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Participant Information Sheet

A feasibility pilot evaluation of a smartphone based Cognitive Behavioural Therapy (CBT) intervention for the treatment of low mood or support for worry management in female armed forces veterans in England, Wales, and Scotland.

Chief Investigator: Professor Paul Farrand

Lead Researcher: Dr Melika Janbakhsh

Thank you for your interest in taking part in this study. The following sections will inform you about this project and your participation in it. Please take time to consider the following information carefully. If you wish to ask any questions about the study, please do not hesitate to contact Melika Janbakhsh mj268@exeter.ac.uk or Beth Turnbull E.Turnbull2@exeter.ac.uk.

What is this study about?

This study aims to explore the feasibility and potential for effectiveness of making adaptations to an intervention for Female Armed Forces Veterans for the treatment of low mood or support worry management. We would also like to get feedback on how engaging and acceptable the above intervention is for the targeted audience.

Iona FV (Female Veterans) is an AI-supported mobile Cognitive Behavioural Therapy (CBT) Low Intensity intervention adapted for female veterans.

If you would like to know more about the study, please contact the Lead Researcher.

What would taking part involve?

You can take up to 7 days to read this document, and if you are interested in taking part, sign the consent form. Taking part involves 3 main stages:

1. You will take part in the initial screening to determine eligibility to participate. To do so, you are asked to complete a short questionnaire about yourself. This questionnaire takes less than 5 minutes to complete.

2. If you are eligible, you will be asked to complete the second screening. This includes a questionnaire about your symptoms of anxiety, depression and well-being. This screening takes about 10-15 minutes, and it is to determine if this study is suitable for you.

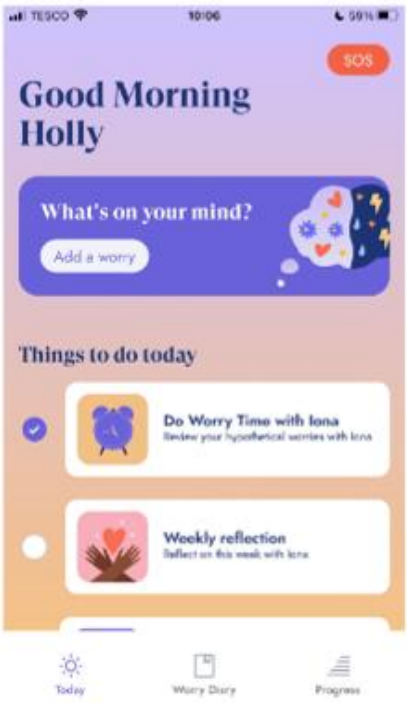
3. If this study is suitable for you, you will be directed to take part in this 10-week trial using the Iona FV intervention app. At this stage we will ask you to complete a sociodemographic questionnaire including questions about your service and also to provide your email address and mobile phone number. This is important to send you reminders and link to assessments. Emails and text messages will never include personal or specific data but will serve as general reminders about open tasks.

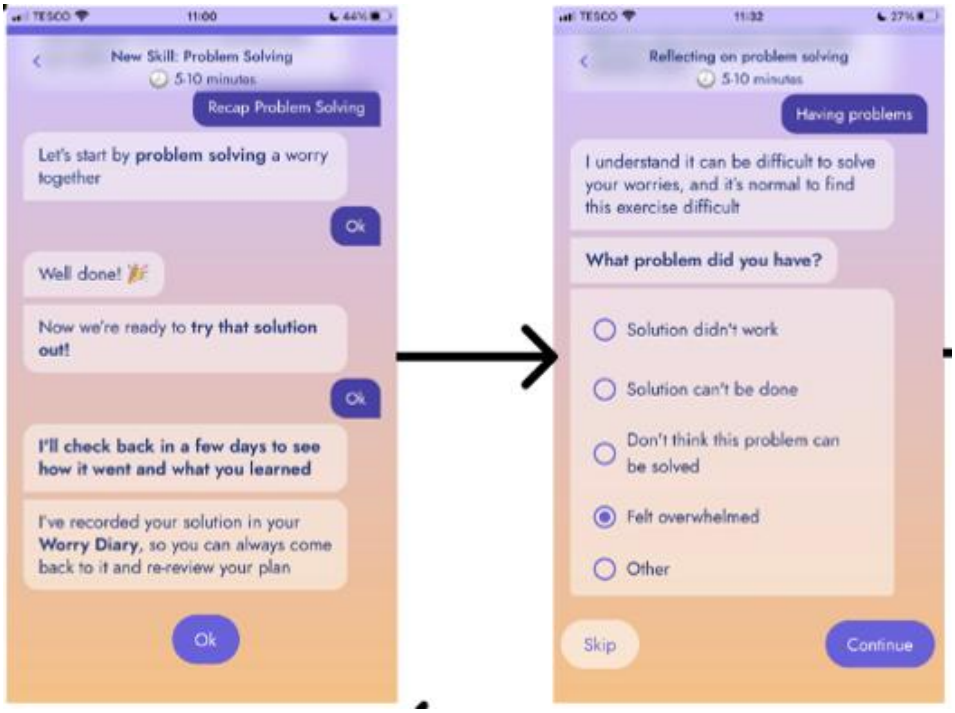
Taking part in this trial includes, using the interventions for 6 weeks. At the end of 6 weeks, you will be asked to complete a questionnaire about your symptoms of anxiety, depression and well-being online (same as the one you completed at the beginning) and a questionnaire about your functioning. 4 weeks later (10 weeks after entering the trial), you will be asked to complete the same set of questions along with a final questionnaire about acceptability and usability of the app. This is expected to take between 20-25 minutes.

