

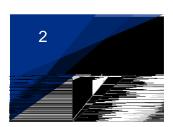
## **CONVALESCENCE** study

### **Participant Information Sheet**

(Ethics ref: 21/SC/0235)

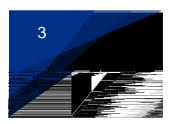
**Chief Investigator: Professor Nishi Chaturvedi** 

We would like to invite you to take part in the CONVALESCENCE study (**CO**ro**N**a**V**irus post**A**cute **L**ong-term **E**ffect**S**: **C**onstructing an Evid**ENCE** base) which explores the long-term effects of COVID-



## **CONTENTS**

What is the purpose of the study?



The measurements described below are included in the study. We may not invite you to participate in all these tests and will only invite you to participate in tests that are safe for you.

### **Questionnaires**

We will ask you some questions about your general health and any medications you may be taking.

# Body composition, blood pressure, electrocardiogram (ECG), eye imaging, muscle function, balance, and blood and urine sample

We will measure your height, weight and percentage fat (using special scales). We will also measure your waist and hip circumferences using a tape measure.

We will measure your heart rhythm using an electrocardiogram (ECG). We will ask you to lie on a couch on your back and attach sticky electrodes to your limbs and across your chest on the left side of your body. We will ask you to relax for 5 minutes while we make recordings.

We will measure your blood pressure lying, sitting and standing using a blood pressure monitor which inflates a cuff around your upper arm.

We will take pictures of the small blood vessels in your eye using a special camera (optical coherence tomography (OCT) imaging). This is similar to the methods used at the optician, it is very safe and does not require eye drops. With your permission, we will store these images (using an anonymous identification code) in a secure electronic database for future analysis. You will not be identifiable from these images. Hand-grip strength will be measured with a hand-grip dynamometer which consists of a gripping handle and a digital display. We will also ask you to do a standing balance test, a walking speed test over a 3 meter distance and 5 sitting to standing chair rises.

We will take a non-fasting blood sample (no more than 30ml which is approximately 6 teaspoons); a fine needle is used to take the blood sample. We will also provide you with a collection pot and instructions for a urine collection (10ml). Some of blood and urine will analysed during the clinic visit and some will be stored for analysis later.

### Lung function, echocardiography and exercise testing

We will assess your heart function using echocardiography. To do this we will ask you to lie on your left side and ultrasound gel will be used on your skin over the chest area. This is not harmful but may be a bit cold. A probe placed on your chest will image your heart beating on the monitor. The technician will make sure that as much as possible of your chest is covered

scan. We will store these images (using an anonymous identification code) in a electronic database for future analysis. You will not be identifiable from these images.

You will be asked to undertake a 10 to 15 minute exercise test on the supine bike in which the intensity will progressively go from light to high intensity. You can stop the test at any point if you feel unable to exercise further. Before starting the exercise test, we will make some measurements of your lung function. We will ask you to blow into a special machine called a spirometer. Before, during and after the exercise test we will measure how much oxygen you are using by asking you to breathe through a special mask. We will also measure your heart rate and blood pressure throughout and take some more pictures of your heart by echocardiography during the exercise. We will also assess the function of the small blood vessels in your muscle using a small device attached to your skin. The device is very safe and works by shining a small amount of near-infrared light into your tissue and measuring how much comes back.

Just as for any exercise, there is a small risk that you will feel unwell (light-headed or faint) following the exercise test, we will monitor you closely to avoid this and you can stop at any time. Very rarely (approximately 1 in 10,000 cases) an exercise test can result in a heart attack or changes in heart rhythm that do not disappear after the test. For this reason, we will not perform this test if there is any evidence you might be at risk. A clinical doctor will be available to respond to any adverse events.

#### **IMAGES OF SOME OF THE TESTS**







MRI uses a powerful magnet and radio waves to form pictures of your body; it is believed to have no harmful effects (there are no x-rays). The scans are highly specialised and they are performed by doctors or radiographers. Before this scan, we will ask you a series of questions to see if there might be any metal in your body (e.g. from previous operations or accidents). The MRI scanner produces a magnetic field which is harmless to the body, but can cause some metal objects to move, including some types of metal that may be found in the body. As long as you have no metal in your body that might cause harm, you can safely have an MRI scan. It is important not to bring metal or jewellery into the scanner room (such as wiring or clasps in your bra, or zips, or buckles in other clothes).

You will be asked to lie down on a flat scanning bed that slides into the tunnel for up to an hour. The scanner can make loud noises. You will be asked to wear headphones during the scan that protect your ears from these noises and allow the person operating the scanner to talk to you. If you have a fear of enclosed spaces (claustrophobia) please let the study team know beforehand. During the scan you will receive an injection of a contrast agent to help visualise your heart. With your permission, we will store MRI images (using an anonymous identification code) in a secure electronic database for future analyses. You will not be identifiable from these images.

### Activity monitoring and health app

At the end of the visit, unless you have asked to have the monitor posted to you, we will give you a wrist-



### What are the possible benefits of taking part?

We will provide you with the results of any clinically relevant tests.

We will not routinely provide you or your doctor with the results of the brain or heart scans as they are for research purposes only. We will let you and your doctor know if we find any though it could be a malignant tumor or another similarly serious condition. On the office and, we would not tell you if we saw typical appearances of gallstones, a simple cyst or scarring (e.g. on the lung) as these abnormalities are common in healthy people and not considered serious. We would also not tell you about something that is clearly related to a health condition that you have already told us about. Finally, we would not tell you about a potentially serious abnormality if it was identified at a later date by researchers analysing the scans and was deemed non-remedial.

Based on other studies, about two or three out of every hundred people (2-3%) will have an abnormality that is potentially serious and which we would write to you and your GP about. About one in three of these people will turn out to have something serious that they may not have been aware of before, while two out of every three of these people will turn out to have something non-serious. This happens because something that looks suspicious on one of our research scans can turn out to be something like a benign cyst, an artefact of the scanning process (a technical glitch), or something that you or your GP already know aG[] )hnaaf392d(w a)6(G97 690).

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All places are undertaken by healthcare professionals with the aim of ensuring your safety an import throughout your visit. All the measurements are well established and have been performed in many studies.

The blood sampling is a routine and very safe procedure, but may cause bleeding, bruising or pain. Some people may become dizzy or feel faint. Very rarely, infection can occur but to minimise this risk, experienced medical personnel will perform the blood sampling using aseptic

to end your involvement in this study at any time. If you decide to withdraw from this study, you will no longer be asked to attend research clinics and we will not contact you in the future for follow-up or for any other reason. We will securely remove any personal information held about you from our database. If you wish to withdraw, your samples will be destroyed. Information about you that has already been collected as part of your involvement may be retained, but there will not be any further processing of your data.

