

MOD Research Ethics Approval Number: 2154MODREC22 MOD Research Ethics Approval date: 20 Sep 2022



# Drinking & Wellbeing in Military Personnel Additional Drinks:Ration App Information

Study Title: Drinking & Wellbeing in Military Personnel Sponsor: King's College London & Defence Research & Innovation Principal Investigator: Dr Kate King

## **Invitation to Take Part**

You have previously agreed to take part in a study looking at drinking behaviours, health and wellbeing in serving military personnel. You have been selected as one of the participants to be offered the Drinks:Ration smartphone application which can help manage and monitor alcohol consumption. This sheet gives additional information about the app and should be read in conjunction with the participant information and consents that you agreed to as part of the Drinking & Wellbeing in Military Personnel study.

If you agree to participate, then you will be asked to download the app and use it for a minimum of one month. You will be asked to answer various surveys through the app instead of having them emailed to you.

# Why have I been invited to take part?

You have been asked to download and use the Drinks:Ration app because you have answered questions which suggest that your drinking could potentially pose a risk to your long term health.

# Do I have to take part?

No, it is your choice. You do not have to use the app.

You may continue with the rest of the Drinking and Wellbeing in Military Personnel study without downloading the app. In this case, you will continue in the study and receive periodic surveys to complete online via email.

You may choose to no longer participate in any aspect of the Drinking and Wellbeing in Military Personnel study. In this case, your data will be combined with others for analysis, but you will no longer be contacted by the researchers.

## What will I be asked to do?

If you decide to participate with the app arm of the study, you will be invited to download the King's College London designed app called Drinks:Ration via the Apple or Google app store. Once you have downloaded the app you will be asked to scan a unique QR code which will allow you to register an account. Once you have registered an account, you will be asked to consent to us collecting additional information. This information includes allowing us to send you notifications. 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 Drinks:Ration app.

The app will also sometimes send you notifications to either fill out some questions about your mood, environment, social aspects of your life, 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 within the app. You will be asked to use the app for a minimum of one month, but you can continue to use the app for as long as you find it beneficial.

# Are there any direct benefits to me of taking part?

The app has been shown to help people manage and monitor their alcohol consumption. It may therefore provide direct benefit to you by helping you reduce your drinking. You will also be helping us test a health intervention that may benefit other military personnel in the future.

## What are the possible disadvantages (or risks) of taking part?

There are unlikely to be any direct disadvantages or risks associated with using the app. You are reminded however, that if we detect that you may be drinking at a harmful level, we may get in touch to provide guidance and support. This will be done using the Independent Medical Officer (IMO) for the study and the conversation will be recorded on your

medical notes. If the IMO believes that there is a significant risk to yourself or others from your drinking, then he may be professionally obliged to seek further medical attention. This will always be discussed with you prior to involving any additional professionals.

## Can I withdraw from the research and what will happen if I withdraw?

Yes, you can withdraw at any time. You can withdraw or delete your data at any time by visiting the "Settings" tab in the app to withdraw. Withdrawing will not affect the care you receive from DPHC in anyway. You do not have to explain why you wish to withdraw.

## Will I receive any expenses or payments, or will this study cost me anything?

No, there is no payment for participating in this study. Participation will not cost you anything.

# Will my taking part or not taking part affect my career?

No. Neither the Ministry of Defence, Defence Primary Health Care, nor your own Chain of Command will know whether you participate or not or be given any information you submit to us as part of the study.

## Who do I contact if I have a complaint?

This information is detailed on the Drinking & Wellbeing in Military Personnel study information leaflet.

# What happens if I suffer any harm?

This information is detailed on the Drinking & Wellbeing in Military Personnel study information leaflet.

# Will my records be kept confidential?

No personal identifiable information is collected by the Drinks:Ration app. To maintain your privacy, your name will be replaced with a code and all the information gathered for the study will be linked to this code. The researchers will have access to this code, but not your name. If there are concerns about your safety throughout the study then the researchers will highlight this and your participant code to the Independent Medical Officer. He will be able to link the code back to your name and contact you to offer further support.

