Application No : 2154/MODREC/22

Ministry of Defence

Ministry of Defence Research Ethics Committee (MODREC)

MODREC Application Form

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Please ensure the Research Sponsor checklist has been completed and this application has received a SAC approval prior to applying to MODREC.

The Research Sponsor checklist and any other supporting documents must be included as annexes to the main body of the application. Once the application has been completed in full, the guidance text in blue italics can be deleted and the application emailed to the MODREC Secretariat (DST-MODRECTeam@mod.gov.uk)

1. Study Title

What is the effectiveness of the Drinks:Ration smart-phone app on modifying alcohol use behaviour in Service personnel at risk of alcohol related harm?

2. Date/Version

Date: 20 Sep 2022	**Version:** 2.4

3. Summary of Project

The Military Drinks:Ration study is a randomised controlled trial of a smartphone application to determine its effectiveness in changing alcohol use behaviours in Service personnel.

Drinks:Ration was designed by King's Centre for Military Health Research (KCMHR), in conjunction with the University of Liverpool, following the Medical Research Council Complex Intervention Guidelines and using co-design methodology. It is a digital platform for alcohol brief interventions grounded in evidence based behavioural change theory[1,2,3]. The application has been studied and developed in recent years. Initial feasibility and acceptability studies led to a randomised controlled trial (RCT) in help-seeking veterans funded by Forces in Mind Trust and supported by Combat Stress. This trial was registered with ClinicalTrials.gov (registration number: NCT04494594) and approved by the local ethics committee of King's College London (registration number: HR-19/20-17438). The RCT concluded in early 2022 and has proven the app's effectiveness in reducing alcohol intake in the veteran population. Alcohol intake reduced by 28.2 units per week [95% CI: -36.9 to -19.5] in the intervention arm compared to 10.5 units per week [95%CI: -19.5 to -1.5] in the control arm (p-value for difference between arms at day 84 = 0.003) (pending publication).

This document presents a proposed replication of the Forces in Mind funded veteran's RCT in a serving military population, alongside a parallel data gathering group which will collect prevalence data on a range of alcohol related behaviours.

4. Investigators

4a. Chief Investigator

Name and Title: Dr Kate King
Grade/Rank: Surg Cdr
Post Title: Post-graduate Research Student
Department: King's Centre for Military Health Research
Establishment: King's College London
Address: Weston Education Centre
10 Cutcombe Road
London
SE5 9RJ
Telephone: +44 300 160 6665
Email: katherine.king415@mod.gov.uk
katherine.king@kcl.ac.uk

4b. Does this project contribute towards a qualification? Yes

Type of qualification: MD(Res) Psychological Medicine

Research Supervisor: Professor Nicola Fear
Post Title: Professor of Epidemiology & Director of King's Centre for Military Health Research
Department: King's Centre for Military Health Research
Establishment: King's College London
Address: Weston Education Centre
10 Cutcombe Road
London
SE5 9RJ
Telephone: 07961 329550
Email: nicola.t.fear@kcl.ac.uk

4c. Other Investigators/Collaborators/External Consultants

Name and Title: Dr Dan Leightley
Post Title: Additional Supervisor & Research Fellow
Department: King's Centre for Military Health Research
Establishment: King's College London
Address: Institute of Psychiatry, Psychology & Neursoscience
16 De Crespigny Park
London
SE5 8AF
Email: daniel.leightley@kcl.ac.uk

Name and Title: Professor Neil Greenberg
Post Title: Clinical Supervisor for MD(Res)
Department: King's Centre for Military Health Research
Establishment: King's College London
Address: Weston Education Centre
10 Cutcombe Road
London
SE5 9RJ
Email: neil.greeberg@kcl.ac.uk

4d. Volunteer Advocate or Independent Medical Officer	
Name:	Professor Mike Smith
Address:	Defence Professor of Military General Practice Research & Clinical Innovation ICT Centre, Birmingham Research Park Vincent Drive BIRMINGHAM B15 2SQ
Telephone:	0121 4158875
Email:	michael.smith119@mod.gov.uk

5. Research Sponsor

Research Sponsor:	Brigadier Duncan Wilson
Organisation:	Research & Clinical Innovation Defence Medical Services
Title:	Dr / Brigadier
Position:	Head of Research and Clinical Innovation (Medical Director)
Address:	Research & Clinical Innovation ICT Centre, Birmingham Research Park Vincent Drive BIRMINGHAM B15 2SQ
Phone Number:	0121 415 8882
Email:	duncan.wilson651@mod.gov.uk

6. Preferred Timetable

6a. Preferred Start Date:	Aug 22
6b. Expected Date of Completion:	Data collection end Nov 22 Thesis submission planned for spring / summer 2023.

7. Other Organisation(s) Involved and Funding

7a. Department/Organisation Requesting Research (if applicable):	Defence Primary Health Care (DPHC)
7b. If you are receiving funding please provide details here:	MD(Res) funded through DMS Higher Degree Board. Research costs funded through DMS Research Steering Group. Report of progress to be sent to DMS Clinical Committee at six month intervals and feedback to Higher Degree Board required annually. No other requirements linked to funding.
7c. Please declare any competing or conflicts of interests:	There are no competing or conflicts of interest.
7d. Type of research:	
i. Psychological/social survey x	

8. Scientific Assessment Approval

8a. Name of SAC that has reviewed/approved this application:	RN SAC
8b. Date of SAC approval:	9 Jun 22
8c. SAC reference number:	Drink-Ration_v2

9. Purpose of the Study and Defence Benefit

Purpose
This study aims to determine whether the Drinks:Ration smartphone application can change alcohol use behaviours in serving personnel.

Introduction
Consumption of alcohol is highly prevalent in the UK with 65% of men, and 50% of women, reporting having consumed an alcohol containing drink in the last week[4]. Consumption has steadily risen since the 1950s, with the most significant increase amongst women[5,6]. This has been driven by increased affordability, accessibility, and higher strength products[5]. A large cross-sectional study demonstrated that UK military personnel consume alcohol at rates higher than age and sex matched civilian personnel[7]. Military personnel are additionally more likely to drink excessively[7,8]. This binge pattern is attributed to the populations being, "young single individuals [who] are less likely to have children and other domestic responsibilities that make heavy drinking less frequent or possible"[7] and the military culture of communal risk taking[8].

Alcohol's negative effects are wide ranging and associated with harm to health, accidents, criminality, social disruption and poor occupational outcomes[4]. For those aged 15-49 in England, alcohol misuse is the single largest risk factor for ill-health and premature death[6]. UK Defence data suggests that 59% of military personnel are at risk of alcohol-related harm[9]. From the health perspective, alcohol is implicated in much of the mental health burden within Defence Primary Health Care (DPHC) and complicates other health related activity through interactions with medication, treatments and direct exacerbation of symptoms[9,10].

Alcohol is implicated in military disciplinary issues[11,12] and occupationally, alcohol misuse is associated with a loss of productivity, in a dose-dependent manner, through increased rates of sickness absence and presenteeism[6,8]. The occupational impacts of alcohol on the military are more extensive than in the civilian workforce due to the nature of military employment[7,8].

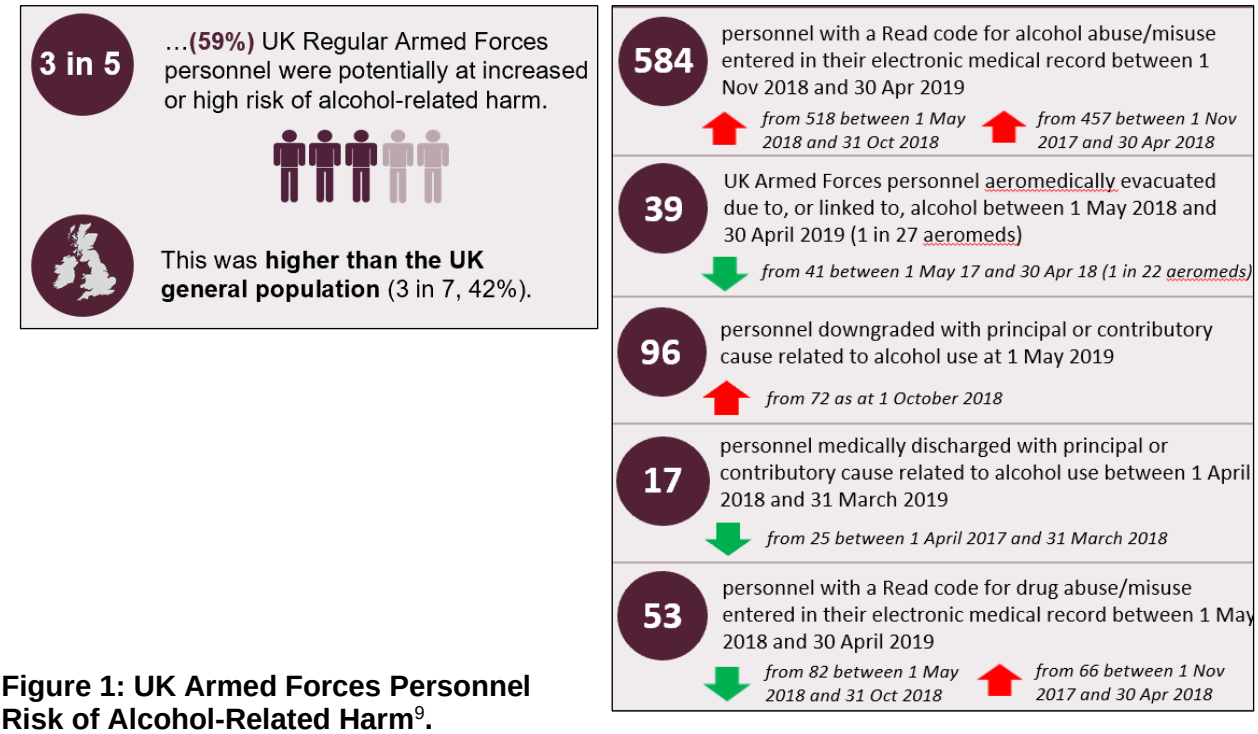


Figure 1: UK Armed Forces Personnel Risk of Alcohol-Related Harm[9].

National guidance recommends alcohol brief interventions (ABI) for patients identified as consuming alcohol at hazardous or harmful levels[13]. An ABI is "a simple intervention aimed at individuals who are at risk through drinking above the guidelines, but not typically seeking help

for an alcohol problem"[14]. All UK Armed Forces (AF) personnel are screened for higher risk drinking behaviours using the Alcohol Use Disorders Identification Test for Consumption (AUDIT-C)[15] at periodic dental inspections. A "brief intervention" is given to personnel who record a score of 4 or more (men) or 3 or more (women). Additional strategies to reduce alcohol use include annual alcohol, and drugs, lectures are mandated for those below 30 years of age, and disciplinary issues complicated by alcohol attract more significant punishment[16]. There is concern, however, that recent apparent reductions in alcohol intake reflect reporting bias rather than actual reduction in order to avoid being given an alcohol brief intervention or offered referral to the GP[17].

Existing evidence for the effectiveness of ABIs appears robust with an extensive Cochrane review determining they can reduce alcohol consumption by 2 standard drinks per week after a year[18]. However this defined an ABI as, "a conversation comprising five or fewer sessions of brief advice or brief lifestyle counselling and a total duration of less than 60 minutes"[18]. This exceeds the time available for opportunistic ABIs within Defence primary care. This review also excluded digital interventions which are intuitively of huge relevance in a young, digital native, population such as the AF. Face-to-face interventions may be effective, but not if they are not accessed by a digital generation[19–21]. A narrative review of 10 studies involving military personnel and veterans found that web-based interventions may be of benefit[22]. There remains, a paucity of evidence available for the effectiveness of ABIs on military populations, or indeed in which aspects of behaviour change theory are effective in a population with rigid Command structures and regulations.

KCMHR have developed the Drinks:Ration smart-phone app and piloted it with good effect in terms of drinking behaviours and user-satisfaction in the veteran community[19,20,23,24]. A trial of Drinks:Ration similar to this proposal, but using a help-seeking veteran population, recently demonstrated that between baseline and day 84, weekly alcohol consumption had a reduction of -10.5 [95% CI: -19.5 to -1.5] units in the control arm and -28.2 [95% CI: -36.9 to -19.5] units in the intervention arm (p-value=0.003; Cohen's d=0.35) (publication submitted).

The Drinks:Ration study in the veteran community integrated various validated surveys in order to capture information about the antecedents, motivations, behaviours associated with, and consequences of alcohol drinking. There are established links between a range of issues and drinking in the civilian population. Loneliness, reduced quality of life and gambling have all been shown to precipitate drinking behaviours as well as be worsened through drinking[25–27]. Drinking is associated with increased rates of domestic abuse and sexual assault. However, there is little information about similar linkages withing a UK military population.

The recent Defence Sub-Committee report on women in the Armed Forces[28] and the Wigston Report on Inappropriate Behaviours[29], found links between alcohol and sexualised behaviours. The "overlap between 'work-space' and 'life-space' in the military", especially with reference to the ritualised drinking, attitudes towards women, and hyper-masculinity, "may in part explain the prevalence of sexual harassment and sexual assault in military populations"[30]. However, due to reticence to report behaviour to the chain of Command and Military Police[28–30], there is little data on the actual prevalence. Reports to the NHS Serving and Ex-Serving Women's Health Improvement Group show significant under-representation of military personnel at Sexual Assault Referral Centres despite a recent national campaign. Gambling is a topic of concern to the Defence Health and Wellbeing team and the Defence Public Health Unit are in the process of reviewing this concern. In all of these areas, policy progression and decision making is hampered by a lack of basic prevalence data. This trial is an opportunity for Defence to get prevalence on a range of topics and to fully understand their link, if there is one, to drinking.

Results

The primary purpose of the Drinks:Ration RCT study is to determine whether similar effectiveness is found in a serving military population.

The secondary aim is to provide data on the prevalence of social behaviours and their potential association with alcohol consumption.

Defence Benefit

The Armed Forces population also has a relationship with alcohol that differs from the general public[7] and there is no existing evidence for the use of brief interventions within the UK Armed Forces. The trial of a military focused smartphone application may be effective at changing alcohol use behaviours. It could support or integrate into the current Defence alcohol management pathways. An effective app would additionally provide support to service personnel while they waited for specialist intervention from Defence Community Mental Health (DCMH) services. Additionally, if the links between drinking behaviours and social & health outcomes are better understood then there is scope for future policy design to target the precipitating factors leading to a more positive and healthy life served.

10. Study Design, Method and Data Analysis

Study Design

Drinks:Ration RCT

This study is a two-arm randomised controlled trial comparing the Drinks:Ration smartphone application with usual care. It is hypothesised that the Drinks:Ration application will be more effective at reducing alcohol consumption compared to the usual care control arm.

