Version 2. 04/04/2024
Annex 2.2 Participant Qualitative Interview

Information sheet and consent form for participation in:
Qualitative interviews 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 a wartime who are experiencing high level of stress and drink alcohol to feel better. 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. You have recently taken part in the CHANGE programme.

You are invited to participate in an interview as part of the study. The purpose of this interview is to hear how you have experienced participating in the CHANGE programme so that we can see if there is anything we can do to further improve it.

What will happen to me if I take part?

If you take part in this interview, we will ask you some questions about your experience of the CHANGE programme. This will help us understand what is working well and whether we need to make any adjustments. The interview will be held in an online format or via phone. This interview will take less than one hour to complete. Interviews will be audio recorded and then transcribed. The purpose of audio recording is to accurately capture the details of our conversation during the interview. This allows us to review and analyze the information shared during the interview at a later date. The recorded data will be used solely for research purposes and will be treated with the utmost confidentiality.

Why have you been contacted?

You are being invited to take part in this interview because you participated in the CHANGE programme.

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. 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 what needs to be done to improve a programme that will contribute to improving the wellbeing of war-affected men in Ukraine.

What are the possible risks and disadvantages of taking part?

We do not expect you to experience any risks or disadvantages from participating in this interview.

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, the London School of Hygiene and Tropical Medicine in London and on an external hard drive located at NaUKMA Center office. Respondent-related data will be labelled by an id number rather than by using your name or by using any other personal identifiers of you. All audio recordings will be deleted once we have finalized the transcripts and completed the analysis.

Reimbursement and compensation:

We will follow ethics committee guidance and reimburse participants for their time after the interview. Participants will receive either a 250 UAH gift card to a local grocery store or 250 UAH in phone credit.

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. These results may include quotes from you, however they will not include information that can be used to identify you.

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, +380660304020 (mobile)

Project Manager

Vita Kachai, v.kachay@ukma.edu.ua, +38095 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 my interview being audio recorded.	
I agree to take part in this study.	

Verbal consent form for semi-structured interviews procedure

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 an interviewee, 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: Do you consent for our discussion to be audio recorded?

Start recording

Interview Reads:

“Thank you for consenting to being recorded. The recording has now started.

Question 2: 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 3: 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 4: 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 5: 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):

_____ _____