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CHANGE: A randomized controlled trial of a psychological intervention for alcohol misuse and mental health comorbidities in conflict-affected populations in Ukraine

Submission date
20/06/2024

Recruitment status
Recruiting

Registration date
05/07/2024

Overall study status
Ongoing

Last Edited
12/08/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
We are currently experiencing the highest levels of forced displacement ever recorded. People affected by conflict are particularly vulnerable to mental health issues and are at a significantly higher risk of developing mental disorders, including problems with alcohol, compared to those not affected by conflict.

To help these populations, the World Health Organization (WHO) has created a program called Problem Management Plus (PM+). This program involves a short series of five sessions, delivered by trained non-specialists, designed to address common mental health issues in communities facing hardship.

The proposal in question is part of a larger, five-year initiative known as the CHANGE project. This project aims to expand on the PM+ program by developing a brief, adaptable intervention that targets both psychological distress and alcohol misuse.

The main goal is to evaluate how effective and cost-effective the CHANGE intervention is. The primary hypothesis is that the CHANGE intervention, when combined with enhanced usual care (EUC), will be more effective than EUC alone in increasing the number of days people abstain from alcohol over a three-month period. Additionally, it is hypothesized that the CHANGE intervention combined with EUC will be more cost-effective and save more money for the healthcare system compared to EUC alone.

This current protocol is based on two previous protocols and utilizes a finalized treatment manual developed after a pilot randomized controlled trial (RCT) (approved by the LSHTM Research Ethics Committee ID: 28853 and its amendment 28853-2). The focus of the current protocol is solely on the full-scale RCT.

Who can participate?
Adult war-affected Ukrainian males (18 years and older) residing in Ukraine, with alcohol use disorder (AUDIT score 8-19) and self-reported elevated levels of psychological distress (K10>16).

What does the study involve?
To determine how effective and cost-effective the CHANGE intervention is, a specific type of study will be conducted in Ukraine. This study is called a parallel arm, single-blind, definitive, individual randomized controlled trial (RCT). It will involve 500 participants who will be randomly assigned to one of two groups: one group will receive the CHANGE intervention along with enhanced usual care (EUC), and the other group will receive only EUC.

The cost-effectiveness of the CHANGE intervention will be measured by calculating the additional cost per disability-adjusted life year (DALY) averted and the cost per quality-adjusted life year (QALY) gained compared to EUC alone. These measures will be considered from a societal perspective over the participants' lifetimes.

Participants in the treatment group will go through five or six sessions in remote format (online or via telephone) of the CHANGE intervention along with EUC. The EUC component will include an information pamphlet that provides advice on reducing alcohol consumption and managing psychological distress. The CHANGE intervention is a low-intensity psychological program, delivered by trained facilitators under the supervision of mental health professionals. The control group will receive only the EUC.

The main outcome of the study will be the increase in the percentage of days participants abstain from alcohol, measured three months after the intervention using a method called the timeline follow back assessment.

What are the possible benefits and risks of participating?
Potential benefits of Participation:
Participants will:
1. Receive our personalized intervention which aims to lower alcohol intake and improve mental well-being.
2. Leaflet with information about impact of alcohol misuse on body and mind to support your healthier lifestyle.
3. Advance research that could benefit many worldwide, starting with Ukraine.
4. Receive compensation, including 250 UAH for assessments and interviews, but not for session attendance.

Potential risks of Participation
Participants might find discussing some details of mental health and alcohol consumption with someone who you do not know uncomfortable or upsetting. If participant become upset, he will be able to speak with an appropriate member of NaUKMA Mental Health Center and provided with information about available mental health resources that can help.

Where is the study run from?
The London School of Hygiene & Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?
April 2024 to January 2026

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

Who is the main contact?
Study PI, Prof. Bayard Roberts, Bayard.Roberts@lshtm.ac.uk
Local Site PI, Dr. Sergiy Bogdanov, s.bogdanov@ukma.edu.ua

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
28853, 219468/Z/19/Z

Study information

Scientific Title
A Randomized Controlled Trial (RCT) of a psychological intervention for alcohol misuse and mental health comorbidities in conflict-affected populations in Ukraine

Acronym
CHANGE

Study objectives
1. The new psychological intervention CHANGE and enhanced usual care reduced amount of alcohol consumption and symptoms of psychological stress better then enhanced usual care only
2. The new psychological intervention CHANGE and enhanced usual care is more cost-effective then enhanced usual care only

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 17/04/2024, LSHTM Research Ethics Committee (15-17 Tavistock Place, London, WC1H 9SH, United Kingdom; +44(0)2076368636; ethics@lshtm.ac.uk), ref: 30122 - 01

2. Approved 03/06/2024, NaUKMA Commettee on Research Ethics (Skovorody str, 2, Kyiv, 04070, Ukraine; +38 (0)44 425 60 64; t.yurochko@ukma.edu.ua), ref: ref: #4 from 03/06/2024

Study design
Parallel arm single-blind randomized controlled trial with a nested qualitative study

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Internet/virtual, Telephone

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Alcohol misuse and psychological stress

Interventions
This research entails a parallel arm, single-blind, definitive, individually randomized controlled trial (RCT) in Ukraine government-controlled territories in a remote format. This RCT will include 500 study participants, randomised 1:1 to treatment (CHANGE) and control arm, and outcome assessment will be collected at baseline, 3 months post-recruitment.