Participants will be recruited through periodic dental inspections, Service specific communications and social media, and through poster advertisements for the trial in military establishments. Participants will be recruited if they are current serving UK military and willing to be sent surveys to study their drinking behaviours, health and wellbeing. Initial screening with AUDIT-C will define eligibility for the trial arms. Participants with an AUDIT-C score of ≥5 will be eligible for the Drinks:Ration RCT. Those scoring ≤4 on AUDIT-C will not be eligible for the RCT but will still be able to partake in the surveys (see data gathering group below).

Randomisation will occur automatically using the Research Electronic Data Capture (REDCap) research management programme[31] after participants have read the participant information leaflet, consented to inclusion and completed basic demographics. Two participant blocks in a 1:1 ratio will be used to ensure equal gender distribution between the control and intervention arms. The REDCap randomisation module will be programmed, by the RCI / University of Birmingham statistician, independently of the research team to maintain blinding to participant treatment allocation.

Participants will be blinded to the intervention as they will be told that the research involves them completing various surveys about drinking behaviours, health and wellbeing. The intervention arm will be emailed copies of the relevant trial information leaflets and a link to download the Drinks:Ration app. They will be asked to use the app for a minimum of 28 days. The control arm will be emailed copies of the relevant trial information leaflets and informed that they will be emailed periodically with various surveys looking at alcohol use and health. There will be no contact between researchers and participants at any stage of the trial. If an adverse event is suspected, then the PI will review non-identifiable data and refer the case to the Independent Medical Officer (IMO) who will have data access rights allowing linking the trial reference number to the participant identification details. This process is explained in detail in section 11. Participant flow is shown in Figure 2 below.

Data Gathering Group

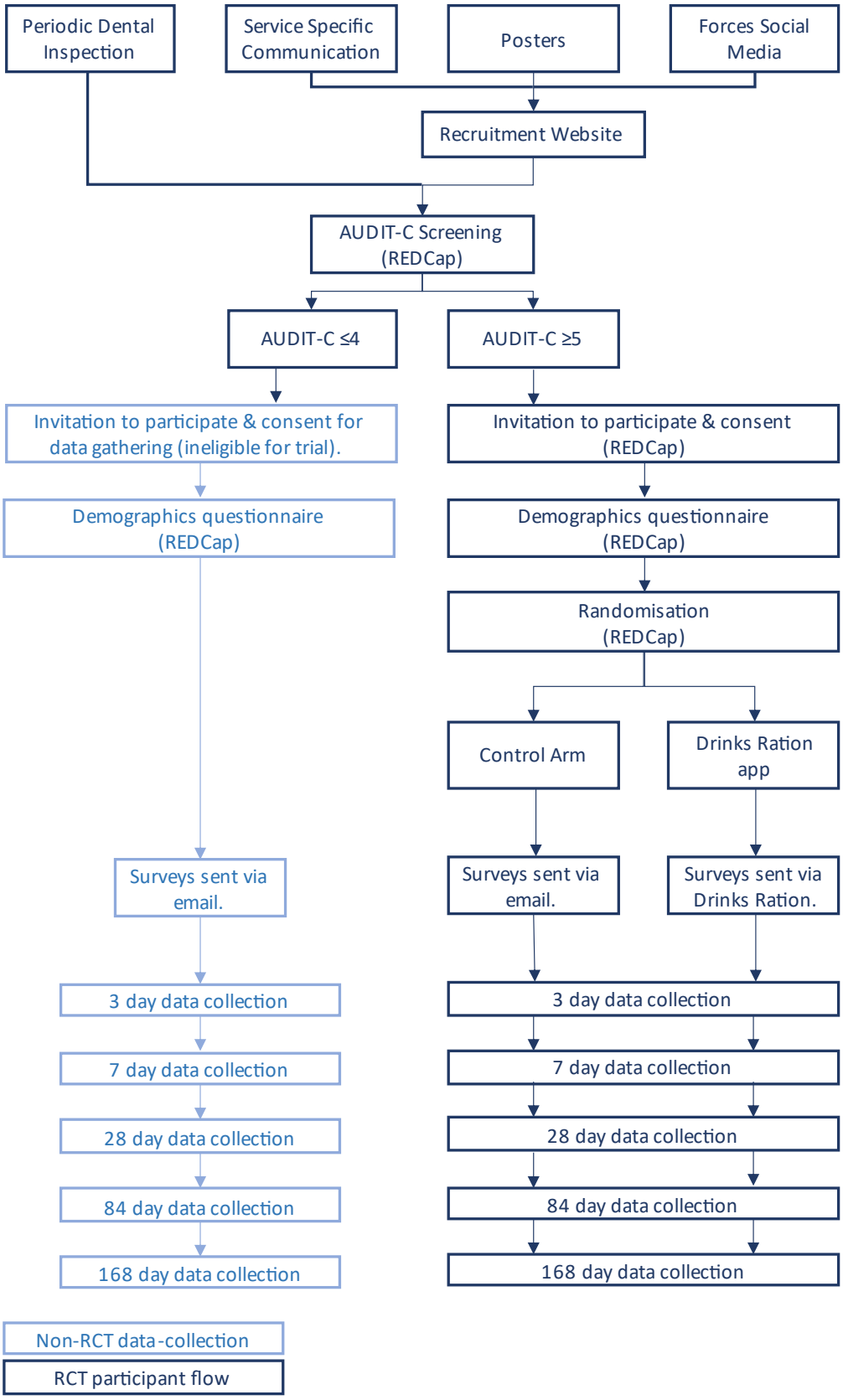
Participants screened out of eligibility for the Drinks:Ration RCT (those scoring ≤4 on AUDIT-C) will be asked to participate in the data gathering group which runs alongside the main RCT. This group receive the same surveys via email.

Intervention – Drinks:Ration RCT

The Drinks:Ration app has been developed by KCMHR and the University of Liverpool following the Medical Research Council Complex Intervention Guidelines[32]. Initial feasibility studies were published under the app title of 'InDEx' and showed that personnel engaged and used the app regularly and that the real time, personalised, credible feedback was appreciated[33,34]. A 7 unit per week reduction was seen in the feasibility study[33]. The app is available on both Android and iOS devices.

The app is designed to provide customised brief alcohol interventions using personalised messaging and feedback on drinking behaviours. It is specifically tailored for a military population. A large trial in veterans sponsored by Forces in Mind Trust and supported by Combat Stress used the app to deliver targeted interventions over a 28 day period. It showed a reduction in the marginal means of units consumed of -15.44 [95% CI: -25.52 to -5.35] at day 84; favouring the Drinks:Ration app over control group.

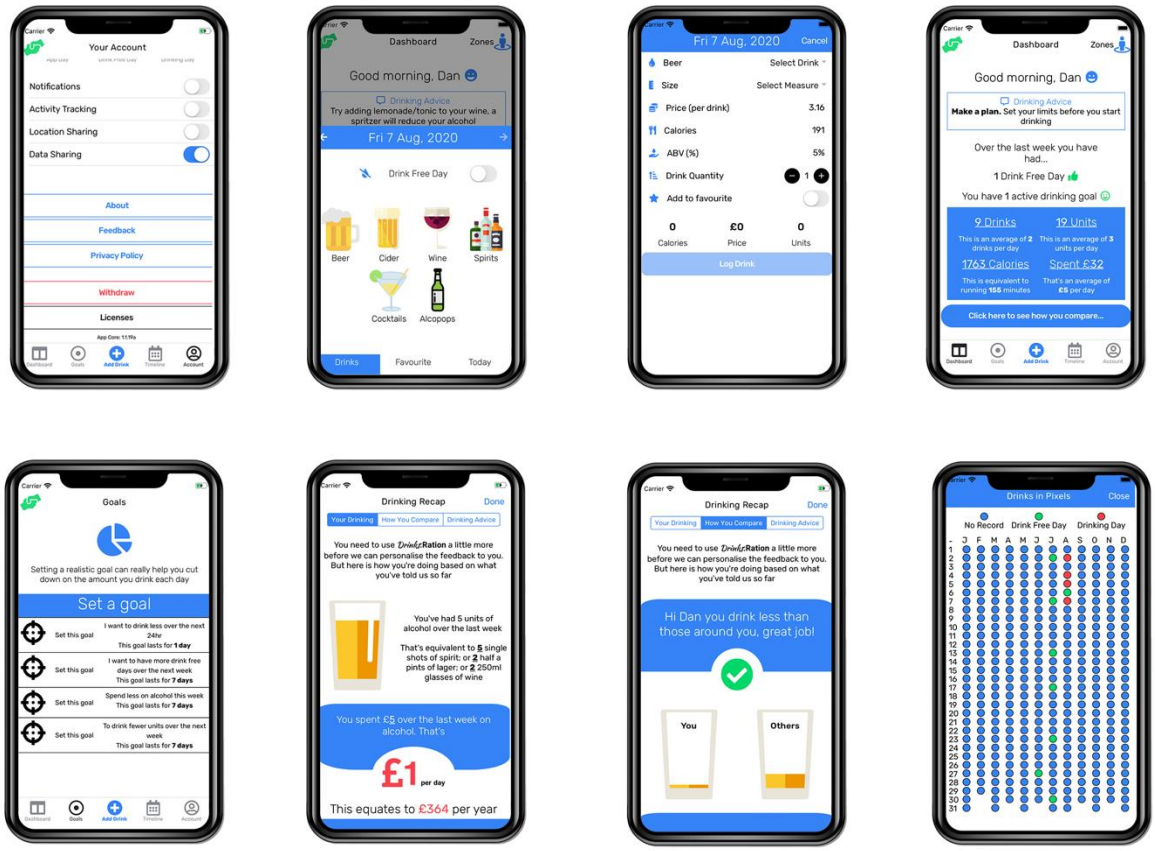
Figure 2: Participant Flow through the Study.



The app has five core modules which are detailed below and shown in the screenshots in Figure 3 below.

- Account management. Includes basic personal information such as first name, and basic app parameters including an option to leave the study. The app does not record user location.
- Questionnaire & individualised normative feedback. Infographics developed using participants' responses compared to data from the general population, the general military community and the other participants of Drinks:Ration.
- Self-monitoring & feedback. Alcohol consumption diary and uses various illustrations and charts to assist the participant monitoring their consumption. The illustrations and comparisons are personalised to provide feedback on personal motivations to reduce alcohol intake such as calories, cost, exercise required to counteract the alcohol.
- Goal setting and review. Users set goals which link to other app data to help inform illustrated feedback on progress towards achieving their goals.
- Personalised messaging. The app sends three types of push notification messages. Tailored messages are personalised based on drinking habits and weekly questionnaires. Tailored and triggered messages are tailored to individual data input and a specific event occurring. Targeted messages are generic ones sent to highlight inactivity or nudge the participant to complete a questionnaire.

Figure 3: Example Screenshots of the Drinks:Ration app[35].



Data Collection

Drinks:Ration RCT

The primary outcome measure is a change in alcohol units consumed per week between baseline and day 84 as measured by the timeline follow back method[36]. Secondary outcomes are change in AUDIT score, change in quality of life assessment, change in drinking motivations

and app usability. While the Drinks:Ration intervention aims to reduce alcohol intake at 84 days, a final data collection at 168 days will demonstrate whether any benefits persist.

Data will be collected through a selection of surveys being pushed to the participants in line with the periodicity detailed in Table 1 below.

Data Gathering Group

Survey data will be collected as per Table 1 below. As this group is not part of the RCT assessing effectiveness, repeated collection of the same measures over time is not required. Participation in this group is complete at 28 days from enrolment.

Table 1: Validated Surveys for Completion and Timeline.

Day/Measure	Total questions	0	0-1	3	7	28	84	168
Demographics	18	✓ β						
AUDIT-C[15]	3	✓ β						
Participation Information & Consent	-	✓ β						
Alcohol Use (AUDIT)[37]	10		✓			✓	✓	✓
Alcohol Intake (TLFB)[36]			✓			✓	✓	✓
Resource Allocation (YAACQ)[38]	24		✓				✓	✓
Readiness to Change Ruler	1		✓					
Self-efficacy Ruler	1		✓					
Depression (PHQ2)[39]	2		✓ β			✓		
Anxiety (GAD2)[40]	2		✓ β			✓		
International Trauma Questionnaire for PTSD (PC-PTSD-5)[41]	5		✓ β			✓		
World Health Organisation Quality of Life-BREF (WHOQOL-BREF)[42]	27			✓ β		✓ β	✓	✓
Loneliness (De Jong Gierveld)[43]	11			✓ β		✓ β		
Drinking Motivations (DMQ-R)[44] *	20			✓ β			✓	
Recent Life Events (RLE-Q)[45] *	21			✓ β				
Gambling Motives (GMQ-9)[46] *	9				✓ β			
Domestic Abuse (NCSE&W[1])[47] *	30				✓ β			
Sexual Assault (NCSE&W)[47] *	13				✓ β			
mHealth App Usability Questionnaire (MAUQ)[48]	16					✓		
Approximate time to answer (min)[2]		10	13	15	9	20	15	15

B= data gathering group.
✓= RCT group.
* = Not included in veterans' Drinks:Ration study

[1] National Crime Survey for England & Wales
[2] Allowing 10 seconds per question, rounded up and with additional comfort time added

Analysis

Drinks:Ration RCT

This study is designed based on the recently completed study in veterans which was sponsored by the Forces in Mind Trust. Analysis will therefore be undertaken in accordance with the published protocol for that study. There will be no interim analysis undertaken. The threshold for significance will be p=0.05. Effect sizes will be reported.

Descriptive statistics (e.g.: demographics and response rate) and independent sample t tests and chi-square tests will be carried out to explore and identify potential differences between the intervention and control arms at follow-up. An intention-to-treat method will be used for primary outcome analysis such that those who are lost to follow-up will be retained in the primary analysis. Multiple imputation will be performed to estimate missing data, where appropriate. The primary outcome analysis will examine whether there is a statistically significant difference between the intervention and control arms on change in self-reported TLFB UK units consumed. Repeated-measures mixed modelling analyses will be conducted to examine the primary hypothesis that those randomised to receive the Drinks:Ration app will report a greater reduction in alcohol consumption compared with control participants from baseline to 3-month follow-up (day 84).

For the secondary outcomes, changes in the AUDIT score and WHOQOL-BREF computed quality of adjusted life years will be assessed using repeated-measures mixed modelling. These analyses will be repeated to assess changes between baseline and follow-up and will serve as a secondary outcome to assess the longer-term impact of the intervention on participants. These analyses will be reported as secondary outcomes.[49]

The study will be reported in line with the CONSORT[50] criteria for RCTs and the Template for Intervention Description and Replication guide[51].

