



Participant Information Sheet (Version 1.1 – 06/06/2023)

Testing a digital intervention: Ration study

You are being invited to participate in a research study. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take some time to read the following information carefully and feel free to ask us if you would like more information or if there is anything that you do not understand. Please also feel free to discuss this with your friends, relatives, and GP if you wish. We would like to stress that you do not have to accept this invitation and you should only agree to take part if you want to.

Invitation to take part

We would like to invite you to take part in a study on a study which is exploring the impact of alcohol use on female veterans of the UK Armed Forces.

What makes me eligible to take part?

You are eligible to take part in this study if you own a smartphone, consume **more than 15 units** of alcohol per week and identify as female.

What happens if I take part?

If you take part in this study, you will be asked to use a digital platform delivered via a smartphone application for 3 months, and to answer questions about your drinking and mental health each month. A small number of participants will be randomly selected and invited to complete an interview to discuss in more detail what they thought about the app.

Who is doing this research?

This study is being conducted by the King's Centre of Military Health Research based at King's College London in collaboration with Lancaster University and Combat Stress and is funded by the Office for Veterans Affairs. King's Centre of Military Health Research has been conducting research into the health and wellbeing of current and former members of the UK Armed Forces and their families since 1996. King's Centre of Military Health Research is **independent** of the Ministry of Defence.

Do I have to take part?

No, it is your choice. You do not have to take part, and if you do decide to participate, **you are free to withdraw from the study, or uninstall our apps, at any time and without giving a reason.** Your decision to take part, or not, will not affect the healthcare you receive in any way.

What will I be asked to do?

If you decide to participate in this study, you will be invited to download a study app via the Apple or Google app store. Once you have downloaded the app you will be asked to enter a unique token which will allow you to register an account. Once you have registered an account, you will be asked to

consent to us sending you notifications, collecting information about how you use our digital platforms and access to physical activity data (recorded by Apple Health and Google Fit). You are not required to install or use Apple Health or Google Fit to take part in this study. If you provide consent that allows us to access data held by these apps, we will collect information related to heart rate and fitness activities which includes walking, running, and swimming. You can decide **not to share any of this information** with us and you can **change your mind at any time** via the 'Settings' tab of the app.

We will also sometimes send you notifications to remind you to fill out some questions about your mood, environment and health or to provide supportive messages to help you reduce your alcohol consumption. If you prefer not to receive these notifications, you can turn them off at any time within the 'Settings' tab on the app.

You will be asked to take part for a **maximum of 3 months**. After 3 months, your account will be disabled, and you will be asked to uninstall our apps. At the end of 28-days, you may be invited to take part in an interview to discuss what you found easy and difficult when using the app. This will take approximately **60 minutes**. We will provide more information about this interview later if you've been selected. We will only be selecting 10 participants to take part.

Who will have access to my data and how will it be used?

King's College London is the sponsor for this study based in the United Kingdom. We will be using information from you to undertake this study and will act as the data controller for this study. This means we are responsible for looking after your information and using it properly. King's College London will keep anonymous information about you for 7 years after the study has finished. Identifiable information about you will be deleted by 1st June 2024.

It is important to understand that your data will be processed under the terms of UK data protection law (including the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018).

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, you have the option to delete your data or allow us to use the data we have already collected from you. If you decide to withdraw, this **must be done by the 1st June 2024** after which data will be extracted and used for analysis. To safeguard your rights, we will use the minimum personally identifiable information possible. You can **withdraw or delete your data at any time** by visiting the 'Settings' tab of the app. You can find out more about how we use your information by contacting Dr Daniel Leightley (daniel.leightley@kcl.ac.uk).

The only people in King's College London who will have access to information that identifies you will be people who need to contact you to check on your progress throughout the study or audit the data collection process. Please note: identifiable information about you will be deleted by 1st June 2024.

To maintain your anonymity, your name will be replaced with a code, and the information collected from the app will only be associated with this code. Your data will be securely stored on servers managed by the King's Centre for Military Health Research, King's College London, located in London, UK. This data will not be linked back to your personal information.

Information you provide via the app, such as drinks diary, questionnaire responses and, if permission is given, activity data, will be checked and followed-up on by the research team. If any information is revealed which suggests a risk of harm to yourself, we may call you to ask further questions and discuss options.

In the unlikely event that you lose capacity to consent during the study, you will be withdrawn, but any data collected up until this point may still be used. You can voluntarily withdraw from the study at any time.

If you take part in any optional interviews to discuss your experiences of participating, only your participation code will be associated with these interviews, not your name, so information you provide will be anonymous.

Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance. Where there is a risk that you can be identified, your data will only be used in research that has been independently reviewed by an ethics committee.

What are the risks and disadvantages of taking part?

There are unlikely to be any direct risks to you if you take part in this study as the app is designed to reduce your consumption of alcohol. However, if we detect that you may be drinking at an increased level, we may get in touch to provide guidance and support to help manage your alcohol consumption. If you have any negative experience as a result of taking part in this study, please let us know immediately by contacting Dr Daniel Leightley (daniel.leightley@kcl.ac.uk).

There is a small risk that the technologies used in this study could be hacked, however this risk is the same as with any smartphone or commercial app. The encryption and data de-identification processes have been put in place to minimise any risk to you in the unlikely event of hacking.

What are the benefits of taking part?

Taking part in this study may benefit you directly and help you to reduce your drinking. You will also be helping the ex-serving community more widely by helping us to test a health intervention which can benefit others in the future.

As a gesture of goodwill, you will receive a £15 Love2Shop voucher as a thank you after completing the final questionnaire.

What will happen to the results of the research?

The results of this study will be published in scientific journals and presented at conferences. You will not be **identified personally** in any report or publication. If you would like to be informed of the findings of this research, please contact Dr Daniel Leightley (daniel.leightley@kcl.ac.uk).

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the Research Ethics Committee of King's College London, Application Number: LRS/DP-22/23-36879

Who do I contact for more information?

If you have any questions or difficulties relating to the study which you would like to discuss with the research team, please contact:

Dr Daniel Leightley
Email: daniel.leightley@kcl.ac.uk
Address: King's Centre for Military Health Research (KCMHR)

Institute of Psychiatry, Psychology & Neuroscience, King's College London
Weston Education Centre (Room 3.11), Cutcombe Road, LONDON, SE5 9RJ

Telephone (9am-5pm Monday-Friday): 020 7848 5351

What do I do if something goes wrong?

If this project has harmed you in any way or if you wish to make a complaint about the conduct of the project you can contact King's College London using the details below for further advice and information: Chair of the PNM RESC, email: rec@kcl.ac.uk or telephone: 020 7848 2020

Thank you for reading this information sheet and for considering taking part in this research.