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What is the effectiveness of the DrinksRation smartphone application on modifying alcohol use behaviour in Service personnel at risk of alcohol-related harm?

Submission date
24/10/2022

Recruitment status
No longer recruiting

Registration date
06/12/2022

Overall study status
Completed

Last Edited
16/10/2023

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This is a study looking at drinking behaviours, health and wellbeing in serving military personnel. 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.

Who can participate?
All members of the UK Armed Forces are eligible to take part if they are seen to be at risk of alcohol related harm on a scoring measure called AUDIT-C.

What does the study involve?
Participants will be asked to complete various surveys about their alcohol consumption, drinking behaviour and health over a 3 month period. The surveys will be sent either by email or through a smartphone application. 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.

What are the possible benefits and risks of participating?
The potential benefits of the study are that participants may become more aware of their drinking behaviours and alcohol use and they will also be helping the wider military community by helping understand what effects drinking behaviours and the impact drinking has.

Potential disadvantages of taking part are considered to be unlikely. If it is detected that participants may be drinking at a harmful level, the independent medical officer may get in touch to provide guidance and support. 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 participants in the event of hacking.

Where is the study run from?
King's Centre for Military Health Research based at King's College London (UK)

When is the study starting and how long is it expected to run for?
March 2021 to April 2023

Who is funding the study?
Defence Medical Services (Ministry of Defence) (UK)

Who is the main contact?
Dr Kate King, katherine.king415@mod.gov.uk

Study website
https://drinksration.app/

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2154MODREC22

Study information

Scientific Title
Military DrinksRation study

Study objectives
That use of the DrinksRation app will reduce alcohol consumption in a population of at risk military personnel

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/09/2022, Ministry of Defence Research Ethics Committee (Defence Science & Technology, DSTL Portsdown West, Fareham, PO17 6AD, UK; +44 300 153 5372; DST-MODRECTeam@mod.gov.uk), ref: 2154/MODREC/22

Study design
Two-arm randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Alcohol behaviour change in military personnel identified as being at risk of alcohol related harm.

Interventions
This study is a two-arm randomised controlled trial comparing the Drinks:Ration smartphone application with usual care.

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 programme31 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.

Intervention Type

Behavioural

Primary outcome measure
Change in alcohol units consumed per week between baseline and day 84 as measured by the timeline follow back method.

Secondary outcome measures
1. Change in alcohol units consumed per week between baseline and day 168 as measured by the timeline follow back method.
2. Change in AUDIT score between baseline and day 84.
3.1. Change in quality of life assessment between baseline and day 84 as measured by World Health Organisation Quality of Life-BREF survey.
3.2. Change in quality of life assessment between baseline and day 168 as measured by World Health Organisation Quality of Life-BREF survey.
4. Change in drinking motivations between baseline and day 84 as measured by the Drinking Motivations Questionnaire (Revised).
5.1. Change in mental health screening parameters (depression, anxiety, PTSD) between baseline and day 84.
5.2. Change in mental health screening parameters (depression, anxiety, PTSD) between baseline and day 168.
6. Assessment of correlation between alcohol intake and loneliness (De Jong Gierveld), recent life events (RLE-Q), gambling behaviours (GMQ-9), domestic & sexual assault (National Crime Survey for England & Wales).

Overall study start date
20/03/2021

Completion date
30/04/2023

Eligibility

Key inclusion criteria
1. Age 16 years - no upper limit (upper age limited by being in active military service)
2. Serving UK Military
3. Scores 5 or more on AUDIT-C screening questionnaire

Participant type(s)
Other

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants

728

Key exclusion criteria
Scores 4 or less on AUDIT-C screening questionnaire

Date of first enrolment
14/01/2023

Date of final enrolment
28/02/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Defence Medical Services
Defence Primary Healthcare
Coltman House
Defence Medical Services Whittington
Lichfield
United Kingdom
WS149PY

Sponsor information

Organisation
Defence Medical Services

Sponsor details
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Sponsor type

Government

Funder(s)

Funder type
Government

Funder Name
Ministry of Defence

Alternative Name(s)
MOD

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results will form part of a thesis for the degree of Doctor of Medicine with King's College London. Additionally publication of all aspects of the study are planned in high-impact peer review journals.

The publication plan includes the following provisionally planned articles:
- 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

Furthermore, results will be translated into an executive report for Defence Medical Services to allow consideration of whether the DrinksRation app should be incorporated into the alcohol management pathway for at risk Service personnel, or whether it should be recommended by Defence Medical Services.

Intention to publish date
01/04/2023

Individual participant data (IPD) sharing plan

The data sharing plans for this study are currently unknown and will be shared at a later date. It is anticipated that the raw data will be made available as a supplement to the subsequent results publication.

Results will also be available from the author (katherine.king415@mod.gov.uk) on a case by case basis providing that there are no breaches of the ethical approval and appropriate data storage can be guaranteed.

IPD sharing plan summary

Available on request, Published as a supplement to the results publication, Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	20/09/2022	24/10/2022	No	Yes
Participant information sheet	App information version 2.0	20/09/2022	24/10/2022	No	Yes
Protocol file	version 2.4	20/09/2022	24/10/2022	No	No
Protocol article		13/10/2023	16/10/2023	Yes	No