Participant Information Sheet

Remote population surveillance for COVID-19 in the Fenland cohort – Sub-Study

Summary

- We would like to remotely monitor Fenland Study participants to look for signs and symptoms of coronavirus to help better detect the disease earlier.
- In order to achieve this we would like to invite you to complete a series of measurements and questionnaires at regular intervals through an App on your smartphone and online via the web.
- We would also like you to provide a blood sample using a home collection kit that is self-administered
- Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve as there are a number of measurements we would like you complete on a weekly and monthly basis.
- Please take the time to read the following information carefully. Discuss it with friends and relatives if you wish.
- You are free to decide whether or not to take part in this research. If you choose not to take part, this will not affect the care you will receive.
- Additionally, it will be important to measure other health-related outcomes such as diet, physical activity and mental health during periods of social distancing and when restrictions are eased.
- Please do ask us if there is anything that is not clear or if you would like more information.
- All of the above measures and information collected will be used for research purposes only, **and will not be used for clinical purposes or shared with you.**
- Thank you for considering to support our research in these uncertain times. Your time is greatly appreciated.

Contents

How to contact us

If you have any questions about this study please talk to:
The Fenland Study Team
Tel/Freephone: 0800 085 6183
Email: fenlandstudy.covid19@mrc-epid.cam.ac.uk

1 Why we are doing this study

What are we studying?

The spread of coronavirus (COVID-19) has created an unprecedented global public health emergency. Now that lockdown is being eased, it is important to know how many people have previously had the infection and to find new ways of rapidly identifying people who become infected in the next few months. New methods of government testing should pick up people who are tested once they develop symptoms. However, infected people can infect others before they have any obvious symptoms; the pre-symptomatic phase of the illness.

Therefore, we plan to measure how many people have evidence in their blood of previous infection with COVID-19. Then we will investigate whether it is possible to identify the COVID-19 pre-symptomatic phase using measurements of signs and symptoms collected via a smartphone App to help scientists develop better measures of early detection.

We also seek to investigate how social distancing and the easing of restrictions impacts on other health-related outcomes such as diet and physical activity.

2 Why am I being asked to take part in this sub - study?

You indicated in your baseline questionnaire that you own an appropriate smartphone which means that you are eligible to take part in this sub-study.

3 What will happen to me if I take part?

If you agree to help us with this research, we will ask you to take part for 6 months, and potentially for a duration of up to 12 months, depending on government and scientific advice and the nature of the COVID-19 at that time. As well as the elements from the main study, you will also be asked to provide information at regular intervals in order for us to remotely monitor signs and symptoms of COVID-19, as well as measures of diet, physical activity and mental health from your home.

We will forward you a link so you can download the smartphone App (Huma).

The App is a piece of software on your phone which you will use to collect data related to the study which will be added to the other data that the MRC Epidemiology Unit is collecting to help identify COVID-19 early. Some of this will be done through your responses to the different questions presented to you in the App. You will also use the App to enter and collect data related to different digital biomarkers. The phone`s camera will be used to calculate your resting heart rate, and if you have a cough, you will be asked to record it using the phones internal microphone. The App will also collect movement data from sensors in your phone. This will be collected in the background, and you do not need to have the App open for this to happen.

We will send you an electronic thermometer and pulse oximeter which measures the level of oxygen in your blood.

The Huma App has modules that require provision of information at different times over the next 6 months – see table of

measurements below and flow of measurements in Appendix 1:

(1) **A baseline COVID-19 questionnaire** to give information on whether you have had symptoms and other important factors.

(2) C**OVID-19 symptom recording**: To record if you have any symptoms 3 times a week.

You will be able to set your own reminders in the App to take these measurements.

(4) **COVID-19 update questionnaire & medication and dietary supplement use** recorded monthly.

(5) **Mental health:** recorded monthly.

(6) **Physical activity and diet:** Self-reported changes in your activity and dietary habits monthly.

