

MOD Research Ethics Approval Number: 2154MODREC22

MOD Research Ethics Approval date: 20 Sep 22

# Drinking & Wellbeing in Military Personnel

## Consent to participate in research

**Study Title:** Drinking & Wellbeing in Military Personnel

**Principal Investigator:** Dr Kate King

**Sponsor:** King's College London & Defence Research & Innovation

### Invitation to Take Part

You are invited to take part in a study looking at drinking behaviours, health and wellbeing in serving military personnel.

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 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 should only agree to take part if you want to.

If you take part in this study you will be asked to complete various surveys about your drinking behaviour and health over a 3 month period. The surveys will be sent either by email or through a smartphone application you can download. All participants will be given access to the app, but at different points in time. There will be a short follow up survey sent out 6 months from now.

### Who is doing this research?

This study is being conducted by Dr Kate King as part of a Doctor of Medicine (Research) degree with King's Centre for Military Health Research based at King's College London. The King's Centre for 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 for Military Health Research is independent of the Ministry of Defence and the Defence Medical Services.

The academic fees and this research are being funded by the Defence Medical Services and Dr King is employed as a GP with the Royal Navy.

### What is the device or procedure that is being tested?

We are looking at what effect various different interventions have on changing alcohol use behaviour in military personnel in order to better support military personnel who are at increased risk of alcohol related harm.

For some people this will involve downloading a smartphone application. All personnel participating will have access to the smartphone application on completion of their data gathering phase.

### Why have I been invited to take part?

All members of the UK Armed Forces are eligible to take part.

### Do I have to take part?

No, it is your choice.

You do not have to take part. If you do decide to participate, **you are free to withdraw from the study**, without giving a reason. Whether or not you decide to take part will not affect the healthcare you receive in any way. We will not disclose to Defence Primary Health Care (DPHC) or your Chain of Command if you do, or do not, take part in this study.

### What will I be asked to do?

If you consent to take part, you will be sent a range of short surveys over the next 3 months and then a final survey in 6 months time. These surveys will ask different things about your drinking behaviours, health and wellbeing. Most people will be emailed the surveys. Some people will be asked to download a smartphone application from the Apple or

Google app stores. Those using the app will need to consent to push notifications being sent to remind you to do the surveys.

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

You may become more aware of your drinking behaviours and alcohol use. You will also be helping the wider military community by helping understand what effects drinking behaviours and the impact drinking has.

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

There are unlikely to be any direct disadvantages or risks to taking part in the study.

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 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.

Some of the survey topics may be emotionally difficult and these surveys are optional for completion. Each will come with a trigger warning and signposting to support services if required.

There is a small risk that the technologies used in this study could be hacked, in the same way as with any smartphone or app. Encryption and data de-identification processes have been built in to minimise any risk to you in the event of hacking.

If you have any negative experiences as a result of taking part in this study, please let us know immediately by contacting Dr Kate King ([katherine.king@kcl.ac.uk](mailto:katherine.king@kcl.ac.uk)).

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

Yes, you can withdraw at any time. You can withdraw by contacting the Principal Investigator via email at [katherine.king@kcl.ac.uk](mailto:katherine.king@kcl.ac.uk) or, those participants using the app can visit the "Settings" tab 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.

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 opt to delete your data, this must be done by 30 April 2023 after which the data will be extracted for analysis. To safeguard your rights, we will use the minimum personally-identifiable information possible.

### **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. If your responses suggest that you are at significant risk of harm to yourself or others then the IMO will contact you directly to discuss the situation. He may be professionally obliged to seek additional professional support but this will always be discussed with you beforehand.

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

If you should have a complaint about the conduct of the research then please contact the Independent Medical Officer for the study, Dr Toby Holland, Academic Department of Military General Practice, ICT Centre, Vincent Drive, Birmingham, B15 2SQ / 0121 414 8853 / [toby.holland634@mod.gov.uk](mailto:toby.holland634@mod.gov.uk).

### **What happens if I suffer any harm?**

If you suffer any harm as a direct result of taking part in this study, you can apply for compensation under the Ministry of Defence's No-Fault Compensation Scheme. Information about this scheme will be sent to you, along with a copy of this consent form, if you consent to take part.

**Will my records be kept confidential?**

Your personal identifiable information is asked for in the initial consent stage and so that we can contact you with the surveys. Your name and contact details are stored separately from all of the other data that you give us. To maintain your privacy, your name will be replaced with a code and all of 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 we share the findings of the study?**

The findings of this study will be published as part of the submission for a Doctorate of Medicine (Research) by Dr Kate King. They may also be published in scientific papers, presentations and reports to various communities interested in military health and wellbeing. They may be used to redesign MOD or NHS policies and processes. You will not be identified personally in any report, submission or presentation. Your data will be grouped and managed in bulk with that of the other participants.

If you would like to be informed of the findings of this research please tick the box below.

Please email me with the findings of this study.

**How will my data be handled?**

All of 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".

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 medical research database which fully complies with UK and Defence data security requirements. UK based encrypted servers managed by the University of Birmingham and King's Centre of Military Health Research (app based information). 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:

1) King's College London Data Protection Officer, Mr Albert Chan (Assistant Director of Business Assurance), Information Compliance Team at King's College London, Waterloo Campus Room 5.20, James Clerk Maxwell Building, 57 Waterloo Road, London. SE1 8WA Email: info-compliance@kcl.ac.uk

and

2) Data Protection Officer, Research & Clinical Innovation, ICT Building, Birmingham Research Park, Vincent Drive, Birmingham. B15 2SQ

**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 Data Protection Officers on the email addresses above.

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 Officers for the study using the contact details above. They will investigate the matter. If you are not happy with their 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](http://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 / [katherine.king@kcl.ac.uk](mailto:katherine.king@kcl.ac.uk) and can be found on the study website: <https://drinksration.app/>

A copy of this information and the arrangements for the payment of No-Fault Compensation to Participants in MODREC approved studies 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.	<input type="radio"/> Yes	<input type="radio"/> No
I understand that if I decide at any time during the research, up until 30 April 2023, that I no longer wish to participate in this project, I can notify the researchers involved 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.	<input type="radio"/> Yes	<input type="radio"/> No
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.	<input type="radio"/> Yes	<input type="radio"/> No
I understand that, in the event that I am a significant risk of harm to myself or others, the Independent Medical Officer may seek additional professional support, but this will be discussed with me beforehand.	<input type="radio"/> Yes	<input type="radio"/> No
I consent to the processing of my personal information as part of future studies into alcohol use and social behaviours.	<input type="radio"/> Yes	<input type="radio"/> No
I understand that in the event of my sustaining injury, illness or death as a direct result of participating as a volunteer in this research, I or my dependants may enter a claim with the Ministry of Defence for compensation under the provisions of the no-fault compensation scheme, details of which will be sent to me.	<input type="radio"/> Yes	<input type="radio"/> No

I have read this form and I am aware that I am being asked to participate in a research study.

I agree to participate in this study

I do NOT agree to participate in this study

**Full Name** \_\_\_\_\_

**Service Number** \_\_\_\_\_

**Phone Number** \_\_\_\_\_

**Signature** \_\_\_\_\_

**E-mail** \_\_\_\_\_

**Date and time** \_\_\_\_\_