Before taking part in this trial, we will randomise participants into one of two groups. One has the Iona FV's intervention, and the other does not, known as the control group. You will not know whether you are receiving the intervention or are in the control group. This is to ensure the results are unbiased and accurate. If you are randomised into the control group, you will be offered to use the Iona FV's intervention after the trial and outside of the study. We will not collect any data for this.

Here are a few examples of what you would expect to see on the app.

These screenshots reflect general features available to all users, not just those using the Iona FV app. Please note that screens may vary between users depending on which features or interventions are accessed during the 6-week period:





Why have I been approached?

You have been approached because you identify as a female veteran.

What are the possible benefits of taking part?

Your participation will help improve the intervention developed for Female Veterans. If effective, the intervention could provide Female Veterans with an additional option for accessing wellbeing support.

Also, the intervention within the trial may benefit individual participants. Versions of techniques within the intervention are commonly adopted within a general adult version of the Iona app which was previously employed as a pilot in an NHS Talking Therapies for anxiety and depression service, with no detected harmful effect.

Will I receive any payment for taking part?

As a thank you and reward for taking part in this study, you will receive a £30 Amazon voucher. To process your voucher payment, we need to share your identifiable information with the finance personnel at the University of Exeter.

If you decide to withdraw from this study prematurely, you will be reimbursed partially:

- £30 voucher (full payment) for those who complete the 4-week follow up (complete the full course of study),
- £20 for those who complete the 6-week questionnaire (but not follow up),
- £10 for those who drop out following downloading the app.

Who can take part?

We have a few eligibility criteria which we will also test during the initial and second screening to make sure if this is study is right for you.

These criteria are to be 18 yrs old and over, identify as female veteran, able to read and understand English, resident in the UK, access to smart phone with internet, and ability to download the intervention app.

We will also ask you to complete an online questionnaire to determine whether the study is suitable for you. To take part, you will be asked to report mild symptoms of anxiety and/or depression during the second screening. Unfortunately, if you changed or started Antidepressant Medication (ADM) in the last month, have ever been diagnosed with bipolar disorder (mania) or psychosis, have a history of substance/alcohol dependence, or if your score on the second screening suggests either no symptoms or more severe symptoms of depression and/or anxiety, you will not be able to take part in the study. This is simply because the intervention is designed for individuals with mild to moderate symptoms and may not be suitable for other levels of severity. If you are not eligible, our automated system will guide you to alternative resources for support and advice.

If you have any questions or would like to have more details about inclusion/exclusion criteria, you can contact Melika Janbakhsh, mj268@exeter.ac.uk or Beth Turnbull E.Turnbull2@exeter.ac.uk.

How do I access the Iona intervention app?

If after both screenings, this is study is right for you, and you want to continue with the trial, you will receive an email from the researcher with a code to download the app. To do so, you need to have access to mobile data or Wi-Fi. It is very important to download the app and use it **immediately** after you receive the confirmation email. If you have any difficulties downloading or accessing the app, please contact Melika Janbakhsh mj268@exeter.ac.uk Beth Turnbull E.Turnbull2@exeter.ac.uk.

Can I withdraw from the study or skip a question?

Your participation in the study is entirely voluntary. You have the right to withdraw at any point during the trial, for any reason without any prejudice or disadvantage. You are not obliged to answer any question(s) in the questionnaire and can skip them accordingly. You will have **3 months** after final data completion to submit your data withdrawal request by emailing Melika Janbakhsh mj268@exeter.ac.uk or Beth Turnbull E.Turnbull2@exeter.ac.uk. Once the 3 months period is finished your data will be fully anonymised and cannot be withdrawn.

How will my information be kept confidential?

The University of Exeter processes personal data for the purposes of carrying out research in the public interest. The University will endeavour to be transparent about its processing of your personal data and this information sheet should provide a clear explanation of this. If you do have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data

Protection Officer by emailing informationgovernance@exeter.ac.uk or going to http://www.exeter.ac.uk/ig/.

Your data will used to explore the potential for effectiveness, engagement, and acceptability of an intervention for Female Armed Forces Veterans for the treatment of low mood or support worry management. Any information you provide will be kept strictly confidential, secure, and will follow the guidelines set out by the Research Ethics Committee. Your data will only be accessible by the lead researcher and the team's Graduate Research Assistant at the University of Exeter. Iona Mind (the app provider) will have no access to individual data. Any personally identifiable data will be removed from the open text responses. Responses from all participants will be combined. In the final report/paper, it will not be possible to identify any individual respondent based on their demographic data.

Demographic data collected during this study and your contact details will be stored on a password protected secure file separate from the rest of your data to ensure anonymity and confidentiality. The lead researcher will assign a unique code to your data to be able to link your assessment data with sociodemographic, and personal data, (i.e., email address and phone number). Only the lead researcher has access to this link-codes and your contact details. We will not collect each participants' name. Only fully anonymised aggregated data will be shared with the rest of the research team at the University of Exeter. No one beyond this team will have access to your information and no identifiable data will be published in any reports. This code-link is important when analysing your data from before and after using the app. Once the 3 months withdrawal period ends, the lead researchers will delete the link code permanently and we will not be able to link any of the data to your sociodemographic data.

You can request to have a copy of the final report. If you are interested, you can indicate this in the consent form. In this case, the lead researcher will keep your email address separate from the rest of the data. Once the report is sent to you, your email address will be deleted permanently.

Data collected will be fully anonymised and electronically stored for a minimum of 10 years, in accordance with the University of Exeter's retention schedules, in a password-protected file space on the University server.

During the 6 weeks of using the app, in-app assessments will be used to understand how you are doing and engaging with the app. This is collected only to inform how Iona FV functions and not understand your progress on interventions. We will not collect this and these will not be shared with us. We only collect data at the beginning (both screenings), end (end of 6 weeks) and 4 weeks follow up.

Iona Mind ensures data privacy and security through robust encryption, compliance with UK data protection laws, and a strict no-sell policy for personal data. Aggregated, anonymized usage metrics may be shared with sponsoring organizations for insights. Users can request account and data deletion anytime. Anonymized data is used to improve app functionality without accessing personal identifiers. You can check Iona app data security link for more details on how your in-use data will be used: Data Security — Iona Mind - Tailored Mental Health Support for your Population.

What are the possible disadvantages of taking part?

Taking part in the study means completing questionnaires and using the Iona app. Some of the questions may ask you about past or present difficult feelings or experiences, and the in-app therapy will help you work through current challenges. This might cause brief and mild upset if it reminds you of something unpleasant, but it's unlikely to be more upsetting than what you might normally feel in everyday life.

We are not aware of any other risks or downsides to using the digital therapy.

What help is provided for me?

If you feel very distressed or have thoughts of harming yourself while completing our assessments (before trial, after 6 weeks and after 10 weeks), we will provide automated advice and guide you to helpful resources. If this happens while using the Iona app, you can select the SOS button and will receive signposting advice and contact numbers and/or links to Emergency, NHS and services developed specifically for the Armed Forces population. It is important to note that, your GP is still responsible for your medical care, so it's important that you contact them if you need further help.

What will happen to the results of this study?

The findings of this study will guide the adaptation of the Iona app and inform future evaluation studies on this app. The results will be disseminated as a report to be presented to the Iona team, academic publications, and conferences. If you are interested in discussing the results of this study, please contact Melika Janbakhsh mj268@exeter.ac.uk or Beth Turnbull E.Turnbull2@exeter.ac.uk.

Who is funding this study and who is involved?

This study is funded by the Office for Veterans Affairs.

Who has reviewed this research?

This study has been reviewed by University of Exeter Psychology Research Ethics Committee. Reference Number: 10130867.

Further information and contact details.

For ethical concerns, please email the Psychology Research Ethics Committee's Co-Chairs, Ciro Civile (c.civile@exeter.ac.uk) and Julian Basanovic (J.Basanovic@exeter.ac.uk), or contact the University Research Ethics and Governance Team (cgr-reg@exeter.ac.uk).

Thank you for your interest in this study.