Data Gathering Group

Survey data will be assessed for distribution and an appropriate analysis of correlation against alcohol intake will be undertaken.

All analyses will be verified by a researcher out with the research team to address risk of bias.

Publication Plan

All data gathered will be written up as part of the thesis submitted for an MD(Res) in Psychological Medicine with King's College London.

In line with best research practice the Drinks:Ration RCT will be registered in an internationally available trials registry and the following academic journal publications are planned as a result of this research:

- Drinks:Ration RCT protocol (partially written, awaiting favourable outcome from MODREC)
- Drinks:Ration trial outcomes
- Prevalence of gambling in the UK Armed Forces
- Motivations for alcohol drinking in the UK Armed Forces
- Patterns of social behaviours and their associations with alcohol in the UK Armed Forces

Where there is anticipated non-academic interest in the outcomes of the study, an "executive summary" will be written for dissemination of the findings. This will be fed back to the key stakeholders within the Defence Medical Services (identified as part of wider MD project management) and the NHS Armed Forces Clinical Reference Group (KK is a nationally appointed member).

11. Safety

11a. How will the safety of the research be managed?

Monitoring for adverse events.
Participant data will be perused weekly by the principal investigator to identify any potential adverse events. Research risks identified include:

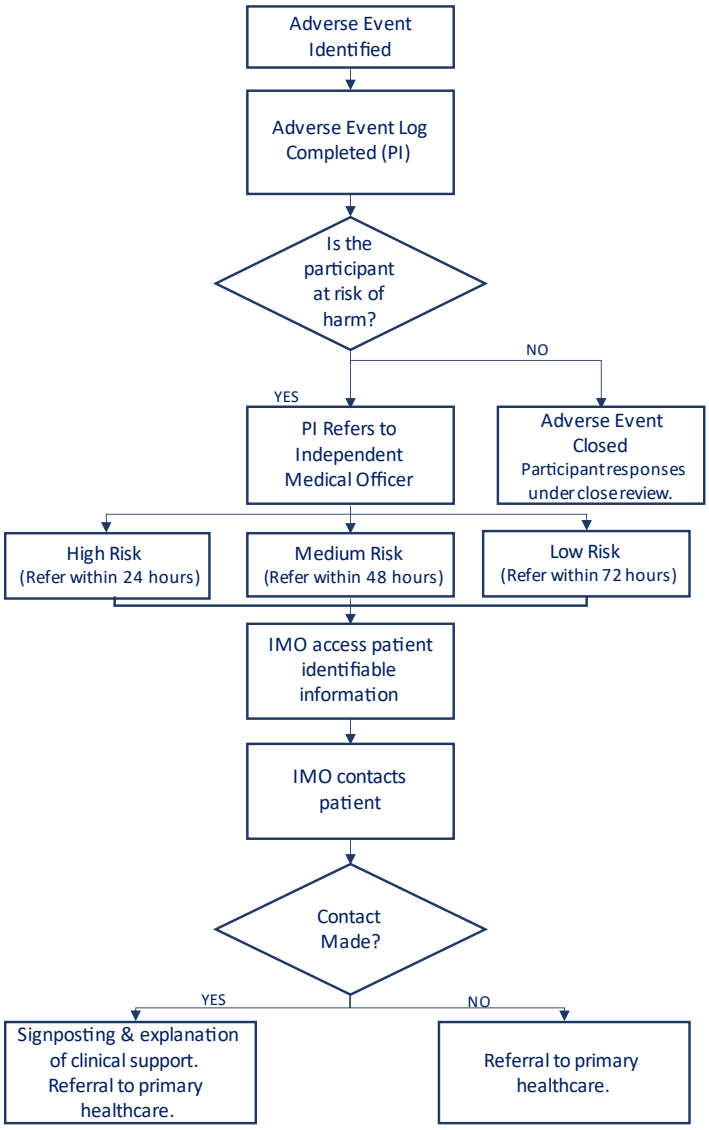
- Vulnerable participants
- Disclosure of alcohol consumption that poses a threat to safety

An adverse event is defined as a participant either:

- consuming more than 25 units of alcohol in a 24-hour period
- questionnaire responses suggestive that the participant has a significant mental health problem

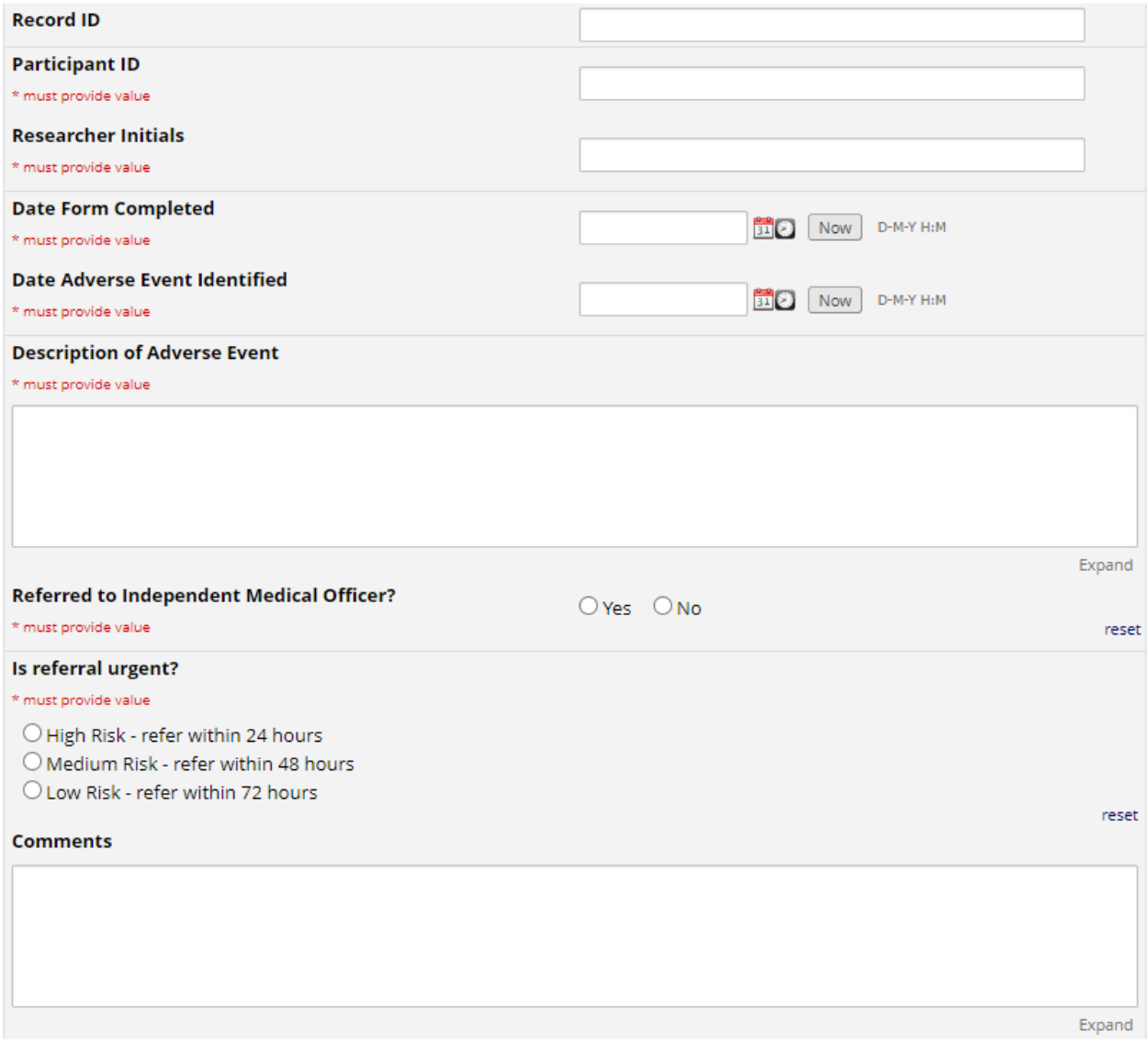
If an adverse event is identified, the PI will review the available data for the participant and, if there are concerns, she will inform the IMO. The IMO will have access to patient identifiable information and will contact the patient to facilitate referral to primary care if required and assess suitability to continue in the trial. See Figure 4: Adverse Event Management.

Figure 4: Adverse Event Management



All potential adverse events will be recorded in a risk event log held within the REDCap research database.

Figure 5: Adverse Event Recording Log



Vulnerable participants.
The research population will not involve participants who are unable to give informed consent or who are dependent. The participants are therefore not routinely vulnerable. However, there is a risk that a patient may become vulnerable during the trial. Responses to questionnaires will be regularly reviewed by the PI to highlight participants who may be suffering from acute distress and these participants will be referred to the Independent Medical Officer (IMO) as per the adverse event management process.

Alcohol & safety risk.
There is a risk that participants will disclose alcohol consumption that poses a significant risk to health either at the initial screening or during the trial. National guidance for alcohol management recommends different interventions (not ABI) for people scoring 12 or more on AUDIT-C questionnaire. These participants will be rung by the IMO to offer additional primary care support and assess suitability to participate in the trial. As the trial is expected to demonstrate a reduction in alcohol consumption, it is anticipated that continuing in the trial will be beneficial even to those drinking large quantities.

During the trial, if any participant is deemed at risk of significant harm from their alcohol consumption (25 units of alcohol within a 24 hour period) then their data will be reviewed (alcohol consumption and survey responses) by the lead investigator. This adverse event will be managed in accordance with the adverse event management process.

All participants will have access to information signposting sources of help should they find themselves in need. Surveys that may be sensitive or trigger emotional distress will be signposted before they are accessed, and the participant will have the option to skip past these sections. Sensitive sections will have details of military and civilian support services that can be accessed if required.

11b. Who is the named person taking responsibility for the overall safety of the research, and who will be responsible for day-to-day safety?	Dr Kate King

11c. How will the researchers conducting this study be made aware of:

i. Their responsibilities for reporting any new safety issues which arise after the start of the project, and

ii. Their responsibilities for reporting adverse events in the conduct of the project?

Surg Cdr King is the principal researcher involved in conducting the study. She has conducted research previously and has support from both KCMHR and ADMGP when advice and guidance is required. She is familiar with JSP 536 Part 2, Chapter 9 – Conduct of Research and the implied responsibilities for reporting new safety issues and adverse events. She is aware of and has access to the Automated Significant Event Reporting system used in the DMS for raising such matters.

Collaborators and supervisors are all aware of the protocol, the safety issues and how to manage them.

12. Ethical Considerations

Ethical considerations identified include:

- Requirement for informed consent
- Inclusion of women
- Alcohol & safety risk
- Inclusion of 16-18 year olds
- Inclusion of pregnant and breast-feeding women
- Vulnerable participants.

Requirement for informed consent
Informed consent is a requirement for inclusion in the trial. See section 16.

Inclusion of women.
Women will be included in the study in line with MODREC's letter to Surgeon General dated 23 Feb 22. It is intended that subgroup analysis will be undertaken to assess if there are any differences between male and female participants in terms of drinking behaviours, motivations and effects.

Alcohol & safety risk
See section 11a.

Inclusion of 16-17 year old participants.
Alcohol use in the military affects all age groups[7] and does not discriminate prior to age 18. UK legislation does limit the sale of alcohol to those aged 18 and over, but it does not prevent consumption of alcohol. NHS Digital data includes 16-17 year olds in the "drinking behaviours among adults" data set. Being under-age for purchasing alcohol does not offer protection against the risks of consumption and so 16-17 year old participants may gain benefit from study participation.

The Health Research Agency presumes that young people over the age of 16 are capable of giving consent on their own behalf to participate in clinical trials[52]. This study does therefore not exclude 16-17 year olds.

Inclusion of pregnant and breast-feeding women.
It is expected that there will be minimal participants due to the small proportions of pregnant and breast-feeding women in the AF. Many will have heeded national recommendations to stop or reduce alcohol intake[53] and are likely to not meet the inclusion criteria of scoring 5 or more on AUDIT-C. They will remain as potential participants because the app may offer benefit to those still drinking.

Vulnerable participants
See section 11a.

13. Participants

13a. Number of Participants:	728 participants
13b. Lower Age Limit:	16
13c. Upper Age Limit:	None
13d. Birth Sex (male/female):	No limitation

13e. Please provide justification for the sample size, and age/sex restrictions:

Sample Size
Drinks:Ration RCT
A protocol for the veterans' RCT of the Drinks:Ration app[20] has a calculated sample size of 37 participants in each arm to achieve significance and a target of 620 invitations to cover non-participation and attrition.

Assessing the sample size for a serving (non-veteran), non-help seeking population, a sample size of 218 per arm has been calculated with 80% power (alpha at 5%, 1:1 allocation and a two-tailed test) to detect a mean change in alcohol consumption of four units per week. The study would aim to recruit 728 participants to allow for a 40% attrition rate.

A mean consumption of 30.5 units/week (standard deviation 14.9) is assumed based on a large systematic review of face to face alcohol brief interventions[54]. The mean change of four units is based on a change of two units detected in the systematic review for the general population[54]; seven units detected in a previous Drinks:Ration study[19,20]; and four units being used in the Forces in Mind funded RCT on a veteran population[20].

Data Gathering Group
There is no sample size calculation required for the data gathering group.

Restrictions
There are no age or sex restrictions beyond those of the military population. Specifically, the age limits for the study match those for service in the UK armed forces. While the purchase of alcohol by those under 18 is illegal, consumption by under-age personnel does happen and age does not proffer any immunity to potentially harmful drinking behaviours.

14. Selection Criteria

14a. List your participant inclusion criteria:

- Current serving UK military
- Has an Android or iOS smart phone and willing / able to download the app.
- Reports an AUDIT-C score of ≥5 on screening
- Provide a mobile phone number or email address (in case of IMO review)

14b. List your participant exclusion criteria:

- Unwilling / unable to download the smart-phone application.
- AUDIT-C screening score of <5.

There is no exclusion on the grounds of harmful drinking if identified by AUDIT-C screening. See section 11a.

15. Recruitment

15a. Describe how potential participants will be identified:

Recruitment would occur through four routes:

- Periodic Dental Inspection
- Service specific communication
- Posters in military establishments
- Military focused social media

All 148,000 Serving military personnel are offered periodic dental inspections (PDI) at least annually. Defence Statistics state that 59% of the serving AF population are at risk of alcohol related harm[9]. This equates to approximately 7250 personnel eligible for the study each month. Dental staff currently screen all personnel with AUDIT-C prior to the PDI. For the recruitment period they will be asked to direct potential participants to the study site to complete initial screening.

