PHOSP-COVID - Tier 3 Sub-Study

PHOSP-COVID - Rehabilitation for lasting symptoms of COVID-19

PARTICIPANT INFORMATION SHEET

Chief Investigator:	Professor Christopher Brightling
Lead Investigators:	Dr Rachael Evans and Professor Louise Wain on behalf of the Leicester NIHR BRC and national consortium
Local Lead Sub-Study Investigator:	Dr Rachael Evans University Hospitals of Leicester NHS Trust

Invitation:

We would like to invite you to take part in a PHOSP-COVID research sub-study. This sub-study is a 'Tier 3' sub-study which is part of the PHOSP-COVID study, which you will already be participating in. We are undertaking a research study involving adults who have been admitted to hospital with suspected or confirmed COVID-19 infection. As you are experiencing symptoms we would like to invite you to our trial for rehabilitation.

Before you decide it is important for you to understand why the research is being done and what it would involve for you. Please take time to read this information carefully. Please use the contact details provided at the end of the document to talk to your local study team if anything is unclear or if you would like more information. Participation in this study is completely voluntary. The decision you make **will not** affect your current or ongoing care or treatment in any way.

What is the study about?

This is a sub-study to the PHOSP-COVID study to explore COVID rehabilitation for people who have lasting symptoms. As COVID-19 is a new disease, and some people have remaining symptoms we want to understand if a rehabilitation programme can improve symptoms.

We want to understand:

- If an exercise and education programme can help improve symptoms following a COVID-19 admission compared to no programme.
- If a face to face programme or web based programme can improve symptoms following COVID-19

- The impact these programmes have on your immune system (measured by optional blood tests) and muscle function (measured by optional biopsies).

Why have I been invited to take part?

You have been invited to take part because you were admitted to hospital with confirmed or suspected COVID-19 and you are part of the PHOSP-COVID study and have agreed to receive information about Tier 3 sub-studies. You are also still experiencing symptoms. We want to offer you a programme to improve your symptoms and we want to see if this can help compared to no programme. A lot of the information we are interested in will have been collected as part of your normal care or during your main PHOSP COVID study visits. We will also ask your permission to do additional tests that are not part of your normal visits to the clinic or normal PHOSP-COVID research study visits.

Do I have to take part?

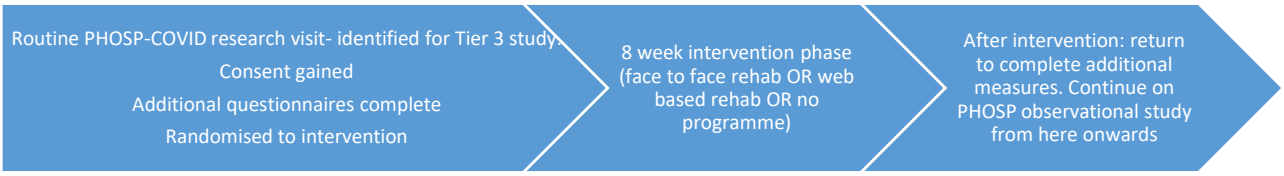
No, participation in the sub-study is voluntary. It is up to you to decide whether or not to take part. If you do decide to take part you will be asked to provide verbal consent over the phone, and sign a consent form at your next visit. If you decide to take part you are free to withdraw from the sub-study at any time and without giving a reason. If you do not take part, or if you withdraw from the sub-study, this will not affect the standard of care you receive and you will still be offered a recovery programme as part of normal clinical care.

What will happen if I take part in this sub-study?

If you agree to take part you will be asked to attend the research site for a minimum of two visits lasting approximately 2 hours each. If you agree to take part you will be allocated to receive one of three different rehabilitation programmes: (1) a **web based programme** (accessed via the internet), (2) **face to face programme** (where you will undertake the rehabilitation programme face to face at the hospital clinic) or (3) **no programme** which means you would receive exactly the same as what is currently offered as part of clinical care. If you are unable to do one of these options (face to face or web based) you are still eligible to take part. You will receive your allocated rehabilitation programme for 8 weeks. If you receive no programme we will offer you one of the other programmes after the research trial. How we allocate you to a programme is by a process called ‘randomisation’ and is just like flipping a coin or picking a name out of a hat.

If you are allocated to receive face to face rehabilitation this will be conducted at Glenfield Hospital, Leicester and lasts approximately 1.5 hours per session, twice a week for 8 weeks. If you are offered web based rehabilitation you will access this via a website that supports you to work through the stages and keeps a record of your progress. Please speak to the researcher to see which options you feel you may be able to participate in.

Everyone will be asked to undertake additional testing and measures. We will take measures before and after your rehabilitation programme, most of which is done during your routine PHOSP-COVID study visit at Glenfield Hospital, Leicester. You will be asked to complete some questionnaires, walking tests, (optional) blood tests and tests of your strength. There will be an additional visit after you finish your rehabilitation programme to collect these measures again. If you are allocated to receiving no programme, you will undertake the measures 8 weeks apart. Descriptions and further information about the tests we would like you to do can be found at the end of this document. There are a few additional but completely optional assessments that you will be invited to do; (1) blood tests, (2) a muscle biopsy procedure which would require a small sample to be taken from your thigh, (3) a cardiopulmonary exercise test, and (4) a wearable vest to assess your breathing.



Can I take part if I am already taking part in another research study?

If you are already enrolled in another research study, this may affect your ability to take part in this study so let us know if you are taking part in another study. Similarly, if you wish to take part in another study you may need to tell them about this one.

How will we use information about you?

To deliver the sub-study we will need to share your personal information with some PHOSP-COVID partners and sites, and Loughborough University (only if you agree to provide the optional blood samples). We will only share the minimum information with these partners to undertake the task they are performing. They are bound by the same rules as us to keep your information confidential and safe. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. This means that your data or samples will be labelled with a unique code. Any researchers receiving data or samples will not be able to identify you.

We will write our study reports and publications in a way that no-one can work out that you took part in the study.

We will keep the minimum personally identifiable information about you indefinitely. This is for safety reasons and because it is a valuable record of this outbreak event. The information will be held securely and be under the control of the University of Leicester as the Sponsor and Data Controller.

A copy of your consent form will be kept with any samples that are retained, this is to demonstrate you gave us your consent to keep them. As with all of the study documents, these will be stored securely and the minimum number of people will have access.

Once we have finished the study we will transfer a copy of our research data into a Trusted Research Environment, also known as a "Data Safe Haven". This is to allow as many researchers as possible to learn from the data we have collected and to conduct their own future ethically approved studies. Any link between the data and you will be stored separately and securely, meaning that researches accessing the Date Safe Haven will not be able to identify you.

What are your choices about how your information is used?

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

If you choose to stop taking part in the sub-study or any of the optional parts, we would like to continue collecting information about your health from central NHS records/ your hospital/ your GP. If you do not want this to happen, tell us and we will stop.

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?

If you would like to know more about how we will process your information you can review a Privacy Notice on our website, or ask a study team member for a printed copy
https://www.phosp.org/

How data is used in research is complicated, if you have any questions, please ask one of the research team, or you can access further details via:

- www.hra.nhs.uk/information-about-patients/
- https://www2.le.ac.uk/offices/ias/dp/data-protection
- by sending an email to PHOSP@leicester.ac.uk, or
- by ringing us on <<insert study team number>>.

The Data Protection officer is:
Elisabeth Taoudi
Data Protection Officer and In-House
Commercial Lawyer,
University of Leicester,
University Road,
Leicester,
LE1 7RH
0116 229 7640

Are there any benefits to taking part in this study?

The rehabilitation programmes are been designed with the aim of helping people manage their lasting symptoms of COVID-19 and you may experience some benefit in taking part, however benefits are not guaranteed. The information we learn may help in caring for other patients in the future.

We will act on any test results including questionnaires that require follow-up. Most commonly this will be informing you and your GP of a particular result. Otherwise, you and your GP will not receive the outcome of any test or assessment.

What are the risks of being in the study?

If you take part in the sub-study and we collect data from your records there is minimum risk, all information will be pseudonymised (no one will know that this information relates to you).

If you are asked and you agree to provide additional blood samples, being a part of this sub-study means that more blood samples will be taken than are needed for normal care. Whenever possible these blood samples will be taken at the same time as other blood samples to reduce the number of extra procedures. There is a risk of pain or discomfort when blood samples are taken, and these are detailed later in the information sheet as part of the initial PHOSP-COVID trial.

What if something goes wrong?

It is unlikely that you will be harmed by taking part in this sub-study. If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this sub-study, you should contact your local investigator Dr Enya Daynes on 0116 2583370 or you may contact the study coordinator 0116 2583370.

If something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against the University of Leicester but you may have to pay your legal costs. The normal NHS complaints service will still be available to you (if appropriate).

What will happen to the samples that I give?

All samples (blood and muscle biopsy, where applicable) will be collected according to recognised guidelines, stored under appropriate conditions and in line with all relevant legislation, and tested and analysed using documented protocols and procedures. The Executive Board for the study will regularly review the ongoing blood sample collection, storage, processing and analysis. Processing of muscle samples for gene expression, epigenetics, telomere length, proteomics and other biomarkers will be subject to funding. Blood samples you provide during the study will be either analysed on the day of collection

or frozen and stored confidentially in a coded and anonymised form in the secure sample storage facility at the National Centre for Sport and Exercise Medicine, Loughborough University, in accordance with the Human Tissue Act 2004. They will be used to analyse various inflammatory and immune measures linked to the outcomes of this study.

As with the main PHOSP-COVID study, some samples and information from the study may be shared and made available to other researchers and partners, here and around the world. They will manage the samples and data safely and securely.

With your permission, we would also like to store your samples after this sub-study has ended, to use them for future ethically approved research that is different to this sub-study. If you agree your consent form will be retained until the sample has been used up or destroyed, this so we can show you provided your consent for us to keep it. The consent form will be transferred with the sample wherever it is kept.

Samples stored after this study ends will be stored in line with all relevant legislation, this may be in a secure central repository. If you wish to find out further information on how we are using samples please speak with a member of the study team.

Can I request that I be withdrawn from the study at any point?

Yes, you can withdraw from this sub-study at any time without giving a reason and without this affecting your care. We would like to ask you to complete a withdrawal form that is accessible via the PHOSP-COVID website https://www.phosp.org/. This is so we are clear whether or not we can continue to access your electronic healthcare records. As in the main study, we would like to continue to access your records for up to 25 years. If you do not want this to happen, you can tell us on the withdrawal form. If you do decide to withdraw then any information and samples already collected will remain and be used in the sub-study. No further samples or data collected will be performed and we will not contact you again about this sub-study. If you wish, you can withdraw from this sub-study but may continue to be part of the main PHOSP-COVID study in the Tier 2 study visits.

Will I be reimbursed or receive any payment for participating in this study?

You will be reimbursed for travel for study visits before and after the programme. If you undertake any research specific visits at the research unit then car parking reimbursement or other reimbursement for travel can be provided.

Who is organising and funding the research?

This is a research study organised by the NIHR Leicester Biomedical Research Centre and sponsored by the University of Leicester. The trial is being funded by the National Institute for Health Research UK Research and Innovation. None of the doctors will be paid

themselves for including you in the trial.

Who has reviewed the trial?

All research that involves NHS patients or staff, information from NHS medical records or uses NHS premises or facilities must be approved by an NHS Research Ethics Committee before it goes ahead. This trial has been approved by Leeds West Research Ethics Committee. Approval does not guarantee that you will not come to any harm if you take part. However, approval means that the committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits and that you have been given sufficient information on which to make an informed decision.

What if I would like further information about the study?

If you would like more information about the study you can contact the Local Investigator in your hospital Dr Enya Daynes on 0116 2583370 or enya.daynes@uhl-tr.nhs.uk or telephone the Local Research office on 0116 2583370. If you would like another copy of the initial PHOSP-COVID participant information sheet that you had at your first visit, please ask the researcher looking after you.

Investigations and Procedures:

Below is a table describing what tests and procedures you will be undertaking as part of this sub-study:

Test/ Procedure	**Is the test/procedure already performed as part of the PHOSP-COVID main trial?**	**How many times will you be asked to undertake these tests/procedures?**
Walking test- Maximal walking test by an externally paced bleep to see your level of exercise ability. You will be able to stop the test at any time. You will be assessed for safety prior to commencement of the test.	Yes	Twice. Before and after your rehabilitation programme (8 weeks). Or 8 weeks apart if receiving no programme. The tests that are performed as part of PHOSP-COVID Tier 2 visits will only be repeated after the 8 weeks. We will use your Tier 2 PHOSP-COVID data where we can so you do not have to
Questionnaires- There will be a number of questionnaires that you can complete on your own or with help from the researcher.	Yes plus we would like to take some additional questionnaires	
Strength- the strength in your legs and hands will be tested through a resistance machine. You will provide a maximal strength test.	Yes	

Physical activity monitoring- We will ask you to wear a monitor for 14 days around your waist	Yes	repeat tests. If you have not undertaken the test as part of your Tier 2 visit, we may ask your permission to undertake the test.
Blood test- this is a simple blood test that you may have had before. We will take a sample of blood from you (most commonly on your forearm).	No- optional extra	
Muscle Biopsy- this is a small sample taken from your thigh. This may cause some discomfort/pain during and after. We will use this to look at changes in your muscles as a result of COVID.	No- optional extra	
Cardiopulmonary exercise test- this is an exercise test performed on a bike or treadmill in which you will wear a device to monitor your heart rate, oxygen levels and blood pressure	No- optional extra	
Wearable vest- this measures your breathing and heart rate over a week, this is worn like a sports bra.	No-optional extra	

Thank you for reading this.

Please keep a copy of this information sheet for your records.