured using Organisation for Economic Co-operation and Development (OECD) guidelines at baseline and 3 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 and 3 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
01/01/2022

Completion date
23/03/2023

Eligibility

Key inclusion criteria
1. Adult South Sudanese men (aged ≥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 ≥16) (Kessler et al., 2010)
4. Speak English and/or Juba Arabic

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Male

Target number of participants
60

Total final enrolment
66

Key exclusion criteria
1. Men with possible alcohol dependence (AUDIT score ≥20), or no alcohol dependence (AUDIT score <8).
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
10/10/2022

Date of final enrolment
02/11/2022

Locations

Countries of recruitment
Uganda

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

Sponsor information

Organisation
NIHR–Wellcome Partnership for Global Health Research

Sponsor details
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215 Euston Road
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Sponsor type
Charity

Website

https://wellcome.org/grant-funding/nihr-wellcome-global-health-research-partnership#contact-us-b4dc

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
30/09/2024

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. Dates of availability are not known yet. Written consent was provided by all participants.

IPD sharing plan summary
Stored in publicly available repository