Service specific communication would involve links / quick response (QR) codes being promoted through single Service information pathways and, if possible, on Defence Intranet. The MyNavy, and similar, applications within Defence Gateway allow announcements for surveys.

Posters with a short link and QR code have been developed and would be sent to large establishments for them to display in key areas.

Military focused social media, such as #MilTwitter and Service specific Facebook groups will be asked to promote the study and contain links to the study screening page.

Recruitment would be targeted over a 3 month period, with the aim of reaching the sample size required. It is anticipated that most participants will be identified through PDIs.

15b. Describe how potential participants will be approached:

On following the link to the study web page, all personnel will be screened using AUDIT-C questions. In order to avoid potential artificial reduction in AUDIT-C responses, it is clearly marked that the responses will not be fed back to the Dental Centre, Defence Primary Health Care or the chain of Command. Those scoring ≥5 will be given written information and brief intervention in line with DPHC guidance. Those scoring 10-12 will be signposted to tier 2 alcohol support services in line with DPHC guidance. This has been approved by DPHC.

- Those scoring ≤4 will be offered the opportunity to be answer a series of surveys asking about drinking behaviours and their health and wellbeing. These personnel are not eligible for inclusion in the Drinks:Ration RCT, but will be asked to participate in the data gathering group.
- Those scoring ≥5 will be eligible for inclusion in the Drinks:Ration RCT.

On completion of screening all participants will be forwarded to the study participant information leaflet and consent form on REDCap.

15c. Describe how potential participants will be recruited:

Potential participants will be recruited to the study when they have consented to participation using the electronic consent form on REDCap.

After consenting, all participants complete an initial demographics survey. Those eligible for the Drinks:Ration RCT are automatically randomised within REDCap. Those participants

randomised to the intervention arm are emailed with the links to download the app and the secondary participant information sheet specific for the app.

The full process for recruitment, consent and study information is found in Figure 2 above.

16. Consent

16a. Describe the process you will use when seeking and obtaining consent:

All participants will be directed to initial AUDIT-C screening on the Research Electronic Data Capture (RedCAP) secure web platform. On completion of screening, personnel will be offered the opportunity to participate in the study through participant information on the REDCap web page (see Participant Information Leaflet below). An online consent form will be presented at the end of the participant information which will capture electronic consent within REDCap.

Personnel can ask questions to the dental staff directing them to the screening and participant information. Staff will be supported by a "Frequently Asked Questions" (FAQ) information sheet and can direct additional questions to the principal investigator via email. A study website will hold the FAQ document which is available to all recruited out-with the periodic dental inspection.

Personnel can opt to read the participant information and subsequently consent by completing the electronic consent process within REDCap. The REDCap consent form gives the option to "save and return later" therefore allowing participants to consider their participation at their leisure.

16b. Do you plan to include participants who are children (under 16 yrs)?	No
16c. Do you plan to include participants who are aged 16 or 17?	Yes

The study does not exclude 16-17 year olds. This is in line with Health Research Agency guidelines on the age limitations for consent for involvement in clinical studies[52].

UK legislation does limit the sale of alcohol to those aged 18 and over, but it does not prevent consumption of alcohol. NHS Digital data includes 16-17 year olds in the "drinking behaviours among adults" data set[4]. Being under-age for purchasing alcohol does not offer protection against the risks of consumption and so 16-17 year old participants may gain benefit from study participation.

16d. Do you plan to include participants who lack capacity to consent?	No
16e. Do you plan to include any prisoners?	No

16f. Are there special pressures that might make it difficult for people to refuse to take part in the study (e.g., subordinates)?

Participation is entirely voluntary, and this is emphasised throughout the participant information leaflet and consent form. The participation information form also explains that neither medical, dental or the chain of Command will be aware of participation or any of the information shared with the study or Drinks:Ration application. There are clear directions available about how to withdraw from the study, which can happen at any time.

17. Participant Involvement: Risks, Requirements and Benefits

17a. Describe potential hazards, risks or adverse effects that may be associated with the study?	See section 11
17b. Will pregnant or nursing mothers be included?	Yes
17c. Does your study involve invasive procedures such as blood taking, muscle biopsy or the administration of a medicinal product?	No

17d. If medical devices are to be used on any participant, do they comply with the requirements of the Medical Devices Directives?

The Drinks:Ration app does not fulfil the definition of a medical device in accordance with the MHRA guidance for standalone software including apps[55].

17e. List the locations or sites where the work will be done:

The study will recruit from all military establishments through either DPHC dental facilities or other communications. The study does not require any physical sites to run it due to the nature of the trial. The research team will access data using University or MOD IT equipment and no data will be stored or processed on personal IT equipment.

17f. Will group or individual interviews/questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting?	Potentially

The surveys forming part of the study may touch on topics that trigger emotional upset. Information about how to seek appropriate medical or welfare support will be available to all participants and will be highlighted at the end of surveys.

Adverse events will be managed in accordance with the risk management process detailed in section 11.

17g. Is it possible that criminal or other disclosures requiring action, e.g. evidence of professional misconduct, could be made during the study?	Potentially

There is a possibility that a participant discloses that they have been a victim of domestic abuse, sexual assault of professional misconduct. If anyone discloses that they have been a victim, on completion of the question section, there will be an automatic reminder that they can report the alleged crime and details signposting how and where they can do this.

There is a possibility that a participant discloses that they have perpetrated a crime or professional misconduct. Disclosure will result in the participant being signposted to welfare and support organisations but will not result in unblinding or any follow up actions by the researchers. The questions about crime are from the National Crime Survey for England & Wales. The questions ask about their involvement in historic acts, which may be many years prior to the survey submission. The NCSE&W methodology allows for not breaching confidentiality in the event of disclosure of a potential historic crime. There is no evidence of ongoing risk of violence, and so there is no moral obligation to breach confidentiality.

17h. Describe any expected benefits to the research participant:

It is hypothesised that use of the Drinks:Ration app will reduce harmful drinking behaviours for those in the application arms. There are unlikely to be any direct benefits to those in the control arm.

17i. Under what circumstances might a participant not continue with the study, or the study be terminated in part or as a whole?
Individuals may choose to withdraw from the study at any point up to the point when the data capture will be extracted for analysis. At this point data will be grouped and it will no longer be possible to select individual data. If a participant is referred to the IMO due to an adverse event being identified, the IMO will discuss the situation with the participant and a decision will be made about suitability to continue in the study. If the study is a factor causing ongoing harm for the participant, then they will be de-enrolled. A similar process was in place for the veterans' Drinks:Ration study. This study involves veterans with known mental health issues and did not result in the removal of any participants, so it is not expected to be encountered in the research population.

18. Financial Incentives, Expenses and Compensation

18a. Will travel expenses be given?	No
18b. Is any financial or other reward, apart from travel expenses, being offered to participants?	No
18c. Has payment of the Experimental Test Allowance been considered? (JSP 752, chap 10 section 3)?	Yes
Having reviewed the relevant sections of the JSP it has been decided not to request payment of ETA as it risks impacting on understanding of the natural attrition rates and adherence to the app usage.	
18d. If this is a study in collaboration with a commercial organisation	No
The Drinks:Ration application has been designed and built by KCMHR, and it is being offered as published open-source coding and not commercially available.	

19. Confidentiality, Anonymity and Data Storage

19a. What steps will be taken to ensure confidentiality?
All study data is held electronically. There is no physical paperwork and no requirement for any. Personal information is collected at the initial screening stage using the Research Electronic Database Capture (REDCap) programme. This utilises University of Birmingham servers and approved by Defence Medical Services for research data management. Data entered to the Drinks: Ration app is held on Google managed UK based servers contracted by King's Centre for Military Health Research. Data is stored and processed using industry standards. All data access and interactions are logged and regularly audited. No personally identifiable information is stored on the Drinks:Ration platform. Personal data is managed separately to the data collected through the Drinks:Ration app.
19b. Give details of any anonymisation procedures to be used (if applicable)
The app does not store any identifying information. Individual participants are identified through a numeric code. This code is linked to the personal data gathered from the initial consent process. Only the Independent Medical Officer has the access rights to personal data such as names and email addresses. The only reason this information will be accessed is for wellbeing purposes in the event of health concerns. See section 17f.

Withdrawal from the study will inevitably give researchers access to the participant's name. Records associated with this name will be deleted within REDCap by the IMO as he is the only person with access to participant identifiable data.

19c. Who will have access to the records and resulting data?

The principal investigator will be the main person accessing and processing the study data. The app data will be accessible by Dr Daniel Leightley as the lead for the Drinks:Ration app at KCMHR.

Non-personal data will be extracted for analysis, and it is anticipated that support from a statistician may be needed at this point.

19d. Where, and for how long, do you intend to store the Consent Forms and other records?

Consent forms and study records will be retained within the REDCap research management system for 7 years.

19e: Have the Consent Form(s) and Participant information been reviewed and confirmed to be DPA 2018/GDPR compliant in accordance with organisational arrangements?	**Yes**

20. Supporting Documentation

The following appendices, where applicable, are included in this document:

✓	**Research sponsors checklist**
X	~~**Letter to general practitioners**~~
X	~~**Letter to parents/guardians**~~
X	~~**Letter of other research ethics committee opinion or other approvals**~~
X	~~**Details of MHRA approval and/or correspondence (*if applicable*)**~~
✓	**Copy of email recruitment circular/poster/press advertisement**
✓	**Questionnaire/topic guide/interview questions**
✓	**Evidence of permission from organisation where research is to be conducted**
X	~~**List of acronyms**~~
✓	**CVs of named investigators (separate document)**
✓	**CV(s) of supervisor(s) (separate document)**
✓	**CV of Independent Medical Officer (separate document)**

Please list any other documents that you are submitting to support this application:

No additional documents.

MODREC members may trial the AUDIT-C screening, participant information consents and initial surveys by using the link here:

https://redcap.link/drinkingandwellbeing

List of Acronyms

ABI	Alcohol Brief Intervention
ADMGP	Academic Department of Military General Practice
AF	Armed Forces
AUDIT	Alcohol Use Disorders Identification Test
AUDIT-C	Alcohol Use Disorders Identification Test for Consumption
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
DCMH	Defence Community Mental Health
DMS	Defence Medical Services
DMSRSG	Defence Medical Services Research Steering Group
DPHC	Defence Primary Health Care
ETA	Experimental Test Allowance
FAQ	Frequently Asked Question
GAD2	General Anxiety Disorder 2 item
GMQ-9	Gambling Motives Questionnaire
GP	General Practitioner
IMO	Independent Medical Officer
IT	Information Technology
KCMHR	King's Centre for Military Health Research
MAUQ	m-Health App Usability Questionnaire
MD(Res)	Doctor of Medicine by Research
MHRA	Medical & Healthcare Products Regulatory Authority
MOD	Ministry of Defence
MODREC	Ministry of Defence Research Ethics Committee
NCSE&W	National Crime Survey for England & Wales
NHS	National Health Service
PC-PTSD-f	Primary Care- Post Traumatic Stress Disorder 5 item
PDI	Periodic Dental Inspection
PHQ2	Patient Health Questionnaire 2 item
PI	Principle Investigator
QR	Quick Response
RCT	Randomised Controlled Trial
REDCAP	Research Electronic Data Capture
RLE-Q	Recent Life Events Questionnaire
RN SAC	Royal Navy Scientific Advisory Committee
TLFB	Time-Line Follow Back
UK	United Kingdom
WHOQOL-BREF	World Health Organisation Quality of Life Questionnaire
YAACQ	Young Adult Alcohol Consequences Questionnaire

Research Sponsor's Checklist

Title of Research:	Drinking & Wellbeing in Military Personnel
Name of Chief Investigator:	Surgeon Commander Kate King
Research Sponsor (organisation):	RCI / KCMHR
Name and position of Research Sponsor's representative:	Sam Brown RCI Business Manager

Responsibility		Achieved? (Y/N)
a. The research has been assessed by a SAC and is suitably designed, and the protocol / ethics application is of a suitable standard (as outlined in JSP536, Part 2, Chapter 2). This includes:		
	1. The research takes into account the literature including systematic reviews of relevant existing research evidence and other relevant research in progress	Y
	2. Where appropriate, makes use of patient and public involvement.	Y
	3. The methods are scientifically sound (e.g. demonstrated through independent expert review), safe, legal and feasible, and remain so for the duration of the research, taking account of developments while the research is ongoing	Y
	4. The research output is relevant to MOD, its partners or Other Government Departments	Y
b. The investigators, research team and research sites are suitable and appropriate contracts are in place for the duration of the research project.		Y
c. The roles and responsibilities of the parties involved in the research and any delegation by the Research Sponsor of its tasks are agreed and documented.		Y
d. Adequate provision has been made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project.		Y
e. Appropriate arrangements for making data and tissue accessible (with adequate consent and privacy safeguards) are in place after the research has finished.		Y
f. Arrangements are in place for review by MODREC (if required) and any other relevant approval bodies before the research begins.		Y
g. Where the Research Sponsor is not the MOD, the research has explicit written approval from an individual within MOD at the minimum of OF5 / B2 level.		NA
h. Regulatory and practical arrangements (such as risk assessments, security assessment and data protection arrangements) will be in place before the research to begins.		Y
i. Adequate finance and management arrangements for the research are in place including competent risk and data management.		Y
j. Effective procedures and arrangements are kept in place and adhered to for reporting (e.g. progress reports, safety reports) and for monitoring the research, including its conduct and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments.		Y
k. Projects are registered, disseminated and reported appropriately.		Y
In addition to the above, Research Sponsors of clinical trials of investigational medicinal products have particular legal duties – see https://www.hra.nhs.uk/planning-and-improvingresearch/ policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/. It is recommended that any research falling under the Clinical Trials Regulations are conducted in collaboration with an established Clinical Trials Research Unit.		

Dr Graeme Nicholson
Acting Chair, RN SAC
Institute of Naval Medicine
Crescent Road
ALVERSTOKE
Hampshire
PO12 2DL

Telephone: 023 92 768115 Mil Net: 9380 68115
Email: graeme.nicholson109@mod.gov.uk

Surgeon Commander Kate King MRCGP MPH PGCMedEd DCH DGM DRCOG RN
Academic Research Fellow in General Practice
Academic Department of Military General Practice

Ref: Drink-Ration_v2
Date: 09 June 2022

MODREC APPLICATION - What is the effectiveness of the Drinks:Ration smart-phone app on modifying alcohol use behaviour in Service personnel at risk of alcohol related harm?: SAC REVIEW.

