

# Plain Language Statement

Department of General Practice/Medicine, Dental and Health Science



**Project:** A phase II, open label non-randomised clinical trial of the safety and efficacy of the CovidCare app to support self-monitoring for Covid19 symptoms in self-isolation and to determine the impacts on mental health.

*Qualitative Sub-Study for CovidCare – experiences of app usage for self-management and monitoring of COVID-19 symptoms and emotional well-being*

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## Introduction

Thank you for your interest in participating in this research project. The following few pages will provide you with further information about the project, so that you can decide if you would like to take part in this research.

Please take the time to read this information carefully. You may ask questions about anything you don't understand or want to know more about.

Your participation is voluntary. If you don't wish to take part, you don't have to. If you begin participating, you can also stop at any time.

## What is this research about?

A COVID-19 diagnosis and the isolation and physical distancing needed to manage this condition is a new experience for many people. The CovidCare app was designed to provide people with self-monitoring support at home during self-isolation. Researchers at the University of Melbourne are working with the app developers and clinicians providing support to people with COVID-19 to learn more about people who used the app, their experiences and their emotional needs. This information is valuable and critical to providing future support and interventions to better support people's needs.

As a part of the study we are inviting a group of people who are using CovidCare after receiving a positive diagnosis of COVID-19. This is a telephone interview about your experiences of self-isolation and emotional well-being.

### **What will I be asked to do?**

Should you agree to participate a researcher will call you on the telephone to discuss your experiences using CovidCare and of your self-isolation experience. The telephone conversation will take about 30-45mins and will be audio-recorded for quality and analysis purposes. You will be asked to provide informed audio consent as a part of the interview. Your information will be allocated a code and no information that could identify you will be linked to the information you provide. We have some set questions we will ask and you can provide any additional perspectives that you feel are valuable. The researchers are not able to link your phone interview with any data you have entered in the CovidCare app. The data from the app and the interview will be separate.

If you do not want to answer a particular question, please let the researcher know and they can skip that question.

### **What are the possible benefits?**

The answers that you give will provide a detailed insight into how people have used the CovidCare app and their experiences in self-isolation. This information will be used to improve the CovidCare app and to develop better ways to help people in self-isolation for COVID-19.

### **What are the possible risks?**

It is possible that being involved in this process and discussing the process of diagnosis and self-isolation could be distressing to some people. You can skip a question if you do not want to answer it. The researchers are experienced in discussing sensitive information and can assist if you find the questions distressing. We are able to direct you to support services if you require, and your GP will also be able to provide support if you feel it is needed.

If you feel that you need support you should contact your GP or support services such as:

- BeyondBlue: Phone: 1300 22 4636  
Web: <https://www.beyondblue.org.au/get-support/get-immediate-support>
- Lifeline: Phone 13 11 44  
Web: <https://www.lifeline.org.au/>

CovidCare is only to be used as a monitoring tool and cannot diagnose or predict outcomes from COVID-19. Your breathing and heart rate symptoms could change rapidly in between scheduled measurements.

**If at any stage following a diagnosis of COVID-19 you are feeling concerned about your health we recommend that you call your doctor or 000 for further follow-up.**

### **Do I have to take part?**

No. Participation is completely voluntary. You are able to withdraw at any time. If you are not interested in being involved, simply let the researcher who phones you know and the team will not make further contact. If you start the conversation and decide you no longer wish to participate, please let the researcher know and they will end the interview and delete the recording. Your decision to participate will not affect your care or relationship with staff at the clinic you attended. You should seek help for your health and well-being as normal.

### **Will I hear about the results of this project?**

The researchers will make a summary of the study available on the study webpage, and accessible via the CovidCare app. This can be found at <https://www.covidcare.io/>.

### **What will happen to information about me?**

These conversations will be audio-recorded for analysis purposes and will be securely stored on University of Melbourne computer servers. Access is limited to the research team named in this ethics application. When we analyse and present the data your private information is not shared, for example, we allocate a code instead of using names. We will be combining the information we collect from you with all people being interviewed, and summaries will be presented. This information will be used to improve the CovidCare app; to better understand your experiences; and will form the basis of scientific papers and presentations. De-identified study data may be used in subsequent studies. All study data will be retained for at least 15 years following publication of the final use of that data after which time it will be destroyed securely.

### **Is there any potential conflict of interest?**

The app has been developed by Two Bulls and the app developers may benefit from a positive assessment of this app. The app developers will have no access to the analysis datasets, analysis code or interpretation of findings arising from this study. All outcomes arising from this study will have a conflict of interest declaration.

### **Where can I get further information?**

If you would like more information about the project, please contact the researchers via the study email address: [covidcare-trial@unimelb.edu.au](mailto:covidcare-trial@unimelb.edu.au).

### **Who can I contact if I have any concerns about the project?**

This research project has been approved by the Human Research Ethics Committee of The University of Melbourne. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Manager, Human Research Ethics, Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 2073 or Email: [HumanEthics-complaints@unimelb.edu.au](mailto:HumanEthics-complaints@unimelb.edu.au). All complaints will be treated

confidentially. In any correspondence please provide the name of the research team or the name or ethics ID number of the research project.