Measurement	**Frequency**	**Time required**
For those participating in the Smartphone sub-study		
(1) COVID-19 symptoms and background questionnaire	At the beginning of the study	5 mins
(2) COVID-19 symptom recording	3 times a week	Up to 10 mins a week
(3) Measurements of biomarkers	3 times a week	Up to 15 mins a week
(4) COVID-19 update questionnaire	Monthly	Up to 5 mins a month
(5) Mental health questions	Monthly	Up to 10 mins a month
(6) Changes in physical activity and diet	Monthly	Up to 5 mins a month
(7) Record your body weight online	Monthly	up to 2 mins a month
(8) Digital measure of physical activity	Continuous	0 – done automatically by the app

(3) **COVID-19 biomarker measures:** We will also ask you to take measures 3 times a week in the morning from the digital thermometer and pulse oximeter and record those in the App. We would also like you take at the same time a measure of resting heart rate using your smartphone camera, a measure of your breathing by placing the smartphone on your chest for 1 minute and a short recording of a cough using your smartphone. We will provide you with videos and user guides to help you to carry these measurements out as consistently as possible.

(7) **Body weight:** Changes in body weight using your own scales whilst wearing light clothing measured once a month and entered into the App.

(8) **Digital measure of physical activity:** With your consent we would like to collect your movement data that your smartphone collects (typically steps). These can be retrieved by the Huma App automatically and may contain your activity prior to the start of this study. Location data will not be collected by the App.

Who are Huma?

Huma (previously called Medopad) is a health technology company that uses data collected from smartphones and devices linked to these to develop early markers for disease, allowing timely intervention and supporting clinical care. We are partnering with them for this study using their newly developed COVID-19 App to try to develop a way to detect the infection early before symptoms develop. This could then be used in the future to understand how to better manage the pandemic with earlier diagnosis, isolation and contact tracing.

You can read more about the company on their website: https://huma.com/.

4 Possible benefits and disadvantages of taking part

What are the possible benefits of taking part?

You will be helping and contributing to vital research in understanding the nature, spread and severity of COVID-19, as well as the impacts it has on your health and health-related behaviours.

Although there are a good number of measurements, by taking all of these you will be helping to develop a prediction model that could identify people in the pre-symptomatic phase of the infection, thereby reducing the number of people they come into contact with the infection.

If you agree to participate in this sub-study, you will be provided with a free pulse oximeter and thermometer for readings to use for the study and to keep afterwards.

What are the possible disadvantages of taking part?

As with other UK studies, **we will not be providing results to individuals on their COVID-19 antibody status**. The body produces these antibodies as part of the process of fighting the virus, so being positive means that someone has previously had the infection.

The tests in this research study are for population screening only and do not replace any diagnostic tests as part of the NHS ongoing COVID-19 testing. The antibody screening test is not 100% accurate. A small proportion of people who have had the COVID-19 infection will be falsely classified as negative for the antibodies. Similarly a small proportion of people who have not had the infection may be classified as positive. Results also depend on the timing of the test relative to the onset of the infection. If you are tested too early in the course of infection when the immune response is still building up in the body, the test may not detect any antibodies.

Having a positive antibody test does not necessarily mean that the individual has long-term protection against being re-infected with the COVID-19 virus. The level of immunity and how long it lasts are not yet known. So everyone should continue to follow national guidance on social distancing and not change their behaviour irrespective of their antibody status.
If you are worried about having COVID-19, you should follow the current government/NHS guidance about obtaining a diagnostic test or call 111.

If you are concerned about your mental wellbeing please visit (https://www.nhs.uk/conditions/stress-anxiety-depression/low-mood-and-depression/) or contact your doctor. In an emergency, call 999.

5 More information about taking part

Do I have to take part?

No, it is up to you to decide whether or not to take part in this additional study. You are free to withdraw at any time, without giving a reason and to continue in the main Fenland study. This would not affect the standard or type of care you receive. You can still be part of future studies even if you chose not to take part this time round.

Will I receive any payment for taking part?

Unfortunately it will not be possible to provide payment for taking part.

What if there is a problem?

If you have a concern about any aspect of this study you should ask to speak to the research team who will do their best to answer your questions on 0800 085 6183.

If you remain unhappy and wish to complain formally, the normal University of Cambridge complaints process is available to you through the University of Cambridge Clinical School Secretary: telephone: 01223 333543 or email: SchoolSec@medschl.cam.ac.uk.

