Participant information sheet for patients

PC-COS STUDY

Post COVID Condition (Long COVID) Core Outcome Set Study

This information sheet is in two parts; the first part explains what the study for, why you've been asked to take part and what taking part involves. The second part gives additional information if

PART 1

We'd like to invite you to take part in our research study.

Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you.

The first part of the Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part.

The second part will give you more detailed information about the conduct of the study. Please ask if anything is unclear.

What is the purpose of the study?

Who are we?
We are an international team of health professionals, researchers and people with lived experience of long COVID (also known internationally as Post Covid Condition). Our goal is to improve research and clinical care by identifying the most important outcomes of long COVID through collecting the views of different people from around the world.

Why are we doing the study?
Currently there is no standardised approach for evaluating health and wellbeing of people with long COVID. This problem is due, in part, to there being no universally agreed outcomes to measure in people with long COVID. Different researchers and health professionals around the world are measuring different outcomes. Hence, their results cannot be easily compared, potentially slowing the improvements in clinical care. This study aims to find the outcomes that are essential to measure in research and clinical care. These outcomes are called **core outcomes** and will be included in a **core outcome set**. In the future, new studies and clinical care can ensure they measure these core outcomes so everyone works together more efficiently and potentially improve clinical care more quickly.

What is an outcome?
When the health of an individual is evaluated, it is very important to know what effects of some condition are the most important and could affect their life the most. The same essential features inform the treatment testing and research. In this project we want to find which features, or outcomes, are the most important in long COVID.

For example, in a study testing patients' recovery after hip fracture, an 'outcome' might include 'mobility' described as 'changing basic body position; walking; moving around in different locations'.

Does it matter how an outcome is measured?
Please remember that we are interested in "what" outcomes should be measured. That means deciding which outcomes are the most meaningful for research or clinical care. Deciding how each outcome should be measured is important and will be decided in the next stage of the study.

Where can I find more information on outcomes?
You can watch a short [3 minute] video explaining what core outcomes are, why they are important and how patients and health professionals are involved in developing them here:
Subtitles are available in French, Portuguese, Dutch, Chinese, German, Spanish, Greek, Italian, Hungarian, Russian, Swedish and Bangala languages.

https://www.youtube.com/watch?v=D0Q9vypSYeE&t=6s

Why have I been invited?
You have been invited to take part in the study because you have Long COVID and have been seen in the King's College Hospital Long COVID clinic.

Patients from other hospitals and clinical settings across the UK, and in other countries, will also be invited to take part. We expect approximately 2000 patients will take part given how common this disorder is and the importance of this research.

Do I have to take part?
It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. You will be able to keep this information sheet and think about taking part. You are free to discuss the information with anyone you wish including your family and friends. If you agree, we will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part?

The study will be run online and involves taking part in two surveys. You can find out more about each survey and future steps on the next pages.

Step 1 – Survey 1 (20-30 minutes to complete):
In the first survey, you will view a list of outcomes. For each outcome, you will rate how important you think it is to measure that outcome for all future research and clinical care of long COVID. At the end of the survey, you can also suggest any other important outcomes are missing from the list. You can add comments to explain your decisions.

Survey 1 will be open from the 4th August 2021. If you register to take part, but haven't completed the survey, we will send you reminder emails.

Once the deadline (25th August 2021 at the earliest) for completing the survey has passed, we will analyse everyone's responses. We will then email you instructions on how to take part in the second survey.

Step 2 – Survey 2 (20-30 minutes to complete):
In the second survey, you will see the same list of outcomes (apart from those reaching an a priori criteria for consensus) from survey 1 with a reminder of your own rating. This time, you will also see a chart that shows how groups of people who took the first survey rated each outcome. Now, when you rate the outcome, please think about how you and the other groups rated each outcome. This is a chance for you to consider the opinions of others and to reflect on your own previous ratings. We are trying to find out which outcomes people with lived experience, health professionals, researchers and others agree must always be measured.

After these two surveys there is the possibility of the need for an 'Online Consensus Meeting' to which a smaller subgroup of people with lived experience, health professionals, researchers and other groups representatives will be invited to discuss the results and agree the final core outcomes. If you would like to be considered for a place at this meeting you can tell us at the end of the second survey. If this meeting is needed a further information about what the online consensus meeting involves (in a separate Patient Information Sheet) will be sent to those who have expressed interested in taking part.

What are the possible benefits of taking part?

The study will not help you personally in the short term but the information we get from this study will help improve the future treatment of people with Long COVID

What are the possible disadvantages and risks of taking part?

Are there any risks in taking part?

We do not expect there to be any major risks, although occasionally some people can find it upsetting thinking about outcomes related to their experience. If you do feel uncomfortable or distressed you can stop taking part at any time and you can provide feedback on any areas of concern.

Who is organising and funding this study?

This unfunded study is run by an international team, with key members based in the UK and is being sponsored by King's College London.

How have patients and the public been involved in this study?

Patients with Long COVID have co-designed all aspects of this study.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Cornwall and Plymouth Research Ethics Committee. It has also been approved by the Health Research Authority and each local hospital will also give confirmation that the study can go ahead.

Expenses and Payments

There are no funds available for payments to those participating in this study.

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

Will my taking part be kept confidential?

Yes. Your responses to the survey and contributions at the online consensus meeting will be labelled with a number rather than your name, to maintain confidentiality, and will only be looked at by members of the study team. Your email will only be used to contact you about this study. Your responses to the surveys will be stored on a secure server at King's College London for ten years after the study ends.

If you consent to take part in the research, any of the information collected about you may be inspected by the sponsor (including representatives of the sponsor). These inspections are solely for the purposes of the research and analysing the results. Your records may also be looked at by the regulatory authorities or ethics committees to check that the study is being carried out correctly.

The organisations listed above will keep information about you confidential and secure. Your name will not be used in any reports about the study and all data is stored in accordance with the principle of the Data Protection Act 2018. However, your hospital doctor may tell your GP about your participation if you agree to enter the study.

What will happen to the results of the research study?

The results will be analysed and published in a medical journal at the end of the study. We will also share a summary with relevant patient and health organisations. You will not be identified in the publication unless you tell us (at the end of the second survey) that you want to be acknowledged for your contribution. If this is the case, your name will be included in a specific acknowledgements section of the publication. We will not present your individual thoughts on outcomes in the publication; rather all results will be presented according to the different groups that took part (i.e. people with lived experience, health professionals, researchers, etc.).

How will we use information about you?

We will need to use information from you for this research project. This information will include your name and email. People will use this information to do the research. People who do not need to know who you are will not be able to see your name or contact details.

We will keep all information about you safe and secure. Your personal details are held on a secure computer at the University of Liverpool who will be hosting the survey.

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.

- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

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/
- by sending an email to the study team at pc.cos@liverpool.ac.uk

What if there is a problem?

If you are unhappy, or if there is a problem, please let us know by contacting the study coordinator – details below and we will try to help.

If you remain unhappy or have a complaint that you feel you cannot come to us with then you should contact the King's College London Research Ethics and Integrity Office – see below for details

Thank you for considering taking part and taking the time to read this information sheet.

Further information and contact details

The study team can be reached at pc.cos@liverpool.ac.uk

The Research Ethics and Integrity Office team can be reached at Research-integrity@kcl.ac.uk - when contacting please provide details of the name of the study (PC-COS), the IRAS ID number (302350) or REC number (21/SW/0109) and the details of the complaint you wish to make.