

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.

CLINIC PLAIN LANGUAGE STATEMENT

Professor Victoria Palmer (Responsible Researcher)
Tel: +61 3 83 44 4987 Email: v.palmer@unimelb.edu.au

Study email: covidcare-trial@unimelb.edu.au

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 involve your clinic 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.

The involvement of your clinic 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 and clinicians. There has been a clinical imperative to minimise the impact of COVID-19 on Emergency Departments and Intensive care units and manage suspected and positive diagnoses in the community. Current experience suggests that this is appropriate for upwards of 80% of positive cases.

People who have been assessed for COVID-19 are expected to isolate until results are returned, and in positive cases are expected to isolate until their symptoms have resolved. This period of self-isolation and symptom monitoring can be difficult for people and could lead to increased anxiety and depression.

The CovidCare app has been designed to provide people with self-monitoring support at home during self-isolation. CovidCare will prompt users to monitor key symptoms of concern associated with COVID-19 including respiratory rate, heart rate, single breath count, body temperature and oxygen saturation (where that is

possible). Recordings will be taken daily in the week following assessment and then twice daily for the following 7 days. If the data are out of threshold, or there is evidence of suspected deterioration, the app will prompt users to contact their GP or call 000.

Additionally, CovidCare includes brief screening tools for anxiety and depression and the app will suggest further follow-up if the scores entered indicate clinical concern.

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. This study has ethics approval at the University of Melbourne.

The aim of the study is to ensure that CovidCare is safe and can effectively help people monitor any symptoms they are experiencing of COVID-19. 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 will allow us to develop future support services and interventions to assist people after being diagnosed with COVID-19

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

More information on the app and project can be found on the study website <https://www.covidcare.io/>

What will I be asked to do?

We are asking participating clinics to do the following:

- Sign a consent form indicating you understand what involvement in the CovidCare study includes
- Have a sign up at the clinic indicating that the clinic is involved in the CovidCare study.
- You agree to be listed as a participating site on the CovidCare website
- Provide a plain language statement and information sheet about CovidCare and how to access it to all adults being tested for COVID-19 through your clinic for the recruitment period.
This information sheet includes a code that will link the patient to this clinic.
- Provide a brief overview of the operation of the clinic through the participation period (information includes, date established; total number of tests; number of positive tests). This will be done over the phone with a researcher and will take ten minutes

What are the possible benefits?

The CovidCare app will provide additional support to people diagnosed with COVID-19 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. If the participants require additional support the data within the app can provide a clearer sense of symptom progression than simple recollection.

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 advice to improve and measure wellbeing, and information participants are receiving contains the following support advice:

If you are concerned about your emotional wellbeing 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/>

The research team is advising all users of CovidCare that the app is only to be used as a monitoring tool and cannot diagnose or predict outcomes from COVID-19. As symptoms can change rapidly in between scheduled measurements users are provided the following advice:

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.

Will I hear about the results of this project?

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

What will happen to information about me?

Your involvement as a clinic will be limited to advising patients and provision of the general activity information outlined above. If you agree to be involved, your clinic will be listed on the study website. The general activity information about your clinic will be included in the study outcomes, but your individual clinic information will not

be identifiable and all information will be presented as group summary data. This information will be stored on password protected servers at the University of Melbourne with access limited to the research team. This information will be used in study outcomes including 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 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.