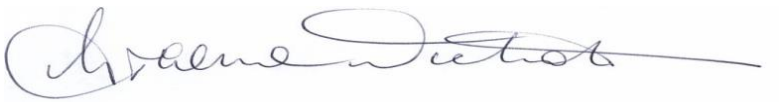
Dear Kate

Thank-you for re-submitting your protocol for review by the RN Scientific Assessment Committee following our initial review and letter dated 20 May 2022. The protocol has been circulated again to the SAC and the SAC has agreed that the protocol at version V2.0 is suitable for submission to MODREC.

Could you please update your protocol by removing any deletions and ensuring the format and colour are consistent throughout. Please add the date of this letter to Section 8 as the date of SAC approval. The protocol, CV document and a copy of this letter should then be sent to the MODREC Secretariat via the e-mail address on the MODREC internet site.

The SAC wishes you good luck with your research and hopes the rest of the approval process and the work itself progress smoothly.

Should you wish to discuss any part of the SAC process or the points raised, please contact me directly.



Participant Information Sheet & Consent Form – all participants (Drinks:Ration & Data Gathering Group)

MOD Research Ethics Review Number: MODREC
MOD Research Ethics Review date: INSERT

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 research team 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 alcohol consumption, 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 (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.

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).

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 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 November 2022 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 Mike Smith, Academic Department of Military General Practice, ICT Centre, Vincent Drive, Birmingham, B15 2SQ / 0121 414 8853 / michael.smith119@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, 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 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 and can be found on the study website: www.kcmhr.org/drinkingandwellbeing

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.	○ **Yes**	○ **No**
I understand that if I decide at any time during the research, up until 30th November 2022, 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 30th November 2022, my data will be combined with other participants and it will no longer be able to be individually identified.	○ **Yes**	○ **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.	○ **Yes**	○ **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.	○ **Yes**	○ **No**
I consent to the processing of my personal information as part of future studies into alcohol use and social behaviours.	○ **Yes**	○ **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.	○ **Yes**	○ **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 _____

MOD Research Ethics Reviewl Number: MODREC
MOD Research Ethics Review date: INSERT

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

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 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.

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 November 2022 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?
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 in the main Drinking & Wellbeing in Military Personnel study information leaflet.

What happens if I suffer any harm?
This information is in the main 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 and social behaviours associated with drinking. 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:

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 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

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 / katherine.king@kcl.ac.uk and can be found on the study website: www.kcmhr.org/drinkingandwellbeing

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**	○ **No**
I understand that if I decide at any time during the research, up until 30th November 2022, 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 30th November 2022, my data will be combined with other participants and it will no longer be able to be individually identified.	○ **Yes**	○ **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.	○ **Yes**	○ **No**

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 _____

Arrangements for the Payment of No-Fault Compensation to Participants in MoDREC Approved Studies[3]

1. The MoD maintains the 'No Fault Compensation Scheme' specifically for the payment of no-fault compensation to, or in respect of, a volunteer who suffers illness and/or personal injury as a direct result of participating in research conducted on behalf of the MoD. The no-fault compensation arrangements apply to research participants (Military, Civilian, or non-MoD) who take part in a trial that has been approved by the MoD Research Ethics Committee.

2. A research participant wishing to seek no-fault compensation under these arrangements should contact the Directorate of Judicial Engagement Policy, Common Law Claims and Policy (DJEP-CLCP), Ministry of Defence, Level 1, Spine 3, Zone J, Whitehall, London, SW1A 2HB who may need to ask the Claimant to be seen by a MoD medical adviser.

3. CLCP will consider reasonable requests for reimbursement of legal or other expenses incurred by research participants in relation to pursuing their claim (eg. private medical advice, clinical tests, legal advice on the level of compensation offered) provided that they have been notified of the Claimant's intention to make such a claim.

4. If an injury is sufficiently serious to warrant an internal MoD inquiry, any settlement may be delayed at the request of the research participant until the outcome is known and made available to the participant in order to inform his or her decision about whether to accept no-fault compensation or proceed with a common law claim. An interim payment pending any inquiry outcome may be made in cases of special need. It is the Claimant's responsibility to do all that they reasonably can to mitigate their loss.

5. In order to claim compensation under these no-fault arrangements, a research participant must have sustained an illness and/or personal injury as a direct result of participation in a trial/study approved by MoDREC. A claim must be submitted within 3 years of when the incident giving rise to the claim occurred, or, if symptoms develop at a later stage, within 3 years of such symptoms being medically documented.

6. The fact that a research participant has been formally warned of possible injurious effects of the trial upon which a claim is subsequently based does not remove MoD's responsibility for payment of no-fault compensation. The level of compensation offered shall be determined by taking account of the level of compensation that a court would have awarded for the same injury, illness or death had it resulted from the Department's negligence.

7. In assessing the level of compensation, CLCP, in line with common law principles, will take into account the degree to which the Claimant may have been responsible for his or her injury or illness and a deduction may be made for contributory negligence accordingly.

8. In the event of CLCP and the injured party being unable to reach a mutually acceptable decision about compensation, the claim will be presented for arbitration to a nominated Queen's Counsel. CLCP will undertake to accept the outcome of any such arbitration. This does not affect in any way the rights of the injured party to withdraw from the negotiation and pursue his or her case as a common law claim through the Courts.

Additional/Alternative Compensation Arrangements

9. **Compensation for Service Personnel.** Service personnel who took part in studies before 06 April 2005 and who consider that they may have suffered later harm or disability due to that study should contact MoD Defence Business Services-Veterans (DBS-Vets), Service Personnel and Veterans Agency (SPVA) for consideration of a war disablement pension. The personnel

[3] Section agreed with DJEP-CLCP Dep Hd 28/10/13.

who are entitled to make claims under the war disablement pension scheme are laid out on the SPVA website,[4] as are details of the claim's process.

10. In the event of service personnel suffering injury or disability as a result of their participation in MoDREC approved MoD research on or after 06 April 2005 then they may be entitled to compensation under the Armed Forces Compensations Scheme (AFCS). The details of the AFCS are promulgated on the MoD Intranet,[5,6] and are also available on the DBS-Vets website.[7] Claims should be made to DBS-Vets following the instructions available on the MoD Intranet and DBS-Vets website.

11. In the event of service personnel suffering injury or disability as a result of their participation in MoDREC approved MoD research which is sufficiently serious for subsequent medical discharge from the services, their medical records will automatically be forwarded to DBS-Vets for consideration of compensation and pension enhancements[8] in addition to whatever MoD pension/gratuity they are already entitled to by virtue of their service. Similarly, in the event of death as a result of their participation in MoDREC endorsed MoD research, their dependants may be entitled to receive a supplemented pension.

12. However, if either a Service person or their dependants receive payment under the MoD 'no fault compensation' arrangements (or as the result of a common law compensation claim) for the same condition as that for which a pension is received, any pension entitlement may be reduced since compensation should not be paid twice for the same injury, disability or death.

13. **Civilian Pensions.** In the event of a civilian research participant suffering injury or disability as a result of their participation in MoDREC endorsed MoD research sufficiently serious for them to subsequently suffer a loss in earnings capacity; they may be eligible for benefits under Section 11 of the Principal Civil Service Pension Scheme (PCSPS). Further details are available in the PCSPS booklet Injury at Work. Similarly, in the event of death as a result of participation in MoDREC approved MoD research, their dependants may be entitled to receive benefits.

14. **Common Law Compensation.** If a research participant or their representative believes that injury, disability or death was caused by the negligence of the MoD or its staff, and do not wish to pursue the possibility of a 'no-fault' compensation payment, a common law claim for compensation should be submitted to Directorate of Judicial Engagement Policy, Common Law Claims & Policy (DJEP-CLCP) (at the address in Para 2 above) detailing the full facts of the claim and stating that common law compensation is being sought.

Multinational/Multicentre Research and Research Involving Other Government Departments

15. When MoDREC is involved in studies which involve Departments other than the MoD there may be a requirement for specific Compensation Arrangements on a study by study basis.

[4] http://www.veterans-uk.info/pensions/wdp_new_index.html
[5] DIN http://defenceintranet.diif.r.mil.uk/libraries/corporate/DINS%20Archive/2008/01102RestrictDINs.pdf
[6] Armed Forces Compensation Scheme - Statement of Policy. http://defenceintranet.diif.r.mil.uk/libraries/library1/DINSJSPS/20110714.1/974_AFCS_Statement%20of%20policy4.pdf
[7] http://www.veterans-uk.info/pensions/afcs_new.html
[8] http://www.veterans-uk.info/pensions/med_discharge.html

Example Poster Advertisement

DRINKING & WELLBEING IN MILITARY PERSONNEL

ANY AGE
ANY SERVICE
ANY GENDER
ANY ONE

King's Centre for Military Health Research are looking for people to take part in a study looking at alcohol drinking behaviors and the health & wellbeing of Service personnel.

Participants will complete online questionnaires about your physical & mental health and experiences that can be associated with drinking alcohol. Some participants will be asked to download a smartphone app to help monitor drinking behavior in more detail.

TO TAKE PART GO TO:
https://redcap.link/drinkingandwell-being

Or scan the QR code below.

FOR MORE INFORMATION:

WWW.KCMHR.ORG/DRINKINGANDWELLBEING/

KCMHR
KING'S CENTRE FOR MILITARY HEALTH RESEARCH

KING'S College LONDON

MODREC review 22/xxx

Demographics Questions

We need a little background information & Service history from you to help with the study.

These questions should only take a few minutes to complete. None of this information will be shared with your medical centre, dental centre or your chain of Command.

Are you: ◯ Female ◯ Male

How old are you?

_____

What is your current relationship status?

◯ Married / Civil Partnership
◯ Living with partner
◯ In long term relationship
◯ Single and not in a long-term relationship
◯ Separated
◯ Divorced
◯ Widowed

Do you have children living in your family home?

◯ Yes ◯ No

Have you achieved a qualification at degree level or above?
(e.g. degree, HND, HNC, NVQ level 4 and above, BTEC level 4 and above, teaching, nursing)

◯ Yes ◯ No

Have you achieved any other qualification?
(Please tick all that apply)

☐ GCSEs or equivalent
☐ AS, A-Levels or equivalent
☐ NVQ Level 3, BTEC level 3, OND, ONC
☐ NVQ Level 1 or 2, BTEC level 1 or 2
☐ Any other qualification
☐ No formal qualifications

Are you currently:

◯ Regular
◯ Full Time Reserve Service
◯ Other Reservist
◯ Royal Fleet Auxiliary
◯ Military Provost Guard Service
◯ Ex-Serving / Veteran

To which Service do you belong?

◯ Royal Navy
◯ Royal Marines
◯ Army
◯ Royal Air Force

To the nearest year, how long have you served?

◯ 0 ◯ 1 ◯ 2 ◯ 3
◯ 4 ◯ 5 ◯ 6 ◯ 7
◯ 8 ◯ 9 ◯ 10 ◯ 11
◯ 12 ◯ 13 ◯ 14 ◯ 15
◯ 16 ◯ 17 ◯ 18 ◯ 19
◯ 20 ◯ 21 ◯ 22 ◯ 23
◯ 24 ◯ 25 ◯ 26 ◯ 27
◯ 28 ◯ 29 ◯ 30 ◯ 31
◯ 32 ◯ 33 ◯ 34 ◯ 35
◯ 36 ◯ 37 ◯ 38 ◯ 39
◯ 40 ◯ 41 ◯ 42 ◯ 43
◯ 44 ◯ 45 ◯ 46 ◯ 47
◯ 48 ◯ 49

This question presents as a free text number between 0 and 49 in the actual survey.

What is your current rank or equivalent?	◯ OR 1-4 (AB-LH / Pte-Cpl / AC-Cpl) ◯ OR 5-7 (PO-CPO / Sgt-CSgt / ◯ OR 8-9 (Warrant Officer) ◯ OF 1-4 (Mid to Cdr / 2nd Lt to Lt Col / Plt Off to Wg Cdr) ◯ OF5 and above (Capt / Col / Gp Capt and above)
What is your main role?	◯ Combat / Infantry / Warfare ◯ Communications / Intelligence ◯ Engineering ◯ Logistics / Supply / Catering ◯ Medical / Welfare / Chaplaincy ◯ Aviation Operations / Aircrew ◯ Military Police / Force Protection ◯ EOD / Bomb Disposal / Military Diving ◯ Other
Did you deploy to OP TELIC or OP HERRICK? ◯ Yes ◯ No	
How often does your spouse / partner / significant other have a drink containing alcohol?	◯ Never ◯ Monthly or less ◯ 2-4 times a month ◯ 2-3 times a week ◯ 4 or more times a week ◯ No spouse, partner, or significant other
How often do you and your spouse / partner / significant other have a drink containing alcohol together?	◯ Never ◯ Monthly or less ◯ 2-4 times a month ◯ 2-3 times a week ◯ 4 or more times a week ◯ No spouse, partner, or significant other
Since the COVID-19 pandemic, do you drink alcohol more than you did before?	◯ No, do not drink alcohol ◯ Less than before ◯ About the same ◯ More than before
What do you think are the biggest barriers to reduce the amount you drink?	◯ Other people encouraging me to have a drink ◯ Social situations that involve alcohol ◯ My partner drinking at home ◯ Spending time with friends who drink a lot ◯ Feeling frustrated, sad, anxious or bored ◯ Feeling really happy
Where do you usually drink the most in a single session?	◯ At home ◯ Military establishment or event ◯ Civilian pubs, bars or clubs ◯ At a civilian friend's house ◯ At a military friend's house
Where do you usually drink most frequently?	◯ At home ◯ Military establishment or event ◯ Civilian pubs, bars or clubs ◯ At a civilian friend's house ◯ At a military friend's house

Alcohol Use Disorders Identification Test

These questions are about your alcohol use. Please answer honestly.

All of this information is kept confidential.

These questions relate to your alcohol use. There are 10 questions to complete.

When filling it in please be aware that 1 unit is:

Half a pint of regular beer, lager or cider Half a small glass of wine 1 single pub measure of spirits 1 small glass of sherry 1 single measure of aperitifs Drinks more than a single unit include:

A pint of regular beer, lager or cider = 2 units A pint of stronger beer, lager or cider = 3 units A bottle of alcopop = 1.5 units A 440ml can of regular beer, lager or cider = 2 units A 440ml can of stronger beer, lager or cider = 4 units A 250ml glass of wine = 3 units A 75cl bottle of wine = 9 units

1. How often do you have a drink containing alcohol?

- ◯ Never
- ◯ Monthly or less
- ◯ 2–4 times a month
- ◯ 2–3 times a week
- ◯ 4 or more times a week

2. How many units of alcohol do you drink on a typical day when you are drinking?

- ◯ 1 or 2
- ◯ 3 or 4
- ◯ 5 or 6
- ◯ 7 to 9
- ◯ 10 to 14
- ◯ 15 to 19
- ◯ 20 to 29
- ◯ 30 or more

3. How often do you have six or more units of alcohol on one occasion?

- ◯ Never
- ◯ Less than monthly
- ◯ Monthly
- ◯ Weekly
- ◯ Daily or almost daily

4. How often during the last year have you found that you were not able to stop drinking once you had started?

- ◯ Never
- ◯ Less than monthly
- ◯ Monthly
- ◯ Weekly
- ◯ Daily or almost daily

5. How often during the last year have you failed to do what was normally expected of you because of drinking?

- ◯ Never
- ◯ Less than monthly
- ◯ Monthly
- ◯ Weekly
- ◯ Daily or almost daily

6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?

- ◯ Never
- ◯ Less than monthly
- ◯ Monthly
- ◯ Weekly
- ◯ Daily or almost daily

7. How often during the last year have you had a feeling of guilt or remorse after drinking?

- ◯ Never
- ◯ Less than monthly
- ◯ Monthly
- ◯ Weekly
- ◯ Daily or almost daily

8. How often during the last year have you been unable to remember what happened the night before because you had been drinking?

- ◯ Never
- ◯ Less than monthly
- ◯ Monthly
- ◯ Weekly
- ◯ Daily or almost daily

9. Have you or someone else been injured as a result of your drinking?

- ◯ No
- ◯ Yes, but not in the last year
- ◯ Yes, during the last year

10. Has a relative or friend, doctor or other health worker been concerned about your drinking or suggested you cut down?

- ◯ No
- ◯ Yes, but not in the last year
- ◯ Yes, during the last year

Branching logic is used here to give feedback on AUDIT score in accordance with standard DPHC alcohol management strategy.

Your score suggests your drinking behaviours are a low risk of causing you harm.

Brief Advice

High risk

Sliders

1) Using the ruler below, indicate how ready you are to make a change to your drinking.

If you are not at all ready, you would select 0 and if you are already trying hard to make the change, you would select 10.

0 5 10

(Place a mark on the scale above)

2) Using the ruler shown below, indicate how confident you are about making a change to your drinking.

If you are not at all confident about making the change, you would select 0. If you are very confident about making the change, you would select 10.

0 5 10

(Place a mark on the scale above)

Drinking Resource Allocation (YAACQ)

While drinking, I have said or done embarrassing things.

○ Yes ○ No

I have had a hangover (headache, sick stomach) the morning after I had been drinking.

○ Yes ○ No

I have felt very sick to my stomach or thrown up after drinking.

○ Yes ○ No

I often have ended up drinking on nights when I had planned not to drink.

○ Yes ○ No

I have taken foolish risks when I have been drinking.

○ Yes ○ No

I have passed out from drinking.

○ Yes ○ No

I have found that I needed larger amounts of alcohol to feel any effect, or that I could no longer get high or drunk on the amount that used to get me high or drunk.

○ Yes ○ No

When drinking, I have done impulsive things that I regretted later.

○ Yes ○ No

I've not been able to remember large stretches of time while drinking heavily.

○ Yes ○ No

I have driven a car when I knew I had too much to drink to drive safely.

○ Yes ○ No

I have not gone to work because of drinking, a hangover, or illness caused by drinking.

○ Yes ○ No

My drinking has got me into sexual situations I later regretted.

○ Yes ○ No

I have often found it difficult to limit how much I drink.

○ Yes ○ No

I have become very rude, obnoxious or insulting after drinking.

○ Yes ○ No

I have woken up in an unexpected place after heavy drinking.

○ Yes ○ No

I have had less energy or felt tired because of my drinking.

○ Yes ○ No

I have felt badly about myself because of my drinking.

○ Yes ○ No

The quality of my work has suffered because of my drinking.

○ Yes ○ No

I have spent too much time drinking.

○ Yes ○ No

I have neglected my obligations to family or work because of drinking.

○ Yes ○ No

My drinking has created problems between myself and my boyfriend/girlfriend/partner/spouse, parents, or other near relatives.

○ Yes ○ No

I have been overweight because of drinking.

○ Yes ○ No

My physical appearance has been harmed by my drinking.

○ Yes ○ No

I have felt like I needed a drink after I'd got up (that is, before breakfast).

○ Yes ○ No

Mental Health (PHQ2 / GAD2 / PTSD5)

Over the last 2 weeks, how often have you been bothered by the following problems?

	Not at all	Several days	More than half the days	Nearly every day
Little interest or pleasure in doing things	○	○	○	○
Feeling down, depressed or hopeless	○	○	○	○
Feeling nervous, anxious or on edge	○	○	○	○
Not being able to stop or control worrying	○	○	○	○

Over the last month, have you:

	No	Yes
Had nightmares about the event(s) or thought about the event(s) when you did not want to?	○	○
Tried hard not to think about the event(s) or went out of your way to avoid situations that reminded you of the event(s)?	○	○
Been constantly on guard, watchful, or easily startled?	○	○
Felt numb or detached from people, activities, or your surroundings?	○	○
Felt guilty or unable to stop blaming yourself or others for the events(s) or any problems the event(s) may have caused?	○	○

Quality of Life (WHO-QOL-BREF)

This questionnaire asks how you feel about your quality of life, health and other areas of your life. Please answer all the questions. If you are unsure about which response to give to a question, please choose the best one you can. There are no right or wrong answers. Your answer will be kept strictly confidential. Please keep in mind your standards, hopes, pleasures and concerns.

We ask that you think about your life in the last two weeks.

The following questions ask about how much you have experienced certain things in the last two weeks, for example, positive feelings such as happiness or contentment. The questions refer to the last two weeks.

		Not at all	Not much	A moderate amount	Very much	An extreme amount
1)	How much do you feel that pain prevents you from doing what you need to do?	○	○	○	○	○
2)	How much do you enjoy life?	○	○	○	○	○
3)	How well are you able to concentrate?	○	○	○	○	○
4)	How much do you need medical treatment to function in your daily life?	○	○	○	○	○
5)	How safe do you feel in your daily life?	○	○	○	○	○
6)	How healthy is your physical environment?	○	○	○	○	○

7) How would you rate your quality of life?

○ Very poor ○ Poor ○ Neither poor nor good ○ Good ○ Very good

The following questions ask about how completely you experienced, or were able to do certain things in the last two weeks, for example activities of daily living like washing, dressing or eating.

Questions refer to the last two weeks.

		Not at all	Not much	A moderate amount	A great deal	Completely
8)	Do you have enough energy for everyday life?	○	○	○	○	○
9)	How much are you able to accept your bodily appearance?	○	○	○	○	○

10)

	To what extent do you have enough money to meet your needs?	○	○	○	○	○
11)	How available to you is the information that you need in your day-to-day life?	○	○	○	○	○
12)	To what extent do you have the opportunity for leisure activities?	○	○	○	○	○

The following questions ask you to say how satisfied, happy or good you have felt about various aspects of your life over the last two weeks, for example, about your family life or you energy level. Decide how satisfied or dissatisfied you are with each aspect of your life and then tick the box that best fits how you feel about this.

Questions refer to the last two weeks.

		Very dissatisfied	Dissatisfied	Neither satisfied or dissatisfied	Satisfied	Very satisfied
13)	How satisfied are you with your health?	○	○	○	○	○
14)	How satisfied are you with your sleep?	○	○	○	○	○
15)	How satisfied are you with yourself?	○	○	○	○	○
16)	How satisfied are you with your ability to perform daily living activities?	○	○	○	○	○
17)	How satisfied are you with your personal relationships?	○	○	○	○	○
18)	How satisfied are you with your sex life?	○	○	○	○	○
19)	How satisfied are you with the support you get from your friends?	○	○	○	○	○
20)	How satisfied are you with the conditions of your living place?	○	○	○	○	○
21)	How satisfied are you with your access to health services?	○	○	○	○	○
22)	How satisfied are you with your transport?	○	○	○	○	○

23) How often do you have negative feelings, such as blue mood, despair, anxiety, depression?

○ Never ○ Seldom ○ Quite often ○ Very often ○ Always

24) This question refers to any work that you do.

Work here means any major activity that you do. This includes voluntary work, studying full-time, taking care of the home, taking care of children, paid work, or unpaid work. So work, as it is used here, means the activities you feel take up a major part of your time and energy.

How satisfied are you with your capacity for work?

○ Very poor ○ Poor ○ Neither poor nor good ○ Good ○ Very good

25) This question asks about how well you were able to move around in the last two weeks. This refers to your physical ability to move your body in such a way as to allow you to move about and do the things you would like to do, as well as the things that you need to do.

How well are you able to get around?

○ Very poor ○ Poor ○ Neither poor nor good ○ Good ○ Very good

26) This question is concerned with your personal beliefs and how these affect your quality of life. These questions refer to religion, spirituality and any other personal beliefs you may hold.

To what extent do you feel life to be meaningful?

○ Not at all ○ Not much ○ Moderately ○ Very much ○ Extremely

27) Finally, how is your health?

○ Very poor ○ Poor ○ Neither poor nor good ○ Good ○ Very good

Loneliness (De Jong Gierveld)

	None of the time	Rarely	Some of the time	Often	All of the time
There is always someone I can talk to about my day-to-day problems	○	○	○	○	○
I miss having a really close friend	○	○	○	○	○
I experience a general sense of emptiness	○	○	○	○	○
There are plenty of people I can lean on when I have problems	○	○	○	○	○
I miss the pleasure of the company of others	○	○	○	○	○
I find my circle of friends and acquaintances too limited	○	○	○	○	○
There are many people I can trust completely	○	○	○	○	○
There are enough people I feel close to	○	○	○	○	○
I miss having people around me	○	○	○	○	○
I often feel rejected	○	○	○	○	○
I can call on my friends whenever I need them	○	○	○	○	○

Drinking Motivations (DMQ-R)

Listed below are 20 reasons people might be inclined to drink alcoholic beverages. Using the five-point scale below, decide how frequently your own drinking is motivated by each of the reasons listed.

	Almost never / Never	Some of the time	Half of the time	Most of the time	Almost always / Always
To forget your worries.	○	○	○	○	○
Because your friends pressure you to drink.	○	○	○	○	○
Because it helps you enjoy a party.	○	○	○	○	○
Because it helps you when you feel depressed or nervous.	○	○	○	○	○
To be sociable.	○	○	○	○	○
To cheer up when you are in a bad mood.	○	○	○	○	○
Because you like the feeling.	○	○	○	○	○
So that others won't kid you about not drinking	○	○	○	○	○
Because it's exciting.	○	○	○	○	○
To get drunk or high.	○	○	○	○	○
Because it makes social gatherings more fun.	○	○	○	○	○
To fit in with a group you like.	○	○	○	○	○
Because it gives you a pleasant feeling.	○	○	○	○	○
Because it improves parties and celebrations.	○	○	○	○	○
Because you feel more self-confident and sure of yourself.	○	○	○	○	○
To celebrate a special occasion with friends.	○	○	○	○	○
To forget about your problems.	○	○	○	○	○
Because it's fun.	○	○	○	○	○
To be liked	○	○	○	○	○
So you won't feel left out.	○	○	○	○	○

Recent Life Events (RLE-Q)

Listed below are a number of events. Please read each item carefully and then indicate whether or not each event has happened to you in the past year.

Please tick the YES box if the event has occurred.
Please tick the 'still affects me' box if the event is still having an effect on your life

*** immediate family includes: mother, father, sister, brother, partner, child**

	No	Yes	Still affects me
Have you had a serious illness or been seriously injured?	○	○	○
Has one of your immediate family * been seriously ill or injured?	○	○	○
Have any of your close friends or other close relatives been seriously ill or injured?	○	○	○
Have any of your immediate family died?	○	○	○
Have any of your other close relatives or close friends died?	○	○	○
Have you separated from your partner (not including death)?	○	○	○
Have you had any serious problem with a close friend, neighbour or relative?	○	○	○
Have you, or an immediate family member been subject to serious racial abuse, attack or /threats	○	○	○
Have you, or an immediate family member been subject to any abuse, attack, threat - perhaps due to you or someone close to you having a disability of any kind (i.e. a mental health problem, a learning disability or a physical problem)?	○	○	○

Have you, or an immediate family member been subject to any other form of serious abuse, attack, or threat?	○	○	○
Have you or your partner been unemployed or seeking work for more than one month?	○	○	○
Have you or your partner been sacked from your job or made redundant?	○	○	○
Have you had any major financial difficulties (e.g. debts, difficulty paying bills)?	○	○	○
Have you, or an immediate family member had any Police contact or been in a court appearance?	○	○	○
Have you or an immediate member of your family been burgled or mugged?	○	○	○
Have you or another individual who lives with you given birth?	○	○	○
Have you or another individual who lives with you suffered from a miscarriage or had a stillbirth?	○	○	○
Have you moved house (through choice)?	○	○	○
Have you moved house (not through choice)?	○	○	○
Have you had any housing difficulties?	○	○	○
Have you had any other significant event (Please specify)?	○	○	○

Gambling (GMQ-9)

These questions are about gambling.

By 'gambling' we mean things like: buying lottery tickets or scratch cards for yourself; playing games or making bets for money on the internet (online gambling); playing football pools, bingo or fruit machines; playing games or making bets with friends for money; betting on races and/or with a bookmaker; and table games in a casino.

Have you spent any money on any of these things in the last 12 months?

○ Yes ○ No

Thinking about the last 12 months:

	Never	Sometimes	Most of the time	Almost always
Have you bet more than you could really afford to lose?	○	○	○	○
Have you needed to gamble with larger amounts of money to get the same feeling of excitement?	○	○	○	○
When you gambled, did you go back another day to try to win back the money you lost?	○	○	○	○
Have you borrowed money or sold anything to get money to gamble?	○	○	○	○
Have you felt that you might have a problem with gambling?	○	○	○	○
Has gambling caused you any health problems, including stress or anxiety?	○	○	○	○
Have people criticized your betting or told you that you had a gambling problems, regardless of whether or not you thought it was true?	○	○	○	○
Has your gambling caused any financial problems for you or your household?	○	○	○	○
Have you felt guilty about the way you gamble or what happens when you gamble?	○	○	○	○

Domestic Abuse (NCSE&W)

Please take a moment to read this screen. It contains important information about the questions you are about to be asked.

The next set of questions may seem very personal but it is important that we ask them to help understand the rates and impact of certain types of crime and how they affect military personnel.

Please remember that all your answers are strictly confidential and your information will be grouped with others in a way that does not identify individuals.

If the questions upset you in any way you can pass over the questions by pressing the 'Don't wish to answer' key. However, we hope you will continue to the end.

