ISRCTN11369479 https://doi.org/10.1186/ISRCTN11369479

CHANGE Study: a pilot trial of a new psychological intervention for alcohol misuse and mental health in Ukraine

Submission date
13/09/2023

Recruitment status
No longer recruiting

Registration date
20/09/2023

Overall study status
Completed

Last Edited
24/01/2024

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 study is a pioneering research project taking place in Ukraine. A dedicated team of experts is committed to developing effective interventions that can make a positive impact on the lives of individuals struggling with harmful alcohol use. This study aims to explore a new transdiagnostic approach that targets both alcohol consumption and psychosocial well-being simultaneously.

Who can participate?
Men aged 18 years or above with a history of harmful alcohol consumption who live in Ukraine.

What does the study involve?
Participants are randomly allocated into a treatment group or a control group.

What are the possible benefits and risks of participating?
A team of professionals will tailor an intervention specifically to participants' needs, helping them reduce their alcohol consumption and enhance their psychosocial well-being. Throughout the study, participants will have access to free counseling sessions and resources that can assist them in their journey towards a healthier lifestyle. Participants will be making a significant contribution to the development of evidence-based interventions that can help countless individuals in the future in Ukraine and globally. As a token of appreciation, participants will be eligible for incentives and rewards for their active participation in the study. The risks of participating in the CHANGE study are minimal and not different from general risks for the public in Ukraine.

Where is the study run from?
1. London School of Hygiene and Tropical Medicine (LSHTM) (UK)
2. National University of Kyiv-Mohyla Academy (NaUKMA) (Ukraine)

When is the study starting and how long is it expected to run for?
January 2023 to June 2024

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

Who is the main contact?
Dr Sergiy Bogdanov, s.bogdanov@ukma.edu.ua

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

Contact information

Type(s)
Principal Investigator

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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 pilot randomized controlled trial of a psychological intervention for alcohol misuse and mental health comorbidities in war-affected populations in Ukraine

Study objectives

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

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 13/06/2023, LSHTM Ethics (Keppel Street, London, WC1E 7HT, United Kingdom; +44 (0)20 76368636; ethics@lshtm.ac.uk), ref: 28853

2. Approved 14/06/2023, NaUKMA Commettee on Research Ethics (Skovorody str, 2, Kyiv, 04070, Ukraine; +38 (0)44 425 60 64; t.yurochko@ukma.edu.ua), ref: 2 from 14/06/2023

Study design
Parallel-arm single-blind 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
https://ukmaedu.sharepoint.com/:w:/s/CHANGEProjectteam/EepaOn5WXwtJuofw2zjOSCgBvj-7u3D6TcTSeF_FCDsPPQ?e=xEGeKb

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

Interventions
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).

Allocation:
Participants will be individually randomised to the trial arms after baseline assessment. The randomisation code will be generated by ODK (and sealed envelopes will be used). Outcome assessors will not be aware of the allocated intervention.

Control group: Enhanced usual care (EUC)
All participants in this research will receive EUC. EUC includes consultation with a community health care worker. 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 by community health workers in the setting, after they have completed the baseline outcome assessment. The community health workers are independent from the outcome assessors and intervention facilitators.

Treatment group: EUC with the CHANGE intervention
The treatment group will receive enhanced usual care (EUC), as well as the CHANGE intervention.

Outcome assessment:
Baseline and 3-month follow-up (after randomisation).

Intervention Type
Other

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. Psychological distress measured using a Mental Health Assessment Inventory (MHAI), psychological distress sub-scale at baseline and 3 months
4. Depression measured using a Mental Health Assessment Inventory (MHAI), psychological distress sub-scale at baseline and 3 months
5. Anxiety measured using a Mental Health Assessment Inventory (MHAI), psychological distress sub-scale at baseline and 3 months
6. PTSD measured using a Mental Health Assessment Inventory (MHAI), psychological distress sub-scale at baseline and 3 months
7. Functional disability measured using a Mental Health Assessment Inventory (MHAI), WHODAS sub-scale, psychological distress sub-scale at baseline and 3 months
8. Perpetration of intimate partner violence measured using a United Nations Multi-Country Study on Men and Violence at baseline and 3 months

Overall study start date
01/01/2023

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. Adult men (aged >18 years)
2. Alcohol Use Disorder Identification Test (AUDIT) score 8-19 (Saunders et al., 1993)
3. Elevated levels of psychological distress (Kessler Psychological Distress Scale (ten-item version) (K10 ≥ 16) (Kessler et al., 2002)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
60

Key exclusion criteria
1. Men with possible alcohol dependence (AUDIT score ≥20)
2. Imminent risk of suicide/other life-threatening risk, acute medical conditions
3. Signs of severe mental disorders such as psychosis (this will be screened by a trained assessor which will refer the participant to a psychiatrist or counsellor if observable signs of severe mental disorders are detected)
4. Signs of severe cognitive impairment (e.g., severe intellectual disability or dementia)
5. Has received formalized brief psychological interventions (e.g., PM+, CETA) or any alcohol-focused treatment (e.g., AA) in the previous year

Date of first enrolment
17/09/2023

Date of final enrolment
29/02/2024

Locations

Countries of recruitment
Ukraine

Study participating centre
National University of Kyiv-Mohyla Academy
Skovorody Street, 2
Kyiv
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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
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
17/01/2025

Individual participant data (IPD) sharing plan
The dataset 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