

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.

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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 is designed to provide people with self-monitoring support at home during self-isolation. This can be used to track your symptoms and to provide information to your doctor if you need further advice or are concerned about your symptoms.

Researchers at the University of Melbourne are working with the app developers and clinicians providing support to people through the COVID-19 diagnosis period and the following period of isolation for people who receive a positive diagnosis. The aim of the study is to ensure that CovidCare is safe and can effectively help people monitor any COVID-19 symptoms they are experiencing.

We also hope to better understand how symptoms change in the weeks following a diagnosis and the impact a COVID-19 diagnosis and isolation have on people's wellbeing. This information is valuable and critical to providing future support and interventions to better support people's needs after being diagnosed with COVID-19

The app is being made available to all adults who have a COVID-19 screening test.

What will I be asked to do?

People being assessed for COVID-19 will be given information on how to access the CovidCare App. Should you agree to participate you will download the app using these instructions. You will enter the clinic code you have been provided and your first name and phone number and answer a series of baseline questions.

Following this you will be asked to enter some information about how your key symptoms related to breathing and heart rate are each day for several days, and then 2 times a day for a second week or until you have been informed you no longer have active COVID-19.

The app will inform you if any of the information you have entered indicates that your condition has worsened and will recommend further assessment or that you contact your GP or call 000.

You may be asked to participate in an additional telephone interview with the research team about your use of CovidCare, being diagnosed with COVID-19 and isolating. This will be voluntary. You will be able to use the CovidCare app and not be involved in the phone interview.

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.

What are the possible benefits?

The CovidCare app will provide people who have been tested for COVID-19 or who have received a diagnosis of COVID-19 additional support during the time that they are in self-isolation following their diagnosis. The data provided from the app to the researchers will give a clearer indication of how physical and mental health symptoms change following a diagnosis of COVID-19 which can be used to provide more effective support to people diagnosed.

What are the possible risks?

It is possible that being diagnosed with COVID-19 and self-isolation could be distressing to some people. CovidCare provides some advice to improve and measure wellbeing, but 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 you don't need to download CovidCare and be involved. If you start using the CovidCare app and decide you no longer wish to participate just stop using it and delete the app from your phone. Your decision to participate will not affect your care or relationship with your GP or 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 at <https://www.covidcare.io/>, and accessible via the CovidCare app.

What will happen to information about me?

All data being collected through the CovidCare app will be stored securely using Amazon Web Services servers located in Australia. Your information is extracted and transferred to the research team by the app developers who apply a code to identify you. . The only personal information being requested is your first name and mobile phone number. These data will be stored separately from the data you enter into CovidCare. All data in the app will be stored in an encrypted format on standard servers used by the app developers. All data in the app will be stored for 60 days after your last use of the app. After 60 days the data is deleted from the app servers.

All app data will be monitored by the research team daily. If you decide to stop using the app, any data you have already entered will form part of the analysis. You won't be asked for any further data.

Data from the app will be exported to the research team for analysis. Access is limited to the research team named in this ethics application. When we analyse and present the data all information will be presented as summaries and will be anonymous.

The information we collect through the CovidCare app will be used to determine whether the CovidCare app is safe and effective; to better understand how physical symptoms and wellbeing are following a COVID-19 diagnosis; 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. The University of Melbourne is acting as the study sponsor, and participants may be recruited through the University of Melbourne health service. No individual or identifiable information will be made available to the study sponsor or its representatives.

Where can I get further information?

If you would like more information about the project, please contact the research team on the study email address: 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. 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.