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Effectiveness & acceptability of rehabilitation for non-hospitalised Long Covid

Submission date
26/09/2024

Recruitment status
No longer recruiting

Registration date
01/10/2024

Overall study status
Completed

Last Edited
14/05/2026

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This is a study to explore rehabilitation for people with Long Covid who have lasting symptoms. As COVID-19 is a new disease, and some people have remaining symptoms we want to understand if an exercise-based rehabilitation programme can improve symptoms.
We want to understand:
• If an exercise and education programme can help improve symptoms following COVID-19 compared to no programme.
• How the programme feels to participants, whether or not it has been helpful, and whether or not they would recommend it to others

Who can participate?
People with Long Covid who were not hospitalised at point of acute infection but still experience Long Covid symptoms

What does the study involve?
Those who agree to take part will be asked to attend the research site for a minimum of two visits lasting approximately 2 hours each. Everyone will be asked to undertake a range of tests and measures before and after their allocated programme. These include some questionnaires, walking tests, and tests of strength, there will also be an option to provide blood samples, and to wear a heart rate monitor. These are optional measures and participants will decide whether they wish to take part in these aspects of the study separately on the consent from.

Participants will be allocated to receive either “face-to-rehabilitation” or “no programme”, through a process called "randomisation". Those allocated to receive “face-to-face rehabilitation” will need to attend rehabilitation classes lasting approximately 1.5 hours per session, twice a week for 6 weeks. Those allocated to receive “no programme” will be offered rehabilitation after the research trial has concluded (i.e. 6 weeks later).

Participants may also be invited to take part in the second phase of this study that will involve taking part in either an interview or a focus group to discuss their experiences.

What are the possible benefits and risks of participating?
The rehabilitation programme has been designed with the aim of helping people manage their lasting symptoms of COVID-19, therefore participants may experience some benefit in taking part, however, benefits are not guaranteed. The information we learn may help in caring for other patients in the future.

There is minimum risk to taking part. Those in the exercise group will be carefully monitored for signs of excessive fatigue. Steps have been taken to ensure those who struggle with excessive fatigue are not recruited to this trial to ensure their symptoms are not worsened, however, if this becomes apparent they will be suspended from the trial and referred to the appropriate clinic(s).

Where is the study run from?
This is a research study organised by the NIHR Leicester Biomedical Research Centre and sponsored by University Hospitals of Leicester NHS Trust (UK)

When is the study starting and how long is it expected to run for?
December 2023 to September 2026

Who is funding the study?
The research is being undertaken as part of the fulfilment of a PhD. Kate Kontou is funded by Wellcome Trust as part of the Leicestershire Healthcare Inequalities and Improvement Programme. The study is supported by the NIHR Leicester Biomedical Research Centre (UK)

Who is the main contact?
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Additional identifiers

Integrated Research Application System (IRAS)
338393

Central Portfolio Management System (CPMS)
61635

EDGE ID
163951

Study information

Scientific Title
Mixed methods study to explore the effectiveness and acceptability of face-to-face exercise-based rehabilitation for patients with Long Covid who were not hospitalised with their acute infection

Study objectives
Face-to-face exercise-based rehabilitation is more effective and acceptable for Long Covid patients who have not been hospitalised than usual care alone

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/09/2024, North West - Greater Manchester West Research Ethics Committee (3rd Floor, Barlow House. 4 Minshull Street., Manchester, M1 3DZ, United Kingdom; +44 207 104 8057; gmwest.rec@hra.nhs.uk), ref: 24/NW/0279

Primary study design
Interventional

Study design
Single-centre mixed methods study comprising a randomized controlled trial (RCT) with embedded qualitative component

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients with Long Covid who were not hospitalised with their acute infection.

Interventions
Randomisation will be generated through online randomisation software 'Sealed Envelope' (https:// www.sealedenvelope.com), using block randomisation with stratified blocks of six participants. Researchers involved in delivering the rehabilitation programmes will implement the randomisation on "Sealed Envelope" and assign participants. Individuals who are able to participate will be randomised on a 1:1 ratio to face-to-face rehab (intervention) or control (usual care). Due to the sample size, stratification will be used to provide additional assurance that important factors are equally represented in the two trial groups to facilitate comparability (FDA, 2013). The covariates deemed important in this case to balance are those of sex and age.

