

COVIDENCE UK

YOUR DATA, FIGHTING CORONAVIRUS

Generating Evidence to Fight Coronavirus: Your invitation to take part in the COVIDENCE UK study

Information for participants

Version 1.0 dated 25th April 2020

We are inviting you to take part in a UK-wide study investigating how lifestyle factors might influence the risk of catching the COVID-19 coronavirus, the severity of symptoms, speed of recovery and any longer term impacts.

We hope the results of this research will help identify those who are at higher risk of serious illness and ensure medical treatment and public health advice is based on the best possible evidence.

Please read the following information carefully before you decide whether or not to sign up. **There are four pages: you can move forwards or backwards by clicking on the arrows at the bottom of each page.** The information will tell you:

- Why the research is being done.
- What you will be asked to do.
- What we hope to learn.

If you do decide to take part, you will be asked to give your consent to participate using an online form. You will be free to withdraw from the study at any time, and without giving a reason.

About the study

The COVIDENCE UK Research Study has been developed in response to the outbreak of coronavirus (COVID-19). People aged 16 and over from all parts of the UK and from all walks of life will be asked to provide some baseline information about their lifestyle and health using an online questionnaire. They will then be contacted once a month to check if they have developed symptoms of coronavirus infection or if they have attended a hospital for treatment. The data they provide will be linked to their medical records, to allow the study team to investigate whether coronavirus infection may affect long-term health. No individual will be recognisable from the data and all information will be strictly confidential. People can take part if they have already had definite or suspected COVID-19, or if they haven't had any suspicious symptoms. The study has four goals:

1. To learn more about risk factors for coronavirus infection in UK adults
2. To find out how quickly people recover from coronavirus infection, and whether there are any long-term complications of this illness
3. To evaluate the impact of coronavirus infection on the physical and mental well-being of the UK population
4. To establish a database of people who may be interested in taking part in future clinical trials, and to invite selected people to participate in those trials.

I have already had COVID-19 – or I think I have. Can I still take part?

Yes, you can still take part in the COVIDENCE UK study even if you have already had symptoms of COVID-19 or tested positive for the virus or antibodies. In fact, information from people who have already had coronavirus infection will be particularly valuable, as this will allow us to make an earlier analysis of risk factors.

Don't we already know what the risk factors for coronavirus infection are?

We know that people with certain medical conditions (e.g. heart disease, lung disease, diabetes and high blood pressure) seem to be at increased risk. However, we don't know WHY this is. Is it simply because people with these conditions tend to be older? Is it something to do with the underlying condition itself? Could particular medications affect the risk? Or are lifestyle factors such as smoking or different dietary patterns which tend to go along with some of these conditions important? By collecting very detailed information about your medical history and lifestyle, we hope to answer these, and many more questions — and this will give us a much better understanding of why some people are more susceptible to coronavirus infection than others. Ultimately this knowledge could help us to reduce risk of infection, by strategies such as altering the way we manage longstanding medical conditions, or by providing specific advice on lifestyle changes that could boost resistance to infection.

Which of my health records will be accessed by the study team, and why?

The study team will access details of your hospital admissions, results of any coronavirus tests that you have and the content of your GP consultations. This will allow them to get a full picture of any long-term effects that coronavirus infection may have on people's health. This is such an important aspect of the study that you would not be able to take part in the research if you withheld permission for us to access your health records.

Who is doing this research, and what is their expertise?

This study is being done by a UK-wide team of doctors, scientists, public health specialists and health economists based at universities in England (Barts and The London Medical School, King's College London and the London School of Hygiene and Tropical Medicine), Scotland (Edinburgh University), Wales (Swansea University) and



Northern Ireland (Queen's University Belfast). Queen Mary University of London is sponsoring this research, with overall responsibility for conduct of the study and keeping your data safe.

Who has approved the research?

This research has been ethically approved by Leicester South Research Ethics Committee (ref 20/EM/0117)

How many people will be in this study?

We need at least 12,000 people for the study. However, there is no upper limit to the number who can take part and we hope many more people will sign up: the more participants we have, the more reliable, and useful, the data will be.

How long will the study last?

Five years.

Am I eligible to take part?

You can take part if you are 16 or over and living in the UK.

What will I be asked to do if I agree to take part?

First, we'll ask you to complete a one-time online baseline questionnaire. It's quite detailed - it needs to be to capture all the information we need. You should allow yourself up to an hour to complete it, although most people will finish in less than 30 minutes. First we'll ask for your contact details and for those of a family member or friend that we can contact if we don't hear from you, e.g. if you are unwell. Then we'll ask for information about your job, housing, lifestyle, diet, use of dietary supplements and quality of life as well as your mental and physical health. Please keep hospital letters and prescriptions handy, as we'll be asking for very precise details about any medical conditions you have or treatment you've been prescribed. We'll also ask some questions about how the coronavirus outbreak has affected your day-to-day life.

