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

Submission date
12/04/2022

Recruitment status
No longer recruiting

Registration date
06/07/2022

Overall study status
Completed

Last Edited
01/08/2025

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Contact information

Type(s)
Principal investigator

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Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
285439

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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 Nijmegan 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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
University of Leicester

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

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?
Results article		22/05/2025	01/08/2025	Yes	No
Protocol article		26/01/2023	27/01/2023	Yes	No
HRA research summary			26/07/2023	No	No
Participant information sheet	version 1.1	23/09/2021	13/04/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes