Training to Improve Dyspnoea sub study- COVID Rehabilitation (TIDe-CORe)

CERS Centre for Exercise and Rehabilitation Science

Invitation & Summary

We will be completing a phone call to assess your rehabilitation needs after being discharged from hospital following a diagnosis of COVID-19. We would like to:

- Gain a better understanding of your rehabilitation needs.
- Understand how COVID-19 has impacted your daily life.

What's involved?

The data we are interested in is gathered over the phone and we will ask questions about you and some questionnaires that explore your quality of life. We would need to understand how this is different to what is normal for you and will ask you to remember what your activities were like prior to your admission with COVID-19. With your permission, only members of the clinical team and research team at the University Hospitals of Leicester will have routine access to your medical records to understand what treatment you had while you were in hospital.

What are the possible benefits of taking part?

The results from this data set help us shape how we offer rehabilitation in the future for people who have experienced COVID-19.

What are the possible disadvantages or risks of taking part?

We are performing these questions over the phone to save you leaving your home and to minimise risk of infection to our staff.

Do I have to take part?

No. This study is voluntary and you are not required to take part. You will still continue to receive phone calls as per the clinical service but your information will not be used for research purposes. If you wish to withdraw from this study you are free to do so without giving a reason and this will not affect the standard of care you receive. After the point of withdrawal we will not continue to use your data for research purposes, though any prior collected data may still be used.

How will my information be kept confidential?

Any information which allows identification of you as an individual is kept strictly confidential and where possible a unique identifier will be used instead. We will store all your information on a password protected database on secure computers. Only certain members of staff will access this database. Procedures for handling, processing, storage and destruction of your data are compliant with GDPR 2018. The paper records are retained and filed in your medical notes.

Regulating authorities will have access to anonymous data only for the purpose of monitoring the quality of the research and clinical service and ensuring patient safety. Anonymous data will be retained for 5 years within University Hospitals of Leicester NHS Trust. Results from any research studies that use clinical data will be disseminated in peer and lay journals, professional publications and in presentations at conferences. Results will be reported to respect confidentiality. No identifiable information will be published. You are entitled to see any results or information about you under the Freedom of Information Act 2000.

What will happen with the results of this study?

Results will be presented at conference and published in scientific journals. This will also help us with our service design.

Who has reviewed this study?

All research that involves NHS patients and staff, information from medical records or uses NHS premises must be granted a favourable opinion from the NHS research ethics committee prior to commencement. This study has been reviewed and given favourable opinion by the Leicester South Research Ethics Committee.

Patient Identification Number:

Researcher to initial

PATIENT CONSENT FORM
COVID Rehabilitation (CORe)

Principal Investigator: Professor Sally Singh

1. I confirm that I have understood the patient information sheet dated **27/04/2020 version 2** for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected and that all data collected up until withdrawal will be retained. ☐
3. I understand that relevant sections of my medical notes and/or study data may be looked at by individuals from the study and clinical team, the sponsor, NHS Trust or from regulatory authorities where it is relevant. I give permission for these individuals to access my records. ☐
4. I would like to be contacted about further research opportunities ☐
5. I agree to take part in the above study. ☐

_____
Name of Patient

_____ _____ _____
Name of consenting researcher **Signature** **Date**