ISRCTN50744553 https://doi.org/10.1186/ISRCTN50744553

Evaluation of a smartphone app to support low mood and worry in female armed forces veterans in Great Britain

Submission date
04/09/2025

Recruitment status
No longer recruiting

Registration date
10/09/2025

Overall study status
Completed

Last Edited
09/03/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
There are many studies looking at the experiences of men when they leave the Armed Forces and difficulties that they sometimes face, such as finding work. These difficulties can impact their emotional wellbeing and sometimes lead to mental health problems. While support for male veterans has improved, there is little research on female veterans, leading to slower progress and unequal access to treatment for depression and anxiety.

This small feasibility study seeks to understand some of the research challenges faced when examining the effectiveness and acceptability of a mobile phone app called Iona FFV for the management of low mood and worry in female armed forces veterans. Results from the study will indicate if it is possible to run a large scale randomised study; best way to run a large scale randomised study of the app and examine acceptability of the intervention.

Who can participate?
The study is for female British armed forces veterans aged 18 and over, experiencing difficulties with low mood or worry management. They will need to own a smartphone, be able to read and understand English, no history of psychosis, mania, substance/alcohol dependence, not receiving mental health support during the study and not have experienced a severe mental health difficulty or changed anti-depressant medication in the last month.

What does the study involve?
This study will take place online. All people wanting to take part in the study will complete questionnaires to ensure they are eligible to take part in the study. If eligible to take part they will be randomly placed into one of two groups of equal sizes.
1. Treatment: This group will use the Iona FFV app for about 10 minutes each day for six weeks. The app will support them to engage with approaches used in cognitive behavioural therapy to manage low mood or worry.
2. Control: This group will use an app designed to look and feel very similar to the Iona FFV app but is not based on real therapy, instead it includes “meditation-like” exercises and a simple dream diary to record dreams.

Researchers will not be aware of which people have been randomly placed into either of the groups so that they cannot influence the results. At the end of the study those initially using the control app will be given the opportunity to use Iona FFV outside of the research.

We are mostly interested in understanding how well the study runs in areas such as number recruited, drop out, reasons for drop out, questionnaire completion, intervention engagement to inform a larger study. We will however also take reliable questionnaires to examine changes in low mood (PHQ-9), generalised anxiety (GAD-7) and functioning (WSAS). These will be taken when someone starts the study, at the end of six weeks treatment, and a four week follow-up. Furthermore, a measure will examine how much those using the Iona FFV app were able to engage with it and found it acceptable.

What are the possible benefits and risks of participating?
As a token of our appreciation, participants will receive £30 Amazon voucher for completing the study. Those who leave the study early will be partially paid:
- £20 Amazon voucher for those who complete the 6-week questionnaire (but not follow up),
- £10 Amazon voucher for those who drop out following downloading the app.

There is no known health risk linked to any of the assessments. Apart from the possibility that the intervention might not work, there is no evidence in the research to suggest that the assessments or interventions could cause harm to the female veterans taking part.

At the end of the study, we will let people know about it by publishing the results in a journal, conference presentations and on the study website. All those taking part in the study will be given the opportunity to have a copy of the results e-mailed to them.

Where is the study run from?
The study will take place online. That is, recruitment, any information about the study and completing all the questionnaires will take place online. Participants will use the app in their own time.

When is the study starting and how long is it expected to run for?
October 2023 to November 2025.

Who is funding the study?
Office for Veterans' Affairs (UK)

Who is the main contact?
Professor Paul Farrand, p.a.farrand@exeter.ac.uk
Dr Melika Janbakhsh, mj268@exeter.ac.uk

Contact information

Type(s)
Public, Scientific

Contact name
Dr Melika Janbakhsh

ORCID ID
https://orcid.org/0000-0001-8860-6557

Contact details
Cedar, Psychology Department, University of Exeter, Washington Singer Building, Perry Road
Exeter
United Kingdom
EX4 4QG
-
mj268@exeter.ac.uk

Type(s)
Principal investigator

Contact name
Prof Paul Farrand

ORCID ID
https://orcid.org/0000-0001-7898-5362

Contact details
Cedar, Psychology Department, University of Exeter, Washington Singer Building, Perry Road
Exeter
United Kingdom
EX4 4QG
+44 1392 725793
P.A.Farrand@exeter.ac.uk

Additional identifiers

Protocol serial number
1339200: DASA

Study information

Scientific Title
Cognitive behavioural therapy smartphone app for low mood and worry management in female armed forces veterans in Great Britain: feasibility randomised controlled trial

Acronym
SAFE (Support App for Female Veterans' Emotions)

Study objectives
This study extends research adapting a low-intensity CBT research app for low mood or enhance worry management to examine methodological uncertainties with running a future randomised controlled trial.

Research objectives are:
- To understand methodological uncertainties (e,g, recruitment) associated with running a definitive RCT on the adapted Iona research app for female veterans (Iona FFV), and engagement with an intervention among Female Armed Forces Veterans. Also, to examine the extent to which the study achieves progression criteria to determine feasibility.