Once a month after that you'll get an email from us, asking you to complete a shorter questionnaire. This will ask about any symptoms you may have had in the previous month. In addition, some of the questions from the baseline questionnaire will be repeated. This will give us updated information on any risk factors for coronavirus infection, and allow us to assess any effect that the coronavirus outbreak may have had on your physical and mental well-being. The monthly questionnaire will take around 10 minutes to complete if you have not had symptoms in the previous month, or around 20 minutes if you have.

Why will I be asked about my mental well-being as well as my physical health?

Our mental health, particularly depression and anxiety, is closely entwined with our physical health and can play a role in how well we fight an illness or respond to treatment. That's why we'll be asking some questions about your mental well-being as well as your physical health.

How do I sign up?

There are three steps:

Step 1: Read this information about the study

- Please read this information carefully and take at least 24 hours to think about what is involved before deciding whether you want to take part. You can drop out at any time.

Step 2: Confirm eligibility and give informed consent to take part

- First, we'll ask you to confirm that you are aged 16 or over, that you live in the UK, and that you give us permission to contact you about the study.
- Next, we'll ask you to confirm that you have read this information, that you understand that taking part is voluntary, and that you agree to take part in the study. These standard safeguards are a requirement of any properly conducted study.
- Next, we'll ask you for permission to link your questionnaire data to your routinely collected health information held in your GP records, your hospital records and Public Health bodies that hold results of any tests for COVID-19 that you may have had.
- Next, we'll ask if you agree to be re-contacted and invited to take part in a clinical trial or other research in the future. This does NOT put you under any obligation to take part in another study, and you'd be asked to read a separate information sheet and sign a separate consent form in each case.
- Finally, we'll ask if you agree for your information to be compared with the information of people who take part in future research trials, even if you have not been invited to join them.

Step 3: Provide your details

- Enter your contact details, date of birth and gender to sign up. We'll also ask for contact details of a family member or friend whom we can get in touch with if we don't hear from you, e.g. if you are unwell. Please ensure you use an email address that you will continue to have access to for the duration of the study. You will then be sent an email containing a link to your baseline questionnaire.

Will my data be kept confidential?

Yes. We'll keep the data you give us strictly confidential. We'll assign you a unique ID number which we'll use to link your questionnaire answers to your medical records. This means your data is linked anonymously - the key that links ID numbers to your personal information will be stored securely in the COVIDENCE UK Study databases and can only be seen by members of the study team. Everyone working on this project has a legal duty to keep your personal information confidential.

Are there any potential downsides or risks to taking part?

Some of the questionnaires ask about topics which some people might find sensitive. You don't have to answer any questions that you don't want to. The only risk relates to potential breaches of data security. We'll keep this risk low by securely storing your data under the terms of the Data Protection Act 2018.

Are there potential benefits of taking part?

There won't be an immediate benefit for you personally, but by taking part you'll be contributing to scientific knowledge about coronavirus. You will also be regularly assessed to see if you are eligible for clinical trials of new ways to reduce risk of coronavirus infection or other illnesses.

What sort of interventions might the clinical trials investigate?

Preventive trials are not yet established, but we are interested in looking at whether specific lifestyle advice or use of particular dietary supplements might reduce people's risk of coronavirus infection or improve their health in other respects. Please note that signing up to the COVIDENCE UK study does NOT commit you to joining a trial later on; it just makes you eligible to be invited to join a trial.

What if I am invited to join a trial?

If you are invited to join a trial, the research team will inform you and give you information about the trial. You will be given time to consider whether you want to take part. You are under no obligation to take part and if you decide not to, it will not affect your medical care or legal rights in any way.

What if I am not invited to join a trial?

Not everyone who is suitable for a trial will be invited to participate. This is because the number of people who can take part may be limited or because the trial treatment can't be offered to everyone. If you are not invited to join a given trial, we will not tell you about that trial. This is because we don't want you to feel disappointed. The process of choosing people to join future trials will be done by a computer programme, based on random chance. Regardless of whether or not you are invited to join a trial, you can remain in the COVIDENCE UK study.

If you are not invited to join a trial, you might still provide important information to help the trial. The information you provide as part of the COVIDENCE UK study may be used to compare your health with that of people who are receiving treatment in a trial. While you are taking part in COVIDENCE UK, you could be considered for multiple trials. Therefore, if you are not invited to take part in one trial, there may be another one in the future that you are invited to take part in.

What will my data be used for?

We'll analyse your information to:

1. Identify risk factors for coronavirus
2. Understand how quickly people recover from coronavirus infection, and whether there are any long-term complications of this illness
3. Evaluate how coronavirus affects your well-being.

Your data may also be used to compare your health with that of other people who are receiving treatment in a clinical trial.

Your data will initially be stored on a secure server owned by Qualtrics, the company who designed the software used to build our on-line questionnaires. Your contact details and your responses to the questionnaire will be held in two separate databases, linked by an ID number unique to you. This maximises security: if one database is breached, the link between you and your data cannot be made. Once your data are collected, they will be downloaded and stored on secure servers at Queen Mary University of London and King's College London for use in current and future ethically approved research aimed at better understanding the development and treatment of coronavirus infection and related health conditions. Your data will be stored for 25 years.

We have a legal obligation to spell out this specific information on the way your data will be used: Queen Mary University of London will use your name and contact details to contact you about the research study, and to oversee the quality of the study. Individuals from Queen Mary University of London, King's College London and regulatory organisations may look at your medical and research records to check the accuracy of the research study. NHS sites will pass these details to Queen Mary University of London and King's College London along with the information collected from you. The only people in Queen Mary University of London and King's College London who will have access to information that identifies you will be people who need to contact you for follow-up questionnaires or to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

Queen Mary University of London and King's College London will keep identifiable information about you from this study unless you choose to withdraw.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways to ensure that the research is reliable and accurate. If you withdraw from the study, we'll keep your anonymised data that we have already used for analysis. To safeguard your rights, we'll use the minimum personally identifiable information possible.

Your information will only be used for scientific research purposes. Other scientists may be allowed to see your anonymised data under strict and confidential legal data-sharing agreements. All requests to use the data will be reviewed by the COVIDENCE UK Study team. Any data released to other researchers will be anonymised using your unique ID number and will contain no personal information.

You can find out more about how we use your information by contacting us at COVIDENCE@qmul.ac.uk.

What if I want to leave the COVIDENCE UK Study?

You can do this at any time without giving a reason. If you choose to leave:

- Details of your initial consent and your withdrawal will be kept along with your name and date of birth.
- If you choose, we won't get any more data from your health-related records, and data we already have won't be used in further analysis wherever possible.
- The data we already have, and data that has already been anonymised and shared with other researchers, cannot be destroyed.

- Once we get your confirmation of your decision to leave, the study team won't contact you again.
- If we can't get your confirmation, data will be kept for future use, but you will not be contacted again.

To withdraw, let the study team know by email (COVIDENCE@qmul.ac.uk).

What if I move abroad in the next 5 years?

If you move abroad in the next 5 years you should notify us by emailing COVIDENCE@qmul.ac.uk and you will be withdrawn from the study.

What if my data are hacked or leaked?

We will take every precaution to keep your data secure - but if you have a concern about any aspect of this project, just email the study team at COVIDENCE@qmul.ac.uk. In the unlikely event that your data are hacked or leaked due to someone's negligence, then you may have grounds for a legal action for compensation against Queen Mary University of London. You may have to pay your legal costs.

What if I want to make a complaint?

If you would like to make a complaint, please contact COVIDENCE@qmul.ac.uk in the first instance.

Where can I get more information?

Go to the Frequently Asked Questions section of our website (www.qmul.ac.uk/covidence). If you can't find the answers to your questions there, email our research team (COVIDENCE@qmul.ac.uk) and they will be happy to answer your queries.

Consent form

Confirmation of Eligibility and Informed Consent Statements

Please answer 'Yes' or 'No' to each statement, then click on the 'forward' arrow at the bottom right of this page.

Part 1: Joining the study

Statement	Response
I have read and understood the information about the study (Version 1.0 dated 25 th April 2020)	YES / NO
I understand that taking part in this study is voluntary and that I am free to withdraw from the study at any time, without giving any reason, and without my medical care or legal rights being affected	YES / NO
I agree to take part in the study by providing baseline information and completing monthly online questionnaires for 5 years	YES / NO

Part 2: My information

Statement	Response
I give permission for my questionnaire data to be linked to my routinely collected health information held in my GP records, my hospital records and by Public Health bodies that hold results of any tests for COVID-19 that I may have had, and for this to be used for research	YES / NO

Part 3: Future Research

Statement	Response
I am willing to be invited to participate in other research studies that I may be eligible for in the future.	YES / NO
I am willing to be invited to join clinical trials, based on random selection, and am aware that if I am not invited to join a given trial then I will not be informed about that trial. I am also aware that the decision to join future trials will be made at the time of discussion, and does not need to be made now.	YES / NO
I agree for my information to be compared with the information of people who take part in future research trials, even if I have not been invited to join them.	YES / NO