

Rehabilitation for those with lasting symptoms of COVID-19 post hospitalisation

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| Submission date 12/04/2022 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 06/07/2022 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 01/08/2025 | Condition category Infections and Infestations | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

This is a sub-study of 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, researchers want to understand if a rehabilitation programme can improve symptoms. They want to understand:

1. If an exercise and education programme can help improve symptoms following a COVID-19 admission compared to no programme
2. If a face-to-face programme or web-based programme can improve symptoms following COVID-19
3. The impact these programmes have on the immune system (measured by blood tests) and muscle function (measured by optional biopsies)

Who can participate?

Individuals with ongoing symptoms following hospitalisation with COVID-19

What does the study involve?

Participants will be randomly allocated to receive either a web-based programme, a face-to-face programme or no programme for 8 weeks. Participants who receive no programme will be offered one of the other programmes after the study. Before and after the intervention, participants complete questionnaires, walking tests, blood tests and strength tests. There is an optional muscle biopsy study which would require a small sample to be taken from the thigh, and an optional exercise test with a wearable vest to assess breathing.

What are the possible benefits and risks of participating?

The intervention is aimed to help people manage their lasting symptoms of COVID and participants may experience some benefit in taking part, but this intervention is being tested and therefore benefits are not guaranteed. The results may help in caring for other patients in the future. There is minimum risk and all information will be used anonymously. Whenever possible the additional samples will be taken at the same time as regular samples to reduce the extra procedures. There is a risk of pain or discomfort when samples are taken.

Where is the study run from?

NIHR Leicester Biomedical Research Centre (UK)

When is the study starting and how long is it expected to run for?

July 2020 to July 2023

Who is funding the study?

1. UK Research and Innovation (UK)

2. National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?

Dr Enya Daynes

enya.daynes@uhl-tr.nhs.uk

Study website

<https://www.phosp.org/>

Contact information

Type(s)

Principal Investigator

Contact name

Dr Enya Daynes

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
285439

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 285439

Study information

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

Acronym
PHOSP Rehab

Study objectives
To understand the clinical effectiveness of the candidate recovery interventions in the post-hospitalised PHOSP-COVID population in those with ongoing symptoms compared to 'usual care'.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 06/10/2021, Yorkshire & The Humber - Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8134; leedswest.rec@hra.nhs.uk), ref: 20/YH/0225

Study design

Multicentre parallel randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Ongoing symptoms following COVID infection and hospitalisation

Interventions

Patients will be randomised on a 1:1:1 ratio. Those that are able to access only one of the two interventions (face to face or digital) will be randomised on a 2:1 ratio to the accessible intervention or usual care (for example if not digitally literate they will be randomised to either f2f or usual care).

1. Web-based rehabilitation programme (Your COVID Recovery® Programme): this intervention is 8 weeks in duration and allows participants to work through four phases, 2 weeks per phase. This is a semi-supported exercise and education programme delivered via a web platform. Participants are contacted every 2 weeks to support progression to next phase.
2. Face-to-face rehabilitation programme: this is an 8-week programme, supervised sessions twice per week. The sessions last 90-120 minutes and cover aerobic and strength training and education sessions.
3. Control (usual clinical care): usual care currently does not include the provision of rehabilitation. Any other routine appointments and treatment plans will continue throughout this intervention.

Intervention Type

Behavioural

Primary outcome measure

Performance is measured using the Incremental Shuttle Walking Test at baseline and 8-week follow up

Secondary outcome measures

1. HRQOL is measured using the Functional Assessment of Chronic Illness Test- Fatigue total score at baseline and 8-week follow up
2. HRQOL is measured using the Nottingham extended Activities of Daily Living questionnaire at baseline and 8-week follow up
3. HRQOL is measured using the EuroQuol 5 domain at baseline and 8-week follow up
4. Breathlessness is measured using the Dyspnoea-12 at baseline and 8-week follow up
5. Cognitive impairment is measured using the Montreal Cognitive Assessment at baseline and 8-week follow up
6. Pain is measured using the Brief Pain Inventory at baseline and 8-week follow up
7. Symptoms of depression are measured using the Patient Health Questionnaire-9 at baseline and 8-week follow up
8. Symptoms of anxiety are measured using the General Anxiety Disorder 7 Questionnaire at baseline and 8-week follow up
9. Presence of sarcopenia is measured using the SARC-F at baseline and 8-week follow up
10. Quadriceps strength is measured using the Quadriceps Maximal Voluntary Contraction at baseline and 8-week follow up
11. Handgrip strength is measured using a grip strength dynamometer at baseline and 8-week follow up
12. Physical activity is monitored using the GENEActiv wrist-worn actigraphy device for 1 week following the initial study visit and between weeks 7-8
13. Breathing dysfunction is measured using the Nijmegen questionnaire at baseline and 8-week follow up
14. Functional capacity is measured using the Short Physical Performance Battery at baseline and 8-week follow up

Overall study start date

16/07/2020

Completion date

10/07/2023

Eligibility

Key inclusion criteria

1. Ongoing symptoms following COVID-19 infection that are deemed modifiable by a rehabilitation programme
2. Hospitalisation during an acute infection of COVID-19

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

159

Total final enrolment

186

Key exclusion criteria

1. Unwilling to consent for the trial
2. Full recovery of symptoms reported by the patient (physical and psychological)
3. Persistent symptoms indicative of other significant medical conditions that require further investigation/management
4. Currently on or recently completed a course of COVID rehabilitation (previous 6 months)
5. Contraindications for exercise (American College of Sports Medicine)

Date of first enrolment

07/12/2021

Date of final enrolment

15/05/2023

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre**NIHR Leicester Biomedical Research Centre**

Gwendolen Rd

Leicester

United Kingdom

LE5 4QF

Study participating centre**NIHR Newcastle Biomedical Research Centre**

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Freeman Hospital

Freeman Road

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United Kingdom

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Sponsor information**Organisation**

University of Leicester

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Sponsor type

University/education

Website

<http://www.le.ac.uk/>

ROR

<https://ror.org/04h699437>

Funder(s)

Funder type

Government

Funder Name

UK Research and Innovation

Alternative Name(s)

UKRI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal (May 2023), presented at a relevant conference in September 2023. Results will be disseminated to participants through an online or face to face event and sent to participants through the post if they are unable to attend.

Intention to publish date

10/10/2024

Individual participant data (IPD) sharing plan

Participants have not consented to share individual data and therefore will not be shared. However, group data can be shared upon reasonable request to Dr Enya Daynes (enya.daynes@uhl-tr.nhs.uk). Data handling and record-keeping will be in accordance with the PHOSP-COVID study procedures. Clinical paperwork arising from the intervention will be inputted onto paper and/or electronic CRFs and stored electronically onto RedCAP alongside the PHOSP-COVID study data. Clinical paperwork will be filled in the medical notes as is standard practice. The sub-study data will be stored on the PHOSP Redcap and eCRF alongside the main PHOSP data.

IPD sharing plan summary

Not expected to be made available

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------|--------------|------------|----------------|-----------------|
| Participant information sheet | version 1.1 | 23/09/2021 | 13/04/2022 | No | Yes |
| Protocol article | | 26/01/2023 | 27/01/2023 | Yes | No |
| HRA research summary | | | 26/07/2023 | No | No |
| Results article | | 22/05/2025 | 01/08/2025 | Yes | No |