Participant Information Sheet

Profiling the response to exercise in Long COVID patients to inform novel rehabilitation guidelines

IRAS Number: 313936

Chief Investigator: Dr Mark Faghy

Principal Investigator: Dr Thomas Bewick

Part 1: Invitation

You have been invited to take part in a research study. Before you decide whether to take part or not, it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

PART 1: Tells you the purpose of this study and what will happen to you if you take part.

PART 2: Gives you more detailed information about the conduct of the study.

Ask us if anything is unclear, or if you would like more information. Take time to decide whether you wish to take part.

1. What is the purpose of the study?

Few studies are looking to understand the important factors that lead to recovery following a COVID-19 infection. The knowledge obtained from this project will increase our understanding of recovery and allow us to develop COVID-19-specific rehabilitation and patient support services which can be implemented to help patients and restore well-being, physical capacity, and functional status.

2. Why have I been chosen?

You have been asked to take part in the study because you are:

- Aged 18 years or older
- You have been:
  - Referred to an established long-COVID clinic
  - Currently engaged with clinical or community long-COVID support groups
- Identified as still having symptoms of Long-COVID as identified as a grade 2, 3 or 4 using the post-COVID functional status scale. This will be done with you over the telephone.
- You can understand verbal or written information in English.

3. Do I have to take part in this study?

No, your participation is completely voluntary, and it is up to you to decide whether or not to take part. If you decide to take part, you will be given this information sheet to keep and be asked to sign a consent form to confirm that you understand what is involved when taking part in this study. If you decide to take part, you are free to leave the study at any time and without giving a reason. If you choose not to or decide to leave, it will not affect your ongoing treatment for Long-COVID.

4. What will happen to me if I take part in the study?

This study is a cross sectional study. This means we would like to test some important markers that we know change with long covid and how it affects your ability to exercise. If we can increase our understanding of recovery, we may be able to develop approaches that can support other patients in the future with their recovery. If you agree to take part, you will be invited to your local testing site to conduct some baseline tests and again on two more occasions, each session lasting approximately 60 minutes.

Our testing sites include:

- University of Derby Kedleston Road, Derby, DE22 1GB
- Sheffield Hallam University, Olympic Legacy Park, Sheffield, S9 3TY
- Northumbria University, Northumberland Building, Newcastle upon Tyne, NE1 8ST
- University of Exeter, Stocker Rd, Exeter, EX4 4PY

What do I have to do?

Study duration:

Study duration will be approximately 3 weeks, but it could be up to 4 weeks as there is some flexibility with your visits to the University to suit your schedule. We will cover any travel and parking associated costs to the Universities.

Your Participation Involves:

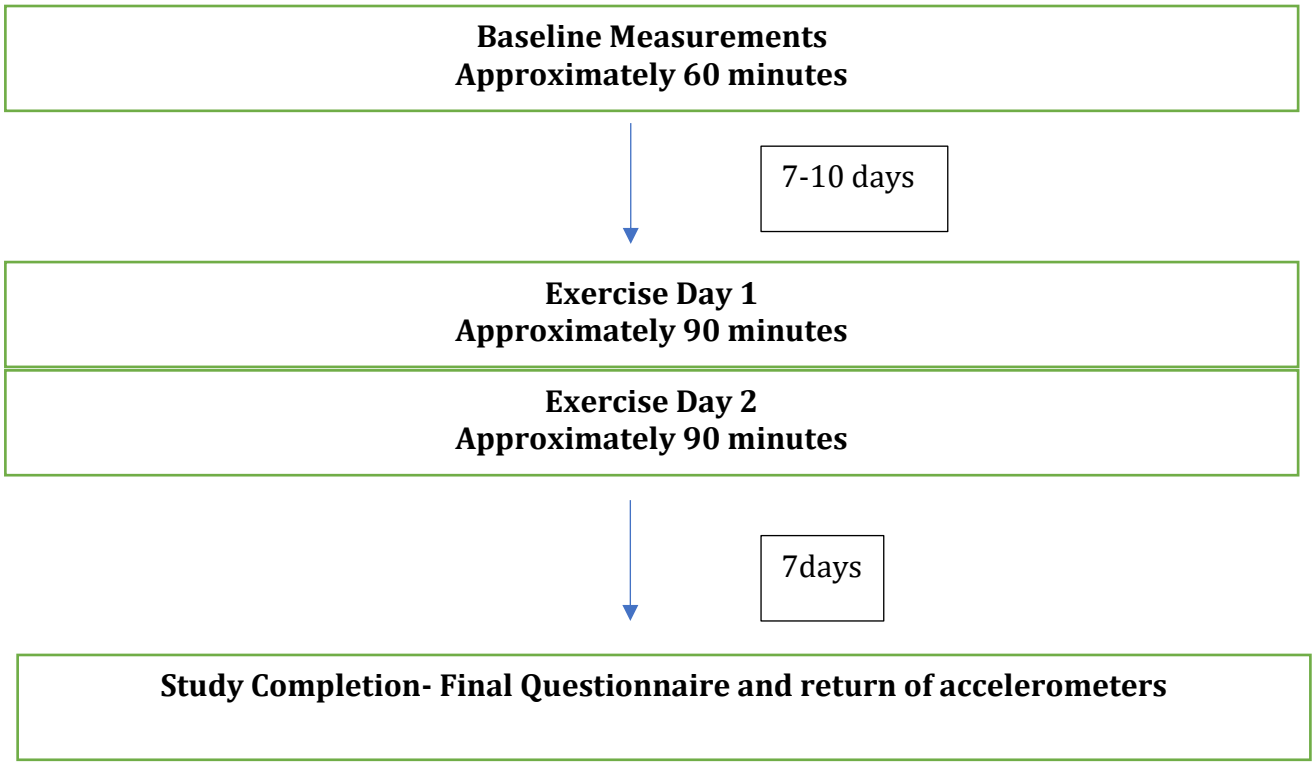
1) A visit your local testing site to conduct a baseline assessment.
   In this visit we will capture the following information:

   - We will take a blood sample from your arm to assess important biomarkers that are associated with COVID-19 severity and recovery.
   - Assess your lung and respiratory muscle function to determine how well your lungs and respiratory muscles are working.
   - Assess your leg muscle size using ultrasound
   - Ask you questions to understand the severity of your symptoms.
   - Gather information about your functional status, quality of life and physical capacity. This will include some physical tests.
   - Ask you questions relating to your cognition and your sleep performance.
   - Monitor for a 3-day period how you are feeling and rate your tiredness using either a mobile application or paper diary.

2) Just over a week after your baseline assessment, we will ask you to come to the laboratory at your local testing site to perform a cardiopulmonary exercise test on 2 days together, we will be looking at how your body responds to exercise measuring your heart and breathing response and if this changes between the 2 days. During the exercise test, we will take some small blood from your finger tip samples to measure your response to exercise and a slightly larger sample (20mL, around 4 teaspoons) before and after (30 minutes) the exercise to see how your body is responding. We will ask you to come to the lab with some light clothing such as shorts and t-shirt to exercise in.

3) We will also provide you with a diary either through mobile application on your smartphone or paper version for the duration of the study where you can record your experiences of your recovery and also an accelerometer to wear on your trousers. This looks at how active you are in terms of how many steps you are walking and how long you spend doing activities such as housework or sitting down watching tv. We want you to spend your time as you normally would.

Study Flow Chart



5. What are the alternatives for diagnosis or treatment?

This study does not involve a diagnosis or a treatment. We want to see how your symptoms change throughout your recovery.

6. What are the side effects of any treatment received when taking part?

There are no treatments involved in this research and we do not anticipate that you will experience any side effects from taking part in this research.

7. What are other possible disadvantages and risks of taking part?

We are looking to profile your response to exercise and recovery to monitor how these change in the days after exercise. There are some low risks for conducting exercise protocols these include myocardial infarction and stroke, you will be monitored throughout the exercise protocols and during periods afterwards. Should a medical emergency occur the investigators are appropriately trained in CPR and resuscitation equipment with the buildings.

We will be collecting blood samples during the study, with this there are risks of bruising on the arm and fingers, this should subside within a few days if it occurs. The blood samples allow us to investigate potential mechanisms behind long covid but it is common that people may feel faint after giving a sample, our investigators are appropriately trained to make sure you are safe and refreshments will be available.

You may experience post-exertional malaise and fatigue following the exercise protocols, we would like you to capture these experiences within your patient diary, the risk of experiencing post-exertional malaise can be reduced by appropriate pacing and management of your energy in the days leading up to the exercise protocol, the study team will provide you with details of how to do this during your initial visit.

Should you experience any problems or have any questions relating to the research then we encourage you to contact the research team using the details provided at the end of the document.

8. What are the possible benefits of taking part?

Your participation in this study is completely voluntary and you can withdraw your participation at any time. There will be no tangible benefits of taking part in the research, but we will be able to cover the cost of your expenses for attending all face-to-face sessions.

Your participation will also contribute to the development of new knowledge into the recovery of patients following a COVID-19 infection. This will allow researchers to understand how your symptoms change and develop approaches to support patients in their recovery in the future.

9. What happens when the research study stops?

Once your participation has been confirmed, your data will be completely anonymized and analyzed by our trial statistician to determine the important areas that we must consider when supporting patients with their recovery.

10. What happens if there is a problem during the study?

If you have a concern about any aspect of this study, you should ask to speak with the trial researchers who will do their best to answer your question.

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital or you can contact PALS (Patient Advice and Liaison Service) telephone 0800 183 0204.

Insurance and indemnity for this study will be provided via the University of Derby's role as sponsor. If you are harmed and this is due to someone's negligence then you may have grounds for legal action for compensation, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

11. Will my taking part in the study be kept confidential?

All data collected will remain confidential under the regulations of the GDPR under the data protection act (2018). Only the research team and research partners will have access to the data and all data will remain strictly confidential and stored in a secure location.

All data collection spreadsheets will not link data directly to individuals and will be encrypted by a password for storage. Individual participants will be unidentifiable in the analysis and write up.

12. Contact Details

Chief Investigator: Dr Mark Faghy – M.Faghy@Derby.ac.uk or 01332 592 109

Principal Investigator (Sheffield): Dr Tom Maden-Wilkinson- t.maden-wilkinson@shu.ac.uk or 0114 225 6607.

Principal Investigator: Dr Thomas Bewick - tom.bewick1@nhs.net or 01332 340 131

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2:

13. What if new information becomes available?

Various COVID-19 research projects are happening around the world in an attempt to better understand the challenges provided by this novel virus. The research team are actively tracking the state of the research in this area and should any new and important information be made available relating to the recovery, the research team will inform you and discuss with you whether you want to or should continue with the study. On receiving new information, we might consider it to be in your best interests to withdraw you from the study, but all details and decisions will be discussed with you first.

14. What will happen if I do not want to carry on with the study?

To withdraw from the study please just contact any of the research team. You can withdraw at any time, for any reason without having to explain your reasons for withdrawing. You can withdraw from participation up to 1 month after your participation in the study has finished. Once this time has passed, it will not be possible to withdraw your data from the research as your data will be anonymised.

15. Will my participation in this study be kept confidential?

If you consent to take part in this study, your data obtained during the study will remain strictly confidential at all times. The information will be held securely on paper and electronically by the research team at the University of Derby under the provisions of the GDPR under the Data Protection Act (2018). Your name will not be passed to anyone else outside of the trial research team or the sponsor.

Your name will appear on your consent form. For the telephone identification, we will keep your anonymised study ID on your record form whilst data is being collected, but this will be removed when the data is entered into the electronic record. All other records will have your name removed and will only feature your anonymised study ID. Please note that for this study we will not be using hospital numbers, we will have a subject enrolment log that will contain the personal details of subjects and their study ID. This will be used to contact you, but all other study documentation will only contain your study ID.

Your data will be available to people authorised to work on the trial but may also need to be made available to people authorised by the Research Sponsor, which is the organisation responsible for ensuring that the study is carried out correctly. A copy of your consent form may be sent to the Research Sponsor during the study. By signing the consent form you agree to this access for the current study.

The information collected about you may also be shown to authorised people from the UK Regulatory Authority; this is to ensure that the study is carried out to the highest possible scientific standards. All will have a duty of confidentiality to you as a research participant.

If you withdraw consent from further study treatment, unless you object, your data will remain on file and will be included in the final study analysis.

In line with the Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for fifteen years. Arrangements for confidential destruction will then be made.

16. Use of your personal data in research

The University of Derby is the sponsor for this study based in the United Kingdom. We will be using information from you to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The research team at the University of Derby will keep identifiable information about you for 15 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 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 minimal identifiable information as possible. You can find out more about how we use your information using the following link (https://www.nuh.nhs.uk/gdpr) or by contacting the Information Commissioners Office on 0303 123 1113.

17. Informing your General Practitioner (GP)

We will contact your GP to inform them via a letter about your participation in this study. We inform them of your participation just in case they see you during your involvement in the study.

18. What will happen to any samples that I give?

During your visits, we will collect a few blood samples from your arm to investigate some important biomarkers. All samples will be analysed at either the University of Derby/Sheffield Hallam University and destroyed in line with University guidelines for sample disposable. No samples collected as part of this research will be stored following analysis or used in future research.

19. Will any genetic testing be done?

Genetic testing will not be carried out in this study.

20. What will happen to the results of this study?

Once the study has been completed all data will be anonymised and used for analysis by researchers at the University of Derby and Sheffield Hallam University. Upon completion of the analysis, all raw data will be disposed of according to appropriate governing bodies. The anonymised results of the evaluation will be shared with the project partners and Gilead who have provided the grant for this study.

All participants will be eligible to receive a summary of the project findings which will be available upon completion of the study (anticipated December 2023). Should you wish to receive a summary please contact the Chief Investigator on the contact details provided on page 6 or 10.

If deemed appropriate, the findings may also be published in a peer-reviewed academic journal. In this instance, all your data will be completely anonymous and not contain any information that will identify you.

21. Who is organising and funding this study?

The University of Derby will act as the sponsor for the research and Dr Mark Faghy will act as the Chief Investigator. Dr Thomas Bewick from the Royal Derby and Burton Hospital will act as the study's Principal Investigator. From Sheffield, Dr Tom Maden-Wilkinson from the Advanced Wellbeing Research Centre will lead the study.

The research has been funded by the GILEAD Sciences COVID-19 RFP Program: COMMIT.

22. Who has reviewed this study?

The research protocol and all study documentation have been reviewed by an independent group of people called a Research Ethics Committee, to protect your safety, rights, well-being, and dignity. This study has been reviewed and given a favourable opinion by the NHS Research Ethics Committee (IRAS number 313936).

The trial will be monitored by a trial steering group that consists of researchers from the University and its research partners who will regularly review the progress of the study and check study documents for accuracy.

23. Contact information and further information?

If you have read the above information and you are still interested in taking part in this study, then please inform a member of the clinical team at the long covid clinic and we will make arrangements for you to attend your first session. If you are at all unsure, you may have more time to think this through.

Thank you for taking the time to read this information sheet and to consider this study.

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