Participant Information Sheet

Clinical phenotyping of prolonged cognitive symptoms after COVID 19

You are invited to take part in a research study. To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

You are being asked to take part in a study that aims to produce the most detailed clinical description of persistent cognitive symptoms after a positive COVID-19 diagnosis to date.

Problems with memory and cognition have been demonstrated to be the most common and disabling complaints after COVID-19. It is possible that the cognitive symptoms of 'long Covid' are in fact due to several alternative conditions. It is important to be able to identify and separate these conditions in order to provide evidence-based treatment and effective rehabilitation strategies that are tailored to them.

It is hoped that this study will improve the understanding of underlying causes of cognitive symptoms in the 'long Covid' population.

Why have I been invited to take part?

Patients who, following a positive test result for COVID-19, have been experiencing cognitive symptoms for 3 months or more are eligible to take part.

A total of 100 participants are being recruited to the study, with 50 being recruited from General Practice referrals to the Department of Clinical Neuroscience and 50 participants recruited post hospital stay.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?

After receiving this information sheet you will have 7 days to decide whether or not you would like to take part in this study.

If you agree to take part you will be contacted at a convenient time by a member of the research team, who will explain the study in more detail and obtain your consent to participate over the phone.

An appointment will be made for you to attend the Anne Rowling Centre for Regenerative Medicine or Department of Clinical Neurosciences Out-patient Clinic; both at the Royal Infirmary of Edinburgh. At this appointment a neurosciences consultant will conduct a clinical assessment of your neurological psychiatric, cognitive and neurological status, they will also perform a standardised general medical assessment and a blood test. This will take approximately 60 -90 minutes to complete.

Following this you will be invited back at a later date to have an MRI of your brain and a lumbar puncture. The MRI and blood tests are an essential component of the study. Patients can opt out of lumbar puncture if they wish.

MRI
An MRI will be conducted in order to get a detailed picture of your brain so that we can see if it has been damaged in anyway by COVID infection. It is a safe, painless procedure. It will require you to lie still on a table in an enclosed space for approximately 45 minutes while an image of your brain is produced. The doctors running the study will explain your brain scan results to. Please note brain scans occasionally uncover incidental findings unrelated to your symptoms, if that occurs the doctors will explain what it means. There will be a chance to discuss having a brain scan with study doctors in more detail prior to your agreeing.

Lumbar Puncture
A lumbar puncture will be conducted in order to get a sample of your cerebrospinal fluid (CSF), this is a fluid that surrounds your brain and spinal cord and will be tested for the presence of certain proteins. These proteins are ones release into the CSF if the cells of the brain are damaged. The skin at your lower back will be cleaned and numbed using a local anaesthetic, a thin needle will then be inserted. This procedure should not be painful but it is possible you may feel some pressure in the lower back area. Once the sample has been obtained the needle will be removed and a plaster applied to the area; 40 mls of CSF will be taken. This should take approximately 45 minutes. There can be problems with headache and some local swelling in your back in the aftermath. The lumbar puncture is optional and will be discussed with you in more detail by the doctor you see before you make up your mind.

Blood Test
A blood test will be conducted in order to obtain a blood sample that can be tested for the presence of certain proteins which are released into the blood following damage particularly to myelin which is the brain wiring's 'insulating' material. You will have your blood drawn from a vein in your arm using a needle; roughly 20ml of blood will be taken. This should take approximately 5 minutes.

You will then be required to complete a series of online tests. It is up to you whether you would prefer to do this during your visit to the Royal Infirmary of Edinburgh with a member of the research team or later on in your own home over the phone.

Results
After analysis of your results, you will receive a final diagnosis from the consultant at the clinic and he or she will discuss the implications for ongoing NHS treatment that is provided for your diagnosis. Your GP will be informed of the findings and any treatment planned.

Is there anything I need to do or avoid?

To be able to have an MRI you will need to remove any metal e.g. belts or jewellery and it is important you let a research team member know if you have a pacemaker fitted or any other metal in your body that cannot be removed.

What are the possible benefits of taking part?

Direct benefits: From taking part in this study, you may receive an updated, accurate diagnosis which will provide an explanation for your persistent cognitive symptoms. This will enable you to receive the correct treatment.

If in the course of the study the research team find out anything about your health that requires treatment, whether related to your current problems or not, this will be discussed with you and appropriate treatment arranged.

Indirect benefits: Your participation will help us to potentially understand the different phenotypes responsible for the symptoms experienced in 'long Covid' and improve the healthcare of patients in the future.

What are the possible disadvantages of taking part?

Taking part in this study will require you to have a blood test and a lumbar puncture, these procedures come with a minimal risk of infection and may cause you slight discomfort.

What if there are any problems?

If you have a concern about any aspect of this study please contact Clare Diamond, Anne Rowling Regenerative Neurology Clinic, Royal Infirmary of Edinburgh, 49 Little France Crescent, Edinburgh EH16 4SB (clare.diamond@ed.ac.uk) who will do her best to answer your questions.

In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What will happen if I don't want to carry on with the study

You have the right to withdraw your consent at any time. If you to withdraw your consent:

- Prior to clinic attendance you will be free to access any NHS service, according to your clinical needs, but you will not have access to this specialist research assessment clinic.
- If you want to withdraw prior to the investigations stage you will not have access to the study investigations, only some of which are available to routine NHS patients, but you will be able to access all NHS investigations according to your clinician's assessment of your need.
- You will be able to ask for any tissue banked blood or CSF samples to be destroyed.

- In the unlikely event that you lose the capacity to give consent during the course of the study the team will withdraw you from the study but will continue to treat you in accordance with your clinical needs in line with best practice, this may include transferring your care to another clinical team ale to meet the needs you have at this time. Any such treatment will be in line with appropriate legislation. If appropriate to clinical needs the investigations planned for the study will be made available.

What happens when the study is finished?

- Blood and CSF products will be retained within the University of Edinburgh Bio-repository unless you specifically ask for them not to be.

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

How will we use information about you?

We will need to use information from you and your medical records for this research project.

This information will include your

- Name
- Address
- Date of birth
- Medication
- Medical history

People will use this information to do the research or to check your records to make sure that the research is being done properly.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from **www.hra.nhs.uk/patientdataandresearch**
- by asking one of the research team

What will happen to the results of the study?

The findings of this research will be published in scientific journals and presented at conferences. You will be informed about the results by the researchers, who will provide you with a plain English summary of the results when the trial is completed. We will also let you know how to access the scientific publications.

The plain English summary will also be sent to the online patient support organization, LongCovidSOS.

Who is organising and funding the research?

This study has been organised by and sponsored by the University of Edinburgh and Research and Development Department of NHS Lothian.

The study is being funded by Chief Scientist Office.

Who has reviewed the study?

The study proposal has been reviewed by Chief Scientists office and by the appropriate Ethical and Regulatory Boards.

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from North of Scotland (2) Research Ethics Committee. NHS and University of Edinburgh Joint Management Approval (ACCORD) has also been given.

Researcher Contact Details

If you have any further questions about the study please contact Clare Diamond, Anne Rowling Regenerative Neurology Clinic, Royal Infirmary of Edinburgh, 49 Little France Crescent, Edinburgh EH16 4SB (clare.diamond@ed.ac.uk)

Independent Contact Details

If you would like to discuss this study with someone independent of the study please contact Dr Shona Scott, Consultant Neurologist, Department of Clinical Neurosciences, Royal Infirmary of Edinburgh, 49 Little France Crescent, Edinburgh EH16 4SB (Shona.M.Scott@nhslothian.scot.nhs.uk)

Complaints

If you wish to make a complaint about the study please contact:

Patient Experience Team
2 – 4 Waterloo Place
Edinburgh
EH1 3EG
feedback@nhslothian.scot.nhs.uk

0131 536 3370