If you are unable or unwilling to answer these questions please tick the box below and you will be taken to the next section.	◯ Continue to questions. ◯ Please skip this section.

Has a partner or ex-partner ever repeatedly or continuously done any of the things listed below?

By partner we mean a boyfriend, girlfriend, husband, wife or civil partner.

	No	Yes	Don't know / can't remember	Never had a partner	Don't wish to answer
Unfairly controlled how much money you could have or how you spent it	◯	◯	◯	◯	◯
Isolated you from your friends and family	◯	◯	◯	◯	◯
Monitored your letters, phone calls, emails, texts or social media	◯	◯	◯	◯	◯
Enforced rules or activities which humiliated you	◯	◯	◯	◯	◯
Controlled how household work or childcare is done	◯	◯	◯	◯	◯
Kept track of where you went or how you spent your time	◯	◯	◯	◯	◯
Bullied or intimidated you, for example by punching walls or destroying property	◯	◯	◯	◯	◯
Forced you to engage in sex or certain sexual acts against your will	◯	◯	◯	◯	◯
Threatened to harm children in the household	◯	◯	◯	◯	◯

Thinking about these actions you experienced, to what extent did you suffer any of the following as a result?

	Very much	Quite a lot	A little	Not at all	Don't know / Can't remember	Does not apply	Don't wish to answer
Fear that violence would be used against you	○	○	○	○	○	○	○
Feeling unable to leave the relationship/household due to fear of coming to harm	○	○	○	○	○	○	○
Constantly living in fear which affected your day-to-day activities	○	○	○	○	○	○	○
Significant changes in routine, behaviour, or appearance to try to avoid the abuse	○	○	○	○	○	○	○
Forced to give up work, education, or volunteering due to fear of coming to harm	○	○	○	○	○	○	○
Fear that you would lose contact with your children or family	○	○	○	○	○	○	○

Has a partner or ex-partner ever:

	No	Yes	Don't know / can't remember	Never had a partner	Don't wish to answer
Frightened or threatened you in any way?	○	○	○	○	○
Used force on you? (For example they may have pushed you, slapped you, hit, punched or kicked you, choked you or used a weapon against you.)	○	○	○	○	○
Injured you, even if only slightly, as a result of using force on you? (For example, bruises, black eyes, cuts or scratches or broken bones).	○	○	○	○	○

Have YOU ever repeatedly or continuously done any of the things listed below to a partner? By partner we mean a boyfriend, girlfriend, husband, wife or civil partner.

	No	Yes	Don't know / can't remember	Never had a partner	Don't wish to answer
Unfairly controlled how much money your partner could have or how they spent it?	○	○	○	○	○

Isolated your partner from friends and family	○	○	○	○	○
Monitored their letters, phone calls, emails, texts or social media	○	○	○	○	○
Enforced rules or activities that humiliated your partner	○	○	○	○	○
Controlled how household work or childcare is done	○	○	○	○	○
Kept track of where your partner when or how they spent their time	○	○	○	○	○
Bullied or intimidated your partner, for example by punching walls or destroying property	○	○	○	○	○
Forced your partner to engage in sex or certain sexual acts against their willl	○	○	○	○	○
Threatened to harm children in the household	○	○	○	○	○

Have you ever, to your knowledge, done any of the following things to a partner or ex-partner?					
	No	Yes	Don't know / can't remember	Never had a partner	Don't wish to answer
Frightened or threatened them?	○	○	○	○	○
Used force on them? (For example you may have pushed them, slapped them, hit, punched or kicked them, choked them or used a weapon against them.)	○	○	○	○	○
Injured them, even if only slightly, as a result of the force that you used? (By injured we mean things such as bruises, black eyes, cuts or scratches, or broken bones).	○	○	○	○	○

Sexual Assault (NCSE&W)

The next few questions are about sexual offences and stalking, which can affect both men and women. Although the questions may seem quite intrusive they are important in helping us understand more about these types of crimes and how they affect military personnel. We are keen to know whether there was an association to your life within the military or whether it was entirely a civilian situation. For example, if those involved were military, or you were at a work event then there is a military association.

If specific questions upset you you can choose not to answer that question, but we hope you will continue to the end.

Please remember that all you answers are strictly confidential and your information will be grouped with others in a way that does not identify individuals.

Please tick below to confirm that you have read through this information fully and are willing to answer the questions. If you are unwilling or unable to answer this section then tick the box below to skip this section.

If you are unable or unwilling to answer these questions please tick the box below and you will be taken to the next section.	◯ Continue to questions. ◯ Please skip this section.
Since you were 16, has anyone ever indecently exposed themselves to you (i.e. flashing) in a way that caused you fear, alarm or distress?	◯ No ◯ Yes, associated with the Armed Forces ◯ Yes, NOT associated with the Armed Forces ◯ Don't know / Can't remember ◯ Don't wish to answer
Since you were 16, has anyone ever touched you in a sexual way (e.g. touching, grabbing, kissing or fondling), when you did not want it?	◯ No ◯ Yes, associated with the Armed Forces ◯ Yes, NOT associated with the Armed Forces ◯ Don't know / Can't remember ◯ Don't wish to answer
Since you were 16, has anyone ever sent you more than one unwanted communication (letter, text message, email, social media message or telephone call) that was either obscene or threatening and which caused you fear, alarm or distress?	◯ No ◯ Yes, associated with the Armed Forces ◯ Yes, NOT associated with the Armed Forces ◯ Don't know / Can't remember ◯ Don't wish to answer
Since the age of 16 has anyone ever put personal, obscene or threatening information about you on the internet on more than one occasion and which caused you fear, alarm or distress?	◯ No ◯ Yes, associated with the Armed Forces ◯ Yes, NOT associated with the Armed Forces ◯ Don't know / Can't remember ◯ Don't wish to answer
Since the age of 16, has anyone loitered outside your home or workplace, or followed you around and watched you, on more than one occasion in a manner which caused you fear, alarm or distress?	◯ No ◯ Yes, associated with the Armed Forces ◯ Yes, NOT associated with the Armed Forces ◯ Don't know / Can't remember ◯ Don't wish to answer

You said that you were harassed or pestered by someone in some way. Which of these do you think best describes what happened to you?	◯ It was a crime ◯ It was wrong, but not a crime ◯ It was just something that happens ◯ None of these ◯ Don't know / Can't remember ◯ Don't wish to answer

These next questions are about sexual assaults such as rape and attempted rape or being forced into some other sexual act when you were not capable of consent or when you made it clear you did not want to. These crimes affect both women and men.

The language used here is very explicit and direct and it may seem very intrusive to you. We ask in this level of detail to help classify the exact type of sexual assault that people may have experienced. Remember, if the questions upset you in any way you can pass over them by ticking "Don't wish to answer". You can skip the entire section by ticking the "Please skip this section" box below.

We will ask first about actual sexual assaults and then about attempted sexual assaults and there are two questions about childhood sexual abuse. We will ask if you were a victim or a perpetrator or being forced.

If you are unable or unwilling to answer these questions please tick the box below and you will be taken to the next section.	◯ Continue to questions. ◯ Please skip this section.
Since the age of 16, has anyone ever penetrated your mouth, vagina or anus with their penis, fingers or other object when you made it clear that you did not agree or when you were not capable of consent?	◯ No ◯ Yes, associated with the Armed Forces ◯ Yes, NOT associated with the Armed Forces ◯ Don't know / Can't remember ◯ Don't wish to answer
Have you, since the age of 16, ever penetrated someone else's mouth, vagina or anus with an object (including fingers or your penis) when they had made it clear that they did not agree or when they were not capable of consent?	◯ No ◯ Yes, associated with the Armed Forces ◯ Yes, NOT associated with the Armed Forces ◯ Don't know / Can't remember ◯ Don't wish to answer
Since the age of 16, has anyone ever forced you to penetrate another person's mouth, vagina or anus with your penis, fingers or other object when you made it clear that you did not agree or when you were not capable of consent?	◯ No ◯ Yes, associated with the Armed Forces ◯ Yes, NOT associated with the Armed Forces ◯ Don't know / Can't remember ◯ Don't wish to answer
Since the age of 16, has anyone ever attempted to penetrate your mouth, vagina or anus with their penis, fingers or other object when you made it clear that you did not agree or when you were not capable of consent?	◯ No ◯ Yes, associated with the Armed Forces ◯ Yes, NOT associated with the Armed Forces ◯ Don't know / Can't remember ◯ Don't wish to answer
Have you, since the age of 16, ever attempted to penetrated someone else's mouth, vagina or anus with an object (including fingers or your penis) when they had made it clear that they did not agree or when they were not capable of consent?	◯ No ◯ Yes, associated with the Armed Forces ◯ Yes, NOT associated with the Armed Forces ◯ Don't know / Can't remember ◯ Don't wish to answer
Before the age of 16, did anyone ever penetrate your mouth, vagina or anus with their penis, fingers or other object when you made it clear that you did not agree or were not capable or too young to consent?	◯ No ◯ Yes ◯ Don't know / can't remember ◯ Don't wish to answer
Before the age of 16, did anyone ever attempt to penetrate your mouth, vagina or anus with their penis, fingers or another object when you made it clear that you did not agree or were not capable or too young to consent?	◯ No ◯ Yes ◯ Don't know / can't remember ◯ Don't wish to answer

mHealth Usability (MAUQ)

The app was easy to use.

1, Disagree 4, Neutral 7, Agree

(Place a mark on the scale above)

It was easy for me to learn to use the app.

1, Disagree 4, Neutral 7, Agree

(Place a mark on the scale above)

I like the interface of the app.

1, Disagree 4, Neutral 7, Agree

(Place a mark on the scale above)

The information in the app was well organized, so I could easily find the information I needed.

1, Disagree 4, Neutral 7, Agree

(Place a mark on the scale above)

I feel comfortable using this app in social settings.

1, Disagree 4, Neutral 7, Agree

(Place a mark on the scale above)

The amount of time involved in using this app has been fitting for me.

1, Disagree 4, Neutral 7, Agree

(Place a mark on the scale above)

I would use this app again.

1, Disagree 4, Neutral 7, Agree

(Place a mark on the scale above)

Whenever I made a mistake using the app, I could recover easily and quickly.

1, Disagree 4, Neutral 7, Agree

(Place a mark on the scale above)

This app provides an acceptable way to receive healthcare services.

1, Disagree 4, Neutral 7, Agree

(Place a mark on the scale above)

The app adequately acknowledged and provided information to let me know the progress of my action.

1, Disagree 4, Neutral 7, Agree

(Place a mark on the scale above)

The navigation was consistent when moving between screens.

1, Disagree 4, Neutral 7, Agree

(Place a mark on the scale above)

The interface of the app allowed me to use all the functions (such as entering information, responding to reminders, viewing information) offered by the app.

1, Disagree 4, Neutral 7, Agree

(Place a mark on the scale above)

This app has all the functions and capabilities I expected it to have.

1, Disagree 4, Neutral 7, Agree

(Place a mark on the scale above)

The app would be useful for my health and wellbeing.

1, Disagree 4, Neutral 7, Agree

(Place a mark on the scale above)

The app helped me manage my health effectively.

1, Disagree 4, Neutral 7, Agree

(Place a mark on the scale above)

Overall, I am satisfied with this app.

1, Disagree 4, Neutral 7, Agree

(Place a mark on the scale above)

Major General Paul Cain QHP
MBChB MMedSci MSc DiPAvnMed FFOM
Director of Defence Healthcare

Headquarters Joint Medical Group
Coltman House,
Defence Medical Services Whittington,
Tamworth Road,
Lichfield, Staffordshire WS14 9PY

Air Cdre R Withnall QHS MD MA MSc FRCGP FAcadMEd CMgr
Head of Research & Clinical Innovation
Royal Centre for Defence Medicine
ICT Centre, Vincent Drive
Edgbaston
Birmingham B15 2SQ

Ref: DMS/DHC/Letter of Support-KING

Date: 2 September 2020

LETTER OF SUPPORT FOR SURGEON COMMANDER KATHERINE KING – HIGHER DEGREE BOARD AND DMS RESEARCH STEERING GROUP SEP 2020

When Surgeon Commander Kate King approached me regarding her MD(Res) research topic, I was immediately drawn to the value this would add not only to her personal development but with that a real opportunity to provide much-needed evidence in/for Defence Primary Healthcare (DPHC) delivery.

As Director of Defence Healthcare, my remit includes the commissioning and delivery of primary healthcare to Defence personnel in the UK and in non-operational overseas locations through DPHC including mental health. Alongside that I am also responsible for leading the development of future healthcare projects and transformation under the auspices of the Defence Healthcare Delivery Optimisation (DHDO) and CORTISONE Programmes and it is clear to me that understanding treatment pathways is something we have not done universally well and yet they are vital to transforming the service and better outcomes.

Beyond the effects on the patient as an individual, alcohol excess is consistently associated with increased demand on healthcare systems and decreased work productivity. It impacts on all aspects of Service life. The development of an evidence-based strategy for managing alcohol use has the potential to directly benefit patient care and offer a truly meaningful effect across the DPHC pillar, and Defence more widely. The utilisation of smartphone app-based intervention aligns well with one of DHDO's aims to embrace proven technological solutions and provide innovative ways to access services and indeed we have already moved to this approach.

Surgeon Commander King has a proven track record in academic research and her superiors speak highly of her capacity, work ethic and passion for research and patient care. Noting this and the obvious merits to Defence and Primary Healthcare, I offer my total support to her work and would ask that both the Research Steering Group and Higher Degree Board very strongly consider endorsing that Surgeon Commander King undertake this MD(Res) study proposal.

Defence Consultant Advisors in
Psychiatry & Clinical Psychology
Defence Primary Health Care Headquarters
Coltman House
DMS Whittington
Lichfield
WS14 9PY

03 Sep 20

LETTER OF SUPPORT FOR SURG CDR KATHERINE KING

Surgeon Commander King is a Royal Navy GP known to us for a number of years. She is keen and determined and has a reputation for driving change in medical centres that she has managed.

She is keen to research the effectiveness of the Drinks Ration App in modifying alcohol use behaviour in at-risk Service personnel. If shown to be effective the App has potential to enhance alcohol interventions by providing a treatment option as part of comprehensive approach to delivery of care for risky alcohol use. This would support ongoing work to implement an evidence-based integrated alcohol pathway for Defence Primary Health Care.

This is a research proposition with merit and links well with the Surgeon General's research priorities in mental health.

To undertake this research, Surg Cdr King will collaborate with the King's Centre for Military Health Research (KCMHR).

We offer our full support to this research proposal and believe that it has the potential to significantly contribute to ongoing work on how we care for Defence personnel at risk of alcohol related harm.