What will happen to information about me collected during the study?

Information we collect during the course of the research will be kept strictly confidential. Any information about you will have your name and address removed so that you cannot be recognised from it and it will not be used or made available for any purpose other than for research.

With your permission, information will be stored at the MRC Epidemiology Unit in a secure database. Codes connecting your individual identity to the stored data records will be kept separately. The database containing personal information is on a secured network drive on computers in the MRC Epidemiology Unit, University of Cambridge and will not be shared with anyone without your explicit consent.

Occasionally our studies may be monitored by local NHS (if applicable) trusts or our Sponsors. This is to ensure our research is conducted soundly. This procedure is routine and carried out by fully qualified personnel and data confidentiality will be adhered to at all times.

Our collaborating partner, Huma, will collect data entered into their App and share the data entered into the modules with us as described above. The data will be shared under a unique ID number that is linked to your study ID. They will use the data collected on the App for joint research with us and with your consent they will also use it for other purposes not related to our research. If you consent to Huma using the data for other research purposes, the data may be sent outside of the UK, but this will not include any personal information that could identify you. It is important that you read and understand their terms and conditions before agreeing to use the App.

With your consent we would also like to share access to data that we have previously collected from you with Huma to carry out research to help further understand the time course of COVID-19 infection and how it affects your health and wellbeing. These data will be fully anonymised in a secure database and Huma will only be able to use this for specific research purposes that we agree with them.

Cambridge University is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this. Cambridge University will keep identifiable information about you for 20 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at https://www.medschl.cam.ac.uk/research/privacy-notice-how-we-use-your-research-data/

Involvement of your GP

With your consent, we would like to access data from your medical records to look for any treatments and outcomes related to COVID-19. We will do this by linking your information to GP and hospital records.

What will happen to the results of the study?

When different aspects of the study are completed, the results will be published in scientific journals so that other researchers and practitioners can see the results. When published, your identity and personal details will be kept confidential. No information that could identify you, like your name, will be published in any report about this study. We will also continue to provide you with a summary of our findings from the study through our newsletters.

The results of this study will contribute to the national and international understanding of the COVID-19 pandemic, particularly how to respond if there is a resurgence in cases of COVID-19 in the future and for any future epidemics. Being able to do home testing on a large scale in the Fenland study will help determine the scale of previous infection, how many new infections there have been during the study period and by repeating the testing at regular intervals, see how long the antibody protection may last. We will also gain valuable insights on the impact of the social distancing methods and other factors on diet and physical activity.

We will provide you with monthly updates on what we are learning from the study and the overall results of the study as soon as they are available.

You would not benefit financially from results from this or other future work.

Who is organising and funding the study?

This study is organised by the MRC Epidemiology Unit, part of the University of Cambridge. The funder is the Medical Research Council.

Who has reviewed the study?

This study has been reviewed by an independent group of people, the Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. The study has been given a favourable opinion by South West – Cornwall & Plymouth Research Ethics Committee.

6 Contact for further information

If you have any questions regarding the study or how you might be involved further contact information can be found below:

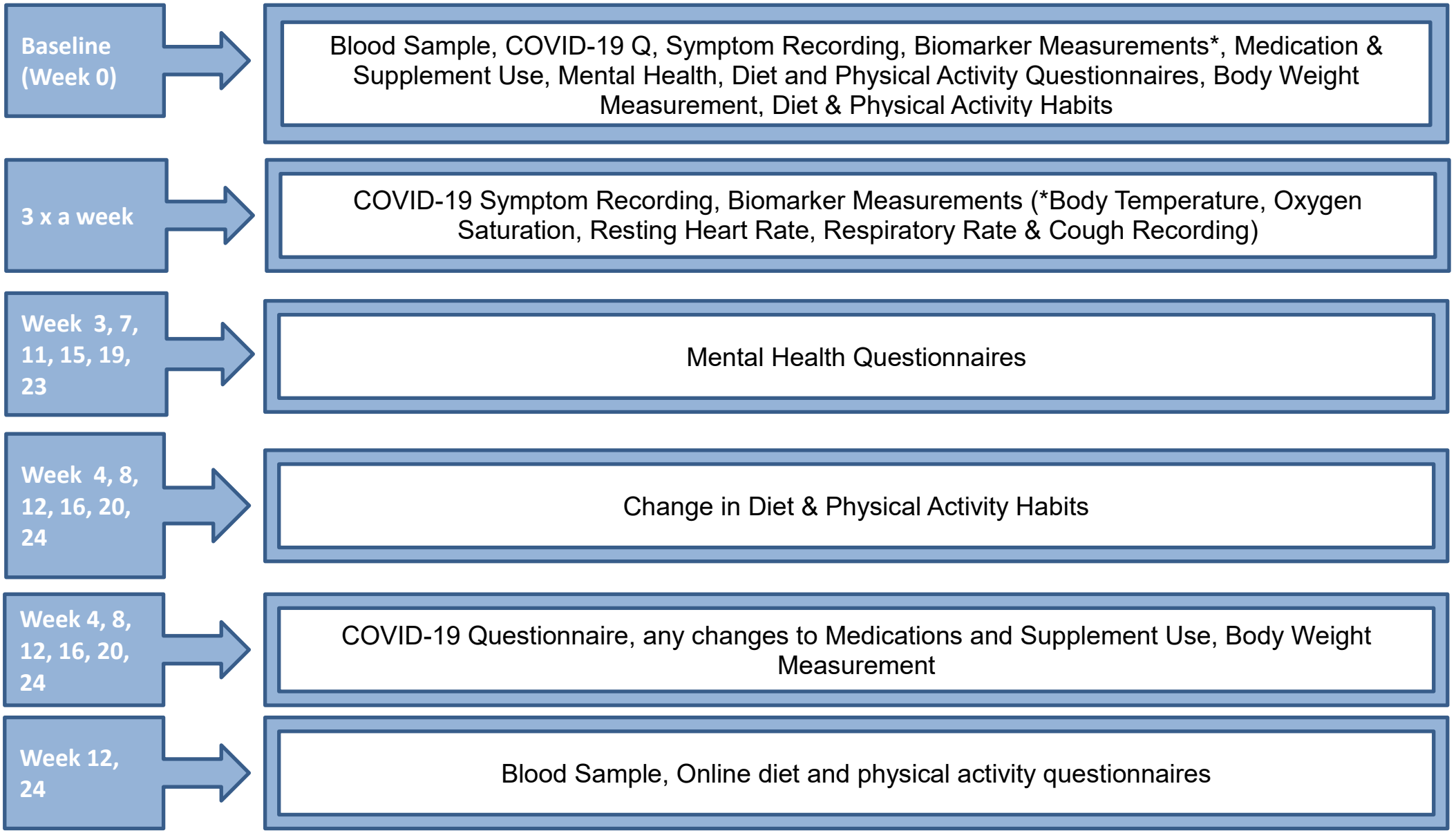
The Fenland Study Team
Tel/Freephone: 0800 085 6183
Email: fenlandstudy.covid19@mrc-epid.cam.ac.uk

Principal Investigator

Prof Nicholas Wareham
Unit Director
MRC Epidemiology Unit, University of Cambridge

Thank you for taking the time to consider taking part in this study.

7 Appendix 1


Baseline (Week 0)
Blood Sample, COVID-19 Q, Symptom Recording, Biomarker Measurements*, Medication & Supplement Use, Mental Health, Diet and Physical Activity Questionnaires, Body Weight Measurement, Diet & Physical Activity Habits
3 x a week
COVID-19 Symptom Recording, Biomarker Measurements (*Body Temperature, Oxygen Saturation, Resting Heart Rate, Respiratory Rate & Cough Recording)
Week 3, 7, 11, 15, 19, 23
Mental Health Questionnaires
Week 4, 8, 12, 16, 20, 24
Change in Diet & Physical Activity Habits
Week 4, 8, 12, 16, 20, 24
COVID-19 Questionnaire, any changes to Medications and Supplement Use, Body Weight Measurement
Week 12, 24
Blood Sample, Online diet and physical activity questionnaires