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Long COVID optimal health program (LC-OHP)

Submission date
14/09/2021

Recruitment status
No longer recruiting

Registration date
08/10/2021

Overall study status
Completed

Last Edited
21/08/2025

Condition category
Infections and Infestations

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
People with long COVID have various symptoms lasting 12 weeks or more beyond the acute infection. The most common symptoms are fatigue, brain fog, and increased risk for developing anxiety and/or depression, all of which significantly affect an individual's quality of life.
As COVID-19 is still a new viral infection, there are lots of unknowns surrounding it and no standard treatment is yet available to either stop long COVID developing or to help with all the symptoms people are living with. Rather, those treatments given are dependent on each presenting symptom, so while people may get help with their fatigue, they may have to go elsewhere to get support to manage their 'brain fog'. The NHS recommends that people with long COVID should receive care that helps with all their symptoms (not just one at a time), including support to mitigate their fatigue, improve mental health and encourage self-management.
The Integrated Care Academy at the University of Suffolk is leading a research project on long COVID. The project is funded by the Mental Health Alliance (East Suffolk, West Suffolk and North East Essex) Board. It aims to provide people with long COVID with better support to improve their quality of life by using the Long COVID Optimal Health Program LC-OHP). This is a program that is delivered in weekly sessions and works to support people with their symptoms, such as helping to reduce fatigue and brain fog, as well as improving physical activities and mental wellbeing.

Who can participate?
Persons aged 18 years old and above who have been experiencing symptoms of long COVID for 12 weeks or more following the start of symptoms.

What does the study involve?
People participating will be randomly divided into two groups, one group will receive the LC-OHP, and the other group will receive usual care. This will help us identify whether the program is effective for long COVID.
For those who receive the LC-OHP, we will deliver this in five sessions (one session per week) and an additional booster session three months after the fifth session. We will provide participants with a booklet that summarises the weekly sessions and will give them access to an online version as well. We will deliver the sessions either on a one-to-one basis or in groups, depending on participants' preferences. We will also deliver the sessions virtually or by phone at a convenient time.

For those who do not receive the LC-OHP, they will still receive all care that they have been receiving either at the hospital clinic or through their GP.
To further understand people's feelings and challenges in living with long COVID and to see if the LC-OHP is working, we will also be asking both groups to complete a number of short questionnaires at the start, middle and end of the project. These will take less than 15 minutes in total to complete. We will also interview some participants who received the LC-OHP to explore their views of the program. We also plan to interview participants who decide to withdraw from the LC-OHP (if any), to identify whether we could do anything to improve the program for other people.

What are the possible benefits and risks of participating?
We do not anticipate any risks associated with the LC-OHP; however, there is a possibility of fatigue from attending the program's sessions. To prevent fatigue, we will provide breaks and rest periods, or if necessary, end the session and complete it at another time at the participant's request. We will support to participants as needed.
While we haven't used the OHP for people with long COVID, it has been really successful in other chronic medical conditions, such as asthma, diabetes, stroke and chronic kidney disease. We are anticipating that the LC-OHP will improve the symptoms, physical activity and mental wellbeing of participants with long COVID. Also, the study will help in identifying which types of support might help people in managing their long COVID.

Where is the study run from?
University of Suffolk (UK)

When is the study starting and how long is it expected to run for?
September 2021 to May 2023

Who is funding the study?
Mental Health Alliance (East Suffolk, West Suffolk and North East Essex) Board (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
304234

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 304234, CPMS 50608

Study information

Scientific Title
Long COVID Optimal Health Program (LC-OHP) to enhance psychological and physical health: a feasibility randomised controlled trial

Acronym
LC-OHP

Study objectives
The LC-OHP program will improve the physical and psychosocial wellbeing of people with long COVID.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 05/10/2021, University of Suffolk ethics committee (Waterfront Building, 19 Neptune Quay, Ipswich IP4 1QJ, UK; +44 (0)1473 338330, s.raychaudhuri@uos.ac.uk), ref: RETH21 /004
2. Approved 01/11/2021, Bristol Research Ethics Committee Centre (Ground Floor, Temple Quay House, Bristol Research Ethics Committee Centre, BS1 6PN, UK; +44 (0)207 104 8029; approvals@hra.nhs.uk), REC ref: 21/SW/0136

Study design
Pilot single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Long COVID

Interventions
Randomisation:
Participants will be randomised following the receipt of baseline data to either intervention or control group via a computer-generated block randomization. To avoid bