

Version 3. 22/05/2024

Annex 2.1 Participant Quantitative Data Collection

Information sheet and consent form for: Quantitative data collection for participants

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

What is the purpose of this study?

The purpose of this study is to investigate how to best support men in Ukraine during wartime who are experiencing high level of stress and who drink too much alcohol. To do this we have developed a new programme called CHANGE which may help people manage the high levels of stress, emotional problems, and problematic alcohol drinking habits. With this research, our goal is to determine if this program benefits individuals with similar experiences and identify ways that can further enhance the program's effectiveness.

Where will the study take place?

We welcome all men in Ukraine who are experiencing high level of stress and are drinking alcohol to come talk with us and see if they are eligible to participate. All the meetings with researchers and facilitators will be held in an online format.

What will happen to me if I take part?

Our project is composed of multiple steps.

1) For the first step you will be invited to meet online with a research assistant to answer a short questionnaire. This will help us understand whether you are eligible to take part in this research programme. The interview will also help us understand if the programme which we are developing could be helpful for you. The programme will not be helpful to you if you **do not** drink alcohol, or if you drink **too much** alcohol. For this reason, we will ask you some questions about your drinking habits, and it is important that you answer these truthfully.

If we find from the interview that our programme is not right for you, we will provide you with the appropriate information about services that will be right for what you are experiencing.

If we think the programme could be helpful for you, you will be invited to participate in our research study as a participant. If you agree to participate, there is a longer questionnaire to fill out online where we will ask you more questions about your background, drinking habits, different aspects of your mental health, and financial state. This questionnaire will take up to 1 hour and you will receive a 250 UAH gift card to a local grocery store or 250 UAH in phone credit as a thank you for your time.

2) If we think the programme could be helpful for you, you will then have a conversation with a project staff about reducing drinking and receive some more information. You will then be randomly put into one of two groups, Group 1 or Group 2. This process is done randomly and it cannot be changed.

If you are in Group 1, you will receive a one-time information leaflet on how to reduce drinking alcohol.

If you are in Group 2, you will be invited to attend a 90-minute online session once a week during six weeks. During the sessions, you will take part in certain activities, receive some information, and discuss the issues that have been affecting you lately with a programme facilitator. You will also be provided with materials to practice helpful techniques at home. If you agree, the programme facilitator will audio record some of the sessions. The audio recordings will only be used to allow the facilitator's supervisor to assess whether the facilitator delivered the programme as intended.

All these services will be provided free of charge. It is important to note that you will not receive any economic or material compensation for participating in the sessions.

3) Regardless of whether you were assigned to Group 1 or Group 2, the research assistant will contact you again in 3 months after the initial interview for a follow up questionnaire to see how you are doing. This questionnaire asks many of the same questions as the first questionnaire and will take approximately 1 hour. You will receive a 250 UAH gift card to a local grocery store or 250 UAH in phone credit as a thank you for your time filling out the questionnaire.

4) As part of the research, you might also be invited to take part in an interview to ask about your experiences participating in the programme. If you refuse to participate in the study, we might invite you to an interview to hear about your perceptions of the CHANGE programme.

Why have you been contacted?

You are being invited to participate in this research because staff from health/social centres or local community-based organization have suggested you might be interested in taking part. Alternatively, you may have heard about our programme from a facilitator or other participants or have seen information about the programme on social media and have contacted us directly. You may be experiencing some difficulties with high levels of stress, and we would like to find out more about this to see if the programme would be helpful for you. The programme we invite you to take part in has been designed to help you manage drinking habits and high levels of stress and/or emotional problems. Your experience of participating in this programme can also help us in developing it further and in improving it, to help more war-affected men in Ukraine and around the world. The entire program is delivered online.

Do you have to take part?

No. Participation is completely voluntary. It is your choice to participate in this study or not. If you choose to participate, you retain the right to refuse answers to any questions that you do not feel comfortable with. You may also change your mind at any time and withdraw from the programme. Also, you retain the right to withdraw from this study at any point during the interview or questionnaire. Refusal to participate will not negatively affect you and will not limit any other rights for you or your family.

What are the possible benefits of taking part?

If you decide to take part, you will be contributing to our understanding of improving the wellbeing of war-affected men in Ukraine. Additionally, we expect that the programme will be helpful for people who have problematic drinking habits and are experiencing high levels of stress and other psycho-social problems. You may find that you learn some important skills for managing your drinking and mental health.

What are the possible risks and disadvantages of taking part?

You might find discussing some details of mental health and alcohol consumption with someone who you do not know uncomfortable or upsetting. You may always skip any questions which make you feel uncomfortable answering. If you become upset, you will be able to speak with an appropriate member of NaUKMA Mental Health Center and provided with information about available resources that can help you. Our researchers and staff are trained in dealing with these situations and emotional disturbances and will help you to cope with such feelings. We do not expect that CHANGE will have any negative effects. Talking about your feelings or upsetting topics may be difficult for some people and cause stress in some. If you find any of the programme activities too stressful and uncomfortable, you do not have to take part in them. You do not have to give us any reason for not taking part.

Confidentiality

All information collected about you will be kept strictly confidential. Please note, that we and any researchers working on this study ensure privacy and confidentiality for all study-related data, documents, and findings. The data, including audio files, will only be accessible to research staff working on the CHANGE project and will be stored on encrypted servers at NaUKMA, London School of Hygiene and Tropical Medicine in London and on an external hard drive located at NaUKMA Center office. Anonymized data and study procedures will also be made available through a public data repository – LSHTM Data Compass, and to other researchers, study monitors, or ethics review boards upon request, however personal information will not be included. Respondent-related data will be labelled by an id number rather than by using your name or any other personal identifiers of you. Audio records from sessions will be deleted once the analysis is completed.

Please note, that our activities are in no way associated with the Ukrainian government's operations, and no personal data is shared with any government agency.

Reimbursement and compensation:

We will follow ethics committee guidance and reimburse you for your time after the initial and final questionnaire. After each questionnaire completion you will receive either a 250 UAH gift card to a local grocery store or 250 UAH in phone credit. You will not be reimbursed for the individual sessions you attend.

What will happen to the findings of the study?

We will use the findings of the study to try and improve the programme. Results from the study may be published in scientific journals or reports, without the use of any information that could identify individual persons or families.

Who is the study sponsor and funder?

The CHANGE project is funded by the NIHR–Wellcome Partnership for Global Health Research. The London School of Hygiene and Tropical Medicine (LSHTM) in London is the sponsor for this research project. In Ukraine, LSHTM is working with National University of Kyiv Mohyla Academy (NaUKMA) and the NGO WordsHelp to implement the study. For further information regarding the sponsorship conditions, please contact the Research Governance and Integrity Office:

London School of Hygiene & Tropical Medicine

Keppel Street

London WC1E 7HT

Tel: +44 207 927 2626

Email: RGIO@lshtm.ac.uk

Who has approved the study?

This study has been reviewed and approved by:

The scientific ethics committee in National University of Kyiv-Mohyla Academy, Ukraine

(Contact information: phone: +38 044 463-58-66, E-mail: t.yurochko@ukma.edu.ua)

Ethics review board at the London School of Hygiene & Tropical Medicine, UK

The study will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki.

Who should I contact for further information?

If you would like to receive more information regarding our study, or if you would like to discuss your rights regarding participation in this study please contact:

Ukrainian Principal Investigator

Dr. Sergiy Bogdanov, s.bogdanov@ukma.edu.ua, +38 066 030 40 20 (mobile)

Project Manager

Vita Kachai, v.kachay@ukma.edu.ua, +38 095 435 53 72 (mobile)

Consent form for screening

Thank you for considering taking part in this research. If you have any questions arising from the information sheet or explanation given to you, please ask the Project Manager Vita Kachai (+38095 435 53 72) before you decide whether to consent to participate or not.

I have read the information sheet concerning this study [and/or have understood the verbal explanation] and have received a copy of it for me to keep. I fully understand what will be required of me to take part in the study.	
I understand that I may withdraw from this study without giving a reason at any point in time. There will be no effect, positive or negative, on me or my household if I decide to withdraw from this study.	
I understand that results from the study may be published in scientific journals or reports, without the use of any information that could identify me.	
I consent to provide contact information of my family/friend or other community members so that the research team can use it in case it is necessary to find me for a follow up appointment and I cannot be reached directly.	
I consent for the research team to audio record some of their sessions with me for the purpose of checking the quality of the sessions delivered.	
I agree to take part in this study.	

Verbal consent form for screening

Verbal consent procedure is to be followed after reading the information sheet to the participant.

Interviewer Reads: “Thank you for considering taking part in this research. Do you have any questions about the project, what we are asking you do as a participant, or how the information you provide will be used?”

Interviewer reads:

Before we begin the interview, I would like to get your consent for participation. Please say "Yes" or "No" after each question.

Question 1: Have you read the information sheet concerning this study [and/or] have understood the verbal explanation of the study? Do you fully understand what will be required of you to take part in the study?

Questions 2: Do you understand that you can withdraw from this study without giving a reason at any point in time. There will be no effect, positive or negative, on you or your household if you decide to withdraw from this study?

Question 3: Do you understand that results from this study including possible quotations from your interview may be published in scientific journals or reports without the use of any information that could identify you?

Question 4: Do you consent to provide the contact information of your family/friend or other community members so that the research team can use it in case it is necessary to find you for a follow up appointment and you cannot be reached directly?

Question 5: Do you consent for the research team to audio record some of our sessions with you for the purpose of checking the quality of the sessions delivered?

Question 6: Do you agree to take part in this study?”

Statement by the researcher/person taking consent

I have made sure that the respondent understands the purpose and process of the study. I confirm that the respondent was given the opportunity to ask questions, and that all the questions asked by the respondent have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and that the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the respondent.

Print name of researcher/person taking the consent:

Print position of researcher/person taking the consent:

Signature of researcher/person taking the consent:

Date (Day/month/year):