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 (Dua, Barbui, Clark, Fleischmann, Poznyak, Ommeren, et al., 2011; W. a Tol et al., 2013; WHO, 2013). PM+ was developed by the WHO and the University of New South Wales, Australia. The manual involves the following empirically supported elements: problem-solving plus stress management, behavioural activation, facing fears, and accessing social support. These elements have been recommended in recent WHO guidelines (Dua, Barbui, Clark, Fleischmann, Poznyak, van Ommeren, et al., 2011; Tol et al., 2013). 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).

Furthermore, to assess the cost-effectiveness of the intervention, we will assess the incremental cost per DALY averted and cost per QALY of the CHANGE intervention compared to EUC from a societal perspective over a lifetime horizon.

Lastly, a nested qualitative study will be carried out wherein qualitative interviews will be conducted with participants, facilitators, research assistants and family members of those who took part in the CHANGE intervention to investigate implementation processes, intervention delivery, fidelity, dose, sustainability, perceived effectiveness, feasibility, and acceptability. Thematic analysis will be used using an inductive approach to analysis.

Intervention Type
Behavioural

Primary outcome measure
PDHD (percentage days of heavy drinking) measured using a Timeline Followback (TLFB) at baseline and 3 months

Secondary outcome measures
1. PDA(percentage of days abstinent) measured using a Timeline Followback (TLFB)at baseline and 3 months
2. Alcohol misuse measured using the Alcohol Use Disorders Identification Test (AUDIT)at baseline and 3 months
3. Alcohol misuse measured using the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) at baseline and 3 months
4. Psychological distress measured using a Kessler-10 (K-10) at baseline and 3 months
5. Depression measured using a Mental Health Assessment Inventory (MHAI), Depression sub-scale at baseline and 3 months
6. Anxiety measured using a Mental Health Assessment Inventory (MHAI), anxiety sub-scale at baseline and 3 months
7. PTSD measured using a Mental Health Assessment Inventory (MHAI), PTSD sub-scale at baseline and 3 months
8. Functional disability measured using a Mental Health Assessment Inventory (MHAI), WHODAS sub-scale at baseline and 3 months
9. Perpetration of intimate partner violence measured using a United Nations Multi-Country Study on Men and Violence at baseline and 3 months
10. Health economics indicators measured using a EQ-5D-5L, Subjective wellbeing (happiness and life satisfaction) and OxCAP-MH at baseline and 3 months

Overall study start date
30/04/2024

Completion date
30/01/2026

Eligibility

Key inclusion criteria
1. Adult men (>18 years)
2. Alcohol Use Disorder Identification Test (AUDIT) score 8-19 (Saunders, Aasland, Babor, de la Fuente, et al., 1993)
3. Elevated levels of psychological distress (Kessler Psychological Distress Scale (ten item version) (K10>16) (Kessler et al., 2010).
4. Speak Ukrainian or Russian

Participant type(s)
Population

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants

500

Key exclusion criteria
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 last month have you had thoughts about suicide? (harming another person)/ or a suicide plan? (a plan to harm another person). Do you have ways to carry out this plan?/Have you tried to kill yourself in the past month? (to kill or harm another person). These participants will be referred to a psychiatrist.
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. Has received formalized brief psychological interventions (e.g., PM+, CETA) in the previous year
5. Has received any forms of any substance use treatment (e.g., AA, detoxication, replacement therapy programs) in their lifetime
6. Men who are actively involved in military action
7. Residence outside of Ukraine

Date of first enrolment
25/06/2024

Date of final enrolment
10/09/2025

Locations

Countries of recruitment
Ukraine

Study participating centre
National University of "Kyiv-Mohyla Academy"
Skovorody Street, 2
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Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

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https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
NIHR–Wellcome Partnership for Global Health Research

Results and Publications

Publication and dissemination plan
Planned publications in a peer-reviewed journals

Intention to publish date
30/06/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr. Sergiy Bogdanov s.bogdanov@ukma.edu.ua

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Facilitator qualitative interview		01/07/2024	No	Yes
Participant information	Non-participant qualitative interview		01/07		

sheet		/2024	No	Yes
Participant information sheet	Participant dropout qualitative interview	01/07 /2024	No	Yes
Participant information sheet	Participant family members qualitative interview	01/07 /2024	No	Yes
Participant information sheet	Participants qualitative interviews	01/07 /2024	No	Yes
Participant information sheet	Participants quantitative data collection	01/07 /2024	No	Yes
Participant information sheet	Research assistant qualitative interview	01/07 /2024	No	Yes
Participant information sheet	Supervisor qualitative interview	01/07 /2024	No	Yes
Statistical Analysis Plan		12/08 /2025	No	No