- Secondary objective of this research is to understand whether there is a potential for the adapted Iona app for female veterans to be effective for the treatment of low mood and support worry management.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/07/2025, FHLS Psychology Ethics Committee, University of Exeter (School of Psychology, Washington Singer Building, Perry Road, Exeter, EX4 4QG, United Kingdom; -; cgr-reg@exeter.ac.uk), ref: 10130867

Primary study design
Interventional

Study design
Interventional double-blinded feasibility randomised controlled trial (RCT) and acceptability

Study type(s)
Treatment, Other

Health condition(s) or problem(s) studied
Mild to moderate depression and anxiety

Interventions
Intervention
Iona Female Forces Veterans (Iona FFV) is a mobile phone app based low-intensity CBT (liCBT) intervention with engagement supported by an Artificial Intelligence driven chat-bot without any form of human support provided. Content is informed by specific factor techniques for managing low mood or worry of mild to moderate severity. Both are based on evidence-based protocols for the treatment of depression and Generalised Anxiety Disorder and recognised by the National Institute for Health and Care Excellence. Engagement with the intervention and specific factor techniques is supported by behaviour change techniques promoting goal setting. Engagement begins with participants landing on the Today home screen and progressing through six educational modules based on the Low-Intensity CBT techniques through which they learn about and interact with the LICBT techniques. Lessons and interactive exercises consist of text, video and audio. Participants are given a 6 weeks treatment period to complete the intervention and encouraged to engage with it for a period of time of their preference. After 6 weeks engagement they are ‘off-boarded’ and no longer able to access the app. Participants are considered an ‘engaged user’ if they complete at least 2 educational modules on at least 2 days.

Control
The sham control is based on a mobile phone app and consists of approximately the same number of educational modules as Iona FFV, with repeatable “meditation-like” exercises. Engagement begins with participants landing on the Today home screen after which they progress through ‘meditation-like’ lessons and introduced to descriptions of approaches such as Freudian Dream Analysis but no specific factor content enabling the approaches to be applied. Lessons and interactive exercises consisting of text, video and audio, will be similar to that of the Iona FFV app. Neither Artificial Intelligence nor human support is provided for intervention engagement. The length of each lesson and exercise has been developed to be approximately the same as the average engagement time per session with Iona FFV to match participant time

on task. The app will be delivered within the same app framework using approximately the same app and cloud infrastructure as Iona FFV to ensure a consistent look and feel and user experience across both apps. Participants are given 6 weeks to complete the intervention and encouraged to engage with it for a period of time of their preference. After 6 weeks engagement they are 'off-boarded' and no longer able to access the app. Participants are considered an 'engaged user' if they complete at least 2 educational modules on at least 2 days.

Randomisation
At the start of the study, two lists of app download groups were provided by the Iona FFV app team, each list corresponding to one of the study arms (Iona FFV and sham). All researchers were blind to which code list belonged to which study arm. Following acceptance into the study, participants were then given codes by the researchers in blocks of three in each study arm.

Intervention Type
Device

Phase
Phase II

Drug/device/biological/vaccine name(s)
Low Intensity CBT smartphone app with Artificial Intelligence (AI) support.

Primary outcome(s)
Feasibility - To collect data on number of participants consented, recruited, completed screening, and to assess recruitment method, measure completion (baseline, 6 weeks, 10 weeks), drop out, drop out reason, and engagement measured using patient records at the end of the study

Key secondary outcome(s)
1. Patient Health Questionnaire (PHQ-9) at baseline, week 6, and week 10
2. General Anxiety Disorder (GAD-7) at baseline, week 6, and week 10
3. Work and Social Adjustment Scale (WASAS) at week 6 and week 10
4. mHealth App Usability Questionnaire (MAUQ) at week 10

Completion date
07/11/2025

Eligibility

Key inclusion criteria
Initial screening:
1. Identify as female armed forces veteran
2. ≥ 18 years old
3. Great Britain resident
4. Ability to read and understand English
5. No history of psychosis, mania, substance/alcohol dependence
6. Ability to download app
7. Access to smartphone with internet access
8. Not started or changed Anti Depressant Medication in the last month
9. Not receiving mental health support during the study

Second screening:
1. PHQ-9≥5;<20
2. PHQ9-Q9 (suicide risk)≤1
3. GAD7<15

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Female

Total final enrolment
59

Key exclusion criteria
Initial screening:
1. Not identify as female armed forces veteran
2. <18 years old
3. Non Great Britain resident
4. Unable to read and understand English
5. History of psychosis, mania, substance/alcohol dependence
6. Unable to download app
7. No access to smartphone with internet access
8. Started or changed Anti Depressant Medication in the last month
9. Receiving mental health support during the study

Second screening:
1. PHQ-9<5;≥20
2. PHQ9-Q9 (suicide risk)≥2
3. GAD7≥15

Date of first enrolment
04/08/2025

Date of final enrolment
22/08/2025

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
Online
Online recruitment through Armed Forces Veterans Charity and Community Sector Organisations.
N/A NO COUNTRY SPECIFIED, assuming England
England
N/A

Sponsor information

Organisation
University of Exeter

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Government

Funder Name
Office of Veterans' Affairs

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		06/03/2026	09/03/2026	Yes	No
Other files	Consent form version 2	21/01/2025	10/09/2025	No	No
Other files	Debrief forms version 2	21/01/2025	10/09/2025	No	No
Participant information sheet	version 1	21/01/2025	10/09/2025	No	Yes
Study website		11/11/2025	11/11/2025	No	Yes