Signed on MODNET

Rik Coetzee
Surgeon Captain
Defence Consultant Advisor in Psychiatry

Rachel Norris DPhil
B1
Defence Consultant Advisor in Clinical Psychology

References

1. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. Implement Sci [Internet]. 2011 [cited 2020 Feb 13];6(1). Available from: http://www.implementationscience.com/content/6/1/42
2. Michie S, Whittington C, Hamoudi Z, Zarnani F, Tober G, West R. Identification of behaviour change techniques to reduce excessive alcohol consumption. Addiction. 2012;107(8):1431–40.
3. Garnett C V, Crane D, Brown J, Kaner EFS, Beyer FR, Muirhead CR, et al. Behavior Change Techniques Used in Digital Behavior Change Interventions to Reduce Excessive Alcohol Consumption: A Meta-regression. Ann Behav Med [Internet]. 2018 May 18 [cited 2021 Mar 16];52(6):530–43. Available from: https://academic.oup.com/abm/article/52/6/530/4827558
4. NHS Digital. Statistics on Alcohol, England 2020 - NHS Digital [Internet]. [cited 2020 Mar 16]. Available from: https://digital.nhs.uk/data-and-information/publications/statistical/statistics-on-alcohol/2020
5. Smith L, Foxcroft D. Drinking in the UK: An exploration of trends [Internet]. 2009 [cited 2020 Nov 25]. Available from: www.jrf.org.uk
6. Burton R, Marsden J. The Public Health Burden of Alcohol and the Effectiveness and Cost-Effectiveness of Alcohol Control Policies An evidence review [Internet]. 2016 [cited 2020 Aug 6]. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/733108/alcohol_public_health_burden_evidence_review_update_2018.pdf
7. Fear NT, Iversen A, Meltzer H, Workman L, Hull L, Greenberg N, et al. Patterns of drinking in the UK Armed Forces. Addiction. 2007;102(11):1749–59.
8. Henderson A, Langston V, Greenberg N. Alcohol misuse in the Royal Navy. Occup Med (Chic Ill) [Internet]. 2009 [cited 2020 Mar 16];59(1):25–31. Available from: https://academic.oup.com/occmed/article-abstract/59/1/25/1420587
9. Ministry of Defence. Lifestyles Steering Group Report Pack. 2019.
10. Stewart D, Mccambridge J. Alcohol complicates multimorbidity in older adults. BMJ [Internet]. 2019 Jun 27 [cited 2020 Nov 24];365. Available from: http://group.bmj.com/group/rights-licensing/
11. Smith J. Drunk Sergeant headbutts soldier in face at alcohol fuelled Army social event [Internet]. Daily Star. 2020 [cited 2020 Nov 26]. Available from: https://twnews.co.uk/gb-news/drunk-sergeant-headbutts-soldier-in-face-at-alcohol-fuelled-army-social-event
12. Rayment S. More than HALF of British military personnel “drinking dangerously high levels of alcohol” - Mirror Online [Internet]. Mirror Online. 2018 [cited 2020 Nov 26]. Available from: https://www.mirror.co.uk/news/uk-news/more-half-british-military-personnel-13291257
13. NICE. Alcohol-use disorders: prevention. 2010;
14. Home Office. The Government’s Alcohol Strategy [Internet]. UK: HM Government; 2012 [cited 2020 Mar 16]. Available from: www.official-documents.gov.uk
15. Bradley KA, Debenedetti AF, Volk RJ, Williams EC, Frank D, Kivlahan DR. AUDIT-C as a brief screen for alcohol misuse in primary care. Alcohol Clin Exp Res [Internet]. 2007 Jul 1 [cited 2020 Mar 16];31(7):1208–17. Available from: http://doi.wiley.com/10.1111/j.1530-0277.2007.00403.x
16. DISCIPLINE AND CONDUCT-GENERAL. In: BR2 Queens’ Regulations for the Royal Navy [Internet]. Royal Navy; 2017 [cited 2020 May 6]. p. para 3624. Available from: https://www.royalnavy.mod.uk/-/media/royal-navy-responsive/documents/reference-library/brd2/ch36.pdf
17. Defence Primary Health Care. Alcohol Intervention Working Group. DMS Whittington; 2019.
18. Kaner EFS, Dickinson HO, Beyer F, Pienaar E, Schlesinger C, Campbell F, et al. The effectiveness of brief alcohol interventions in primary care settings: A systematic review [Internet]. Vol. 28, Drug and Alcohol Review. John Wiley & Sons, Ltd; 2009 [cited 2020 Feb 11]. p. 301–23. Available from: http://doi.wiley.com/10.1111/j.1465-3362.2009.00071.x
19. Leightley D, Puddephatt JA, Jones N, Mahmoodi T, Chui Z, Field M, et al. A smartphone

app and personalized text messaging framework (InDex) to monitor and reduce alcohol use in ex-serving personnel: Development and feasibility study. JMIR mHealth uHealth. 2018 Sep 1;6(9).
20. Leightley D, Rona RJ, Shearer J, Williamson C, Gunasinghe C, Simms A, et al. Evaluating the Efficacy of a Mobile App (Drinks:Ration) and Personalized Text and Push Messaging to Reduce Alcohol Consumption in a Veteran Population: Protocol for a Randomized Controlled Trial. JMIR Res Protoc [Internet]. 2020 [cited 2020 Nov 24];9(10). Available from: https://doi.org/10.2196/preprints.19720
21. Prensky M. Digital Natives, Digital Immigrants Part 1. Horiz. 2001 Sep 1;9(5):1–6.
22. Wigham S, Bauer A, Robalino S, Ferguson J, Burke A, Newbury-Birch D. A systematic review of the effectiveness of alcohol brief interventions for the UK military personnel moving back to civilian life. J R Army Med Corps. 2017;163(4):242–50.
23. Leightley D, Puddephatt JA, Goodwin L, Rona R, Fear NT. InDEx: Open source iOS and android software for self-reporting and monitoring of alcohol consumption. J Open Res Softw. 2018;6(1).
24. Puddephatt JA, Leightley D, Palmer L, Jones N, Mahmoodi T, Drummond C, et al. A qualitative evaluation of the acceptability of a tailored smartphone alcohol intervention for a military population: Information about drinking for ex-serving personnel (inDEx) app. JMIR mHealth uHealth. 2019 May 1;7(5).
25. Wootton RE, Greenstone HSR, Abdellaoui A, Denys D, Verweij KJH, Munafò MR, et al. Bidirectional effects between loneliness, smoking and alcohol use: evidence from a Mendelian randomization study. Addiction. 2021 Feb 1;116(2):400–6.
26. Ugochukwu C, Bagot KS, Delaloye S, Pi S, Vien L, Garvey T, et al. The importance of quality of life in patients with alcohol abuse and dependence. Vol. 21, Harvard Review of Psychiatry. 2013. p. 1–17.
27. Alcohol Concern, Royal College of Psychiatrists. A losing bet? Our work in Wales [Internet]. Cardiff; 2013 [cited 2022 May 1]. Available from: https://s3.eu-west-2.amazonaws.com/files.alcoholchange.org.uk/documents/A-losing-bet-Alcohol-and-gambling-investigating-parallels-and-shared-solutions.pdf
28. Defence Select Committee. Protecting those who protect us: Women in the Armed Forces from Recruitment to Civilian Life Second Report of Session 2021-22 Report, together with formal minutes relating to the report [Internet]. 2021 [cited 2022 May 1]. Available from: www.parliament.uk/copyright.
29. Wigston M. Report on Inappropriate Behaviours [Internet]. London: Ministry of Defence; 2019 [cited 2022 May 1]. 41 p. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/817838/20190607_Defence_Report_Inappropriate_Behaviours_Final_ZKL.pdf
30. Centre for Military Justice. DEFENCE COMMITTEE INQUIRY WOMEN IN THE ARMED FORCES-From Recruitment to Civilian Life. Submission from the Centre for Military Justice (CMJ) 2 CONTENTS [Internet]. London; 2021 [cited 2022 May 1]. Available from: www.centreformilitaryjustice.org.uk
31. Patridge EF, Bardyn TP. Research electronic data capture (REDCap). Vol. 106, Journal of the Medical Library Association. Medical Library Association; 2018. p. 142–4.
32. Craig P, Dieppe P, Macintyre S, Mitchie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: The new Medical Research Council guidance. BMJ [Internet]. 2008 Sep 29 [cited 2022 Mar 23];337(7676):979–83. Available from: https://www.bmj.com/content/337/bmj.a1655
33. Leightley D, Puddephatt JA, Jones N, Mahmoodi T, Chui Z, Field M, et al. A smartphone app and personalized text messaging framework (InDex) to monitor and reduce alcohol use in ex-serving personnel: Development and feasibility study. JMIR mHealth uHealth [Internet]. 2018 [cited 2022 Mar 23];6(9). Available from: http://mhealth.jmir.org/2018/9/e10074/
34. Puddephatt JA, Leightley D, Palmer L, Jones N, Mahmoodi T, Drummond C, et al. A qualitative evaluation of the acceptability of a tailored smartphone alcohol intervention for a military population: Information about drinking for ex-serving personnel (inDEx) app. JMIR mHealth uHealth [Internet]. 2019 [cited 2022 Mar 23];7(5). Available from: http://mhealth.jmir.org/2019/5/e12267/
35. Leightley D. Evaluating the efficacy of a smartphone application (Drinks:Ration) to reduce

alcohol consumption in a help-seeking veteran population: Randomised Controlled Trial. pending Publ. 2022;
36. Sobell LC, Brown J, Leo GI, Sobell MB. The reliability of the Alcohol Timeline Followback when administered by telephone and by computer. Drug Alcohol Depend. 1996 Sep 1;42(1):49–54.
37. Bohn MJ, Babor TF, Kranzler HR. The Alcohol Use Disorders Identification Test (AUDIT): Validation of a screening instrument for use in medical settings. J Stud Alcohol. 1995;56(4):423–32.
38. Read JP, Kahler CW, Strong DR, Colder CR. Development and Preliminary Validation of the Young Adult Alcohol Consequences Questionnaire*.
39. Arroll B, Goodyear-Smith F, Crengle S, Gunn J, Kerse N, Fishman T, et al. Validation of PHQ-2 and PHQ-9 to screen for major depression in the primary care population. Ann Fam Med. 2010;8(4).
40. Sapra A, Bhandari P, Sharma S, Chanpura T, Lopp L. Using Generalized Anxiety Disorder-2 (GAD-2) and GAD-7 in a Primary Care Setting. Cureus. 2020;
41. Prins A, Bovin MJ, Smolenski DJ, Marx BP, Kimerling R, Jenkins-Guarnieri MA, et al. The Primary Care PTSD Screen for DSM-5 (PC-PTSD-5): Development and Evaluation Within a Veteran Primary Care Sample. J Gen Intern Med. 2016;31(10):1206–11.
42. Harper A, Power M, Orley J, Herrman H, Schofield H, Murphy B, et al. Development of the World Health Organization WHOQOL-BREF Quality of Life Assessment. Psychol Med [Internet]. 1998 [cited 2022 Apr 7];28(3):551–8. Available from: https://doi.org/10.1017/S0033291798006667
43. de Jong Gierveld J, van Tilburg T. The De Jong Gierveld short scales for emotional and social loneliness: Tested on data from 7 countries in the UN generations and gender surveys. Eur J Ageing. 2010;7(2):121–30.
44. Cooper ML. Motivations for alcohol use among adolescents: Development and validation of a four-factor model. Psychol Assess [Internet]. 1994 [cited 2022 Apr 7];6(2):117–28. Available from: https://oce.ovid.com/article/00012030-199406000-00005/PDF
45. Brugha T, Bebbington P, Tennant C, Hurry J. The List of Threatening Experiences: a subset of 12 life event categories with considerable long-term contextual threat. Psychol Med [Internet]. 1985 [cited 2022 Apr 7];15(1):189–94. Available from: https://www.cambridge.org/core/journals/psychological-medicine/article/list-of-threatening-experiences-a-subset-of-12-life-event-categories-with-considerable-longterm-contextual-threat/FB664C28AB2D02D875F73D18DFCBA0D3
46. Stewart SH, Zack M. Development and psychometric evaluation of a three-dimensional Gambling Motives Questionnaire. Addiction [Internet]. 2008 Jul 1 [cited 2022 Apr 7];103(7):1110–7. Available from: https://onlinelibrary.wiley.com/doi/full/10.1111/j.1360-0443.2008.02235.x
47. Office for National Statistics. Crime and justice methodology - Office for National Statistics [Internet]. 2019 [cited 2022 Apr 7]. Available from: https://www.ons.gov.uk/peoplepopulationandcommunity/crimeandjustice/methodologies/crimeandjusticemethodology#questionnaires
48. Zhou L, Bao J, Setiawan IMA, Saptono A, Parmanto B. The mhealth app usability questionnaire (MAUQ): Development and validation study. JMIR mHealth uHealth [Internet]. 2019 [cited 2022 Apr 7];7(4). Available from: http://mhealth.jmir.org/2019/4/e11500/
49. Leightley D, Rona RJ, Shearer J, Williamson C, Gunasinghe C, Simms A, et al. Evaluating the Efficacy of a Mobile App (Drinks:Ration) and Personalized Text and Push Messaging to Reduce Alcohol Consumption in a Veteran Population: Protocol for a Randomized Controlled Trial. JMIR Res Protoc [Internet]. 2020 Oct 2 [cited 2021 Mar 1];9(10):e19720. Available from: https://www.researchprotocols.org/2020/10/e19720
50. Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomised trials. BMJ [Internet]. 2010 [cited 2021 Oct 28];340(7748):698–702. Available from: www.consort-statement.org
51. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide. BMJ [Internet]. 2014 [cited 2022 Apr 5];348. Available from: http://www.bmj.com/content/348/bmj.g1687?tab=related#datasupp

52. NHS Health Research Authority. Research involving children - Health Research Authority [Internet]. Research Involving Children. 2021 [cited 2022 Mar 21]. Available from: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-involving-children/
53. NHS. Drinking alcohol while pregnant - NHS [Internet]. Nhs.Uk. 2017 [cited 2022 Mar 21]. Available from: https://www.nhs.uk/pregnancy/keeping-well/drinking-alcohol-while-pregnant/
54. Kaner EFS, Beyer FR, Muirhead C, Campbell F, Pienaar ED, Bertholet N, et al. Effectiveness of brief alcohol interventions in primary care populations. Cochrane Database Syst Rev. 2018 Feb 24;2018(2).
55. MHRA. Medical devices: software applications (apps) - GOV.UK [Internet]. 2018 [cited 2022 Mar 22]. p. 39. Available from: https://www.gov.uk/government/publications/medical-devices-software-applications-apps