## How will my data be handled?

All the information you give us will be managed in line with the General Data Protection Regulation (GDPR) which is part of the Data Protection Act (2018). We will store and process the data related to this study on the basis of Article 6(1.e) "processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller". The special condition category is article 9(2)(j) of GDPR; "processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject".

We will use your data primarily for the purposes of this research project. If the results of this research will indicate that further studies are beneficial for the military community, we may process your personal data for the purpose of extending our research in the field of alcohol behaviour change. You will be informed before the further compatible processing takes place. Your data will not be shared for marketing purposes or to make decisions about future services available to you.

Your data will be stored on secure encrypted servers through King's College London and King's Centre for Military Health Research. These comply fully with UK and Defence data security requirements. Only the research team will have access to the data. The data files used for analyses by the study team will be de-identified, meaning that your name and other identifiable information is removed. The data will be kept for 7 years after the study has finished to allow us to manage and analyse the data. If no future analyses are planned after 7 years, all of the data will be securely destroyed.

## **Rights of access.**

You are entitled to see the information we hold about you. Participants using the app can access a copy of all of the data held on the app through the app settings. If you would like to access your other data please contact:

King's College London Data Protection Officer, Information Compliance Team, Waterloo Campus Room 5.20, James Clerk Maxwell Building, 57 Waterloo Road, London. SE1 8WA Email: info-compliance@kcl.ac.uk

# How do I object to my data being used?

Article 21 of the GDPR gives you the right to object to the processing of your personal data. If you wish to object please email the King's College London Data Protection Officer, Information Compliance Team, Waterloo Campus Room 5.20, James Clerk Maxwell Building, 57 Waterloo Road, London. SE1 8WA Email: info-compliance@kcl.ac.uk

If you want to complain about how the researchers have handled your information, you should contact the principal researcher, in the first instance, using the contact details below. If you are not happy after that, you can contact the Data Protection Officer using the contact details above. He will investigate the matter. If you are not happy with his response or believe that we are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Officer (ICO) at www.ico.org.uk or 0303 123 1113.

## Who has reviewed this study?

This study has been reviewed and given favourable opinion by the Ministry of Defence Research Ethics Committee.

#### **Further information:**

Further information is available from Dr Kate King, MD(Res) Student, King's Centre of Military Health Research, King's College London, SE5 9RJ / +44 300 160 6665 / <u>katherine.king@kcl.ac.uk</u> and can be found on the study website: <u>https://drinksration.app/</u>

A copy of this additional information will be emailed to you on completion of this form.

#### Compliance with the Declaration of Helsinki.

This study will be conducted in accordance with the principles defined in the Declaration of Helsinki as adopted at the 64th WMA General Assembly at Fortaleza, Brazil in October 2013.

#### Consents:

The nature, aims and risks of the research have been explained to me. I have read and understood this Participant Information Sheet and understand what is expected of me. All my questions have been answered fully to my satisfaction.	○ Yes	0 <b>No</b>
I understand that if I decide at any time during the research, up until 30 <sup>th</sup> April 2023, I no longer wish to participate in this project, I can notify the researchers in-volved and be withdrawn from it immediately without having to give a reason. I also understand that I may be withdrawn from the study at any time by the research team. In neither case will this be held against me in subsequent dealings with the Ministry of Defence. After 30 <sup>th</sup> April 2023, my data will be combined with other participants and it will no longer be able to be individually identified.	○ Yes	○ <b>No</b>
I consent to the processing of my personal information for the purposes of this research study. I understand that such information will be treated as confidential and handled in accordance with the provisions of the Data Protection Act 2018.	○ Yes	0 <b>No</b>

I have read this form and I am aware that this information is supplemental to the participant information sheet for the Drinking & Wellbeing study and relates to the Drinks:Ration app.

• I agree to download the Drinks:Ration app and continue in the app arm of the study.

• I do not wish to download the app, but I do wish to continue with the rest of the Drinking & Wellbeing in Military Personnel study.

• I do not wish to download the app, and I do not wish to continue with the rest of the Drinking & Wellbeing in Military Personnel study.

Full Name

Signature