

Participant Information Sheet

Remote population surveillance for COVID-19 in the Fenland cohort

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 online via the web.
- We would also like you to provide a blood sample using a home collection kit that is easy to administer.
- 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 to complete on a monthly and quarterly 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.
- 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.
- Thank you for considering to support our research in these uncertain times. Your time is greatly appreciated.

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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 web-based interface to help scientists develop better ways of detecting COVID-19 early.

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?

Approximately 12,500 people from across Cambridgeshire took part in the first phase of the Fenland Study. We would like to invite participants who attended an initial Fenland Study visit between 2005 and 2014 and who agreed to be re-contacted to participate.

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. With your consent, we will send you a home collection kit to collect a blood sample and post back to the MRC Epidemiology Unit using a pre-paid envelope. Full written instructions will be given with the home collection kit. The blood test is to check whether or not you have antibodies to COVID-19 and, therefore, have had the infection. We will ask you to repeat the test at 3 monthly intervals during the 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 and physical activity from your home.

All participants will be asked to provide the following information through web-based questionnaires –see table and flow chart:

- (1) A COVID-19 questionnaire to give information on whether you have had symptoms and other important factors, administered once a month.
- (2) Physical activity and diet: self-reported changes in your activity and dietary habits to be collected every 3 months.
- (3) Body weight: Changes in body weight using your own scales (if you have some) whilst wearing light clothing measured once a month.

Measurement	Month							Time required
	0	1	2	3	4	5	6	
Take a blood sample	x			x			x	15 mins
Diet and physical activity questionnaire	x			x			x	25 mins
COVID-19 symptoms and background questionnaire	x							7 mins
COVID-19 update questionnaire and record your body weight online		x	x	x	x	x	x	5 mins

If you have access to an appropriate smartphone (iOS version 13 and above or Android version 6 and above), you will be invited to participate in a sub-study alongside this main study. Instructions to find out which smartphone version you have can be found on our website (<<website>>). If you are eligible, you will be invited to provide further information through an App provided by our collaborating partner Huma. We will send you a separate Patient Information Sheet and consent form for this sub-study.

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.

By taking all these measurements 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.

At the end of the study (and if you wish), we will be able to share the results from the antibody tests conducted throughout the duration of the study. You will be given the chance to **“opt in” in order to receive these results. We will ask for your preference separately as we are not able to provide individual test results during the study.**

What are the possible disadvantages of taking part?

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. 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 study. You are free to withdraw at any time, without giving a reason. This would not affect the standard or type of care you receive. You can still be part of future studies even if you choose 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 <<insert tel. no>>.

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.

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 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, results will be published in scientific journals so 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, your antibody test results at the end of the study (if you wish) 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.

Adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project.

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 <<insert name>> 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

