Informed Consent Form

Participant ID:
Researcher ID:

Title of the proposed study
Alcohol use in Humanitarian settings: a programme of work to address alcohol and associated adversities among conflict-affected populations in Uganda and Ukraine (CHANGE)

Investigators

#	Name		Roles of the investigators	Address
1	Prof. Wietse A. Tol	Principle investigator	Acts as the over all in management of the integrity of the design, conduct, and reporting of the research project	Department of Public Health, Global Health Section CSS, Øster Farimagsgade 5, bg. 9, DK-1014 Copenhagen DK Tel: +256793391552 / +4561656824 E-mail: wietse.tol@sund.ku.dk
4	Prof. Eugene Kinyanda	Site principal investigator	Takes up the role of management of the integrity of the design, conduct and reporting at site.	Mental Health Section, MRC/UVRI & LSHTM Uganda Research Unit 51-59 Nakiwogo Street, Entebbe P.O. Box 49 Entebbe, Uganda Tel: +256788461950 E-mail: Eugene.Kinyanda@mrcuganda.org

A description of sponsors of the research project
CHANGE is a five-year research project funded by the NIHR–Wellcome Partnership for Global Health Research. The is led jointly by the London School of Hygiene and Tropical Medicine (LSHTM), HealthRight Uganda, and the University of Copenhagen.

What is the purpose of this study?
The purpose of this study is to investigate how to best support male refugees who are thinking too much and drinking too much in Uganda. This program can **only** help you if you are thinking too much and drink alcohol. If you do not drink alcohol, you will not benefit from this program, and you should not take part as it won't address your problems.
Thinking too much, high levels of stress, and drinking alcohol can be very common, especially when people have left their homes due to violence or other problems. Many people who experience high levels of stress and drink too much alcohol often do not get the help that they need.

We have developed a new programme of care for refugees that are experiencing high levels of stress and drink alcohol. This programme is called Problem Management Plus Alcohol (PM+A). We believe that participating in this programme may help you to manage the high levels of stress and emotional problems that you have told us about. We would like to see through this research whether this programme helps people with similar experiences and how we may improve the programme to better help other people. If you agree to take part in this study, you will be randomly put into one of two groups. Group 1 will receive a one-time information leaflet on how to reduce drinking alcohol, and group 2 will take part in a 6-week program to help reduce their drinking. This will be decided randomly, and we cannot guarantee which of the two groups you will be in. Some people will also be invited to take part in some qualitative interviews to ask about their experience of participating in the program.

What will happen to me if I take part?

Our project is composed of different parts. We will ask you some questions before you start the programme and after you finish the programme. Your answers to these questions will help us to improve the programme. If you take part in this study, you will be interviewed by a member of our research team that will ask you some questions about yourself, your wellbeing, and about some stressful experiences you might have experienced. This first interview will help us understand whether you are experiencing any stressful experiences and whether you are finding it hard to cope with them. The interview will also help us understand if the programme which we are developing could be helpful for you. The program will not be helpful to you if you **do not** drink alcohol. For this reason, we will ask you some questions about your drinking habits, and it is important that you answer these truthfully. If the programme could be helpful for you, you will be invited to participate, and will be randomly assigned to one of the two groups. This programme will be offered to you free of charge. This first interview will take approximately 10 minutes. If you are in group 1, we will have a conversation with you about reducing your drinking and we will give you some information. If you are in group 2, you will be asked to attend five or six individual sessions every week that will take about 90 minutes. During the sessions, you will take part in certain activities, receive some information, and discuss the issues that have been affecting you lately. You will also be provided with materials to practice helpful techniques at home. It is important to know that you will not receive any economic or material compensation for participating in the sessions.

Why have you been contacted?

You are being invited to take part in this research because you may be finding it difficult to cope with some stressful experiences and you may be thinking too much and drinking too much alcohol. The programme we invite you to take part in has been designed to help you manage 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 refugees experiencing high levels of stress or emotional problems.

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 stop doing the programme. Also, you retain the right to withdraw from this study at any point during the interview. Refusal to participate will have no negative effect 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 improve the wellbeing of refugees in Uganda. Additionally, we expect that the programme will be helpful for people experiencing high levels of stress and emotional problems including drinking too much alcohol. You may find that you learn some important skills for managing high levels of stress or emotional problems and that your levels of stress may reduce.

What are the possible risks and disadvantages of taking part?
You might find discussing some details of your mental health and alcohol use with someone who you do not know upsetting. You may always skip any questions which make you feel uncomfortable. If you become upset, you will be able to speak with an appropriate member of our research team. Our researchers and staff are trained in dealing with these situations and will help you to cope with such feelings. We will also refer you to a healthcare provider at the Arua Regional Hospital if needed.
We do not expect that PM+A 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. Respondent-related data will be labelled by a code rather than by using your name or by using any other personal identifiers of you. Audio files will be securely stored, and password protected at the London School of Hygiene and Tropical medicine and only the researchers will be able to access them. The study results will be reported in a way that ensures complete confidentiality to the fullest extent possible.

Reimbursement and compensation:
We will follow UNCST guidance and reimburse participants for their time during screening and at the end of the project. Participants will not be reimbursed for the individual sessions they 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.

The data may also be made available through a public data repository or to other researchers so it can be used to improve how health services are provided. Your personal information will not be included.

Who has approved the study?
This study has been reviewed and approved by Uganda National council for Science and Technology (UNCST), MildMay Uganda Research Ethics Committee in Uganda and the London School of Hygiene & Tropical Medicine, UK and 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 think of any questions after we have left about your rights and wellbeing, please feel free to contact Mildmay Uganda Research Ethics Committee (MUREC) chairperson Ms. Susan Nakubulwa; Tel: 0392174236, murec@mildmay.or.ug, Uganda National Council for Science and Technology (UNCST) and Geoffrey Akudrabo HealthRight International West Nile Sub Region, Plot 17, Garden Square, Junior Quarters, Central Division, Arua City, P.O. Box 16497, Wandegeya-Uganda, Tel: +256774595059.

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 research assistant before you decide whether to sign this form or not.

	Please tick if you agree
I have read the information sheet concerning this study and I have received a copy of it for me to keep. I fully understand the content.	
I am aware that I can withdraw at any time. I understand that by signing this form will not have any impact on my legal rights, it just means that I the study has been explained to me and I am willing to participate.	
Results from the study may be published in scientific journals or reports, without the use of any information that could identify me.	

I agree to take part in this study
Name:……Signature or thumbprint:……Date……

Name of the participant written by the witness

…….Signature of witness……Date……..

Name of the witness……. Signature of impartial witness (if respondent

is illiterate): ……..Date: …...../…...../…..... [dd/mm/yyyy]

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):

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