Individuals randomised to the intervention group will complete an individualised symptom-titrated programme of exercise, education and self-management for 6 weeks. The programme will comprise of two supervised sessions per week delivered by healthcare professionals.
The rehabilitation programme will consist of aerobic exercise [i.e. treadmill/ground walking at 80% of the incremental shuttle walk test (ISWT) speed where tolerated and lower-limb cycling on a static bike] and resistance exercise training (upper and lower limb strength exercises). The exercise intensity and duration will be tailored to the individual's current abilities, assessed in their first visit and calculated using a predicted speed determined by the ISWT.
In addition to the supervised sessions, patients will be asked to perform home-based exercise sessions which align with the supervised sessions: three aerobic exercise sessions and one resistance exercise session each week in which they will be asked to record in a self-reported diary. This will be used in conjunction with self-reported symptoms at the face-to-face sessions for the delivering clinicians to monitor symptoms and guide exercise modifications.
Each rehabilitation session will conclude with an educational discussion (approx. 30–60 min) delivered by a member of the multidisciplinary team. These discussions will be facilitated by information sheets saved from the Your COVID Recovery (YCR) website repository. Topics include: getting moving again, managing activities of daily living, breathlessness, fatigue management and recognising symptoms of worsening in response to exercise, fear and anxiety, mood and coping, memory and concentration, cough, eating well, sleep hygiene, goal setting, headaches, managing symptom exacerbation and fluctuations and returning to work. Each session will conclude with a question-and-answer session and next steps.

Participants in the control arm will receive usual care for 6 weeks. Routine clinical care will continue such as medical follow-up, mental health service provision and other specialist services. After involvement in the trial has concluded, individuals allocated to the control group will be offered face-to-face rehabilitation if desired.

Intervention Type
Mixed

Primary outcome(s)

Maximal exercise tolerance as measured by absolute change in ISWT distance after the intervention phase.

Key secondary outcome(s)
1. Acceptability is measured using quantitative completion rates at 75% of scheduled sessions or follow-up assessment at baseline and follow-up
2. Acceptability is measured using qualitative focus groups with completers and semi-structured interviews with decliners and drop-outs at follow-up
3. Physical function is measured using the Short Physical Performance Battery (SPPB) at baseline and follow-up
4. Maximum isometric quadriceps strength is measured using a dynamometer (Edwards et al., 1977) at baseline and follow-up
5. Physical activity is measured using the ActiGraph accelerometer device (daily step count) at baseline and follow-up
6. Endurance exercise capacity is measured using the Endurance Shuttle Walk Test (ESWT) at baseline and follow-up
7. Generic HRQoL is measured using the EQ-5D-5L at baseline and follow-up
8. Covid-specific HRQoL is measured using the Modified C19-YRS at baseline and follow-up
9. Depression is measured using the Patient Health Questionnaire (PHQ9) at baseline and follow-up
10. Anxiety is measured using the Generalised Anxiety Disorder 7-item scale (GAD7) at baseline and follow-up
11. Breathlessness is measured using the MRC Dyspnoea scale at baseline and follow-up
12. Fatigue is measured using the Functional Assessment of Chronic Illness Therapy Fatigue Scale (FACIT-Fatigue) at baseline and follow-up
13. Cognitive function is measured using the Montreal Cognitive Assessment (MoCA) at baseline and follow-up
14. Post Exertional Malaise is measured using the DePaul Symptom Questionnaire Short Form (DSQ-SF) at baseline and follow-up
15. Markers of immune ageing are measured using blood samples at baseline and 6 weeks
16. Heart rate variability is measured using a 12-lead ECG NORAV Holter device continuously for 24 hours before and after the intervention period, and resting 12-lead ECG recordings for 10 minutes at baseline and after the intervention

Completion date
30/09/2026

Eligibility

Key inclusion criteria
1. Over the age of 18 years old
2. NOT admitted to hospital during the acute phase of their Covid infection (if a patient attended accident and emergency care for medical assessment, they will still be eligible to take part)
3. Have a clinician diagnosis of Long Covid (from a dedicated Long Covid Assessment Clinic). The acute Covid-19 does not require PCR confirmation
4. Have ongoing symptoms that may be modifiable by a rehabilitation programme
5. Are willing and able to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Exercise is contraindicated as outlined in the American College of Sports Medicine guidance (American College of Sports, 2022)
2. Further investigation / management for an unstable comorbidity is required
3. Exercise based rehabilitation has been attended / completed in the preceding 6 months
4. Hospital admission was required during their most recent acute SARS-Cov-2 infection
5. Severe debilitating fatigue (home bound or bed bound) that worsens with activity is experienced – regardless of formal post-exertional malaise/Myalgic Encephalomyelitis (ME) diagnosis
6. Not willing or unable to provide consent

Date of first enrolment
30/09/2024

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals of Leicester NHS Trust
CERS, Respiratory BRC
Glenfield Hospital

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Sponsor information

Organisation
University Hospitals of Leicester NHS Trust

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
NIHR Leicester Biomedical Research Centre

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		21/01/2026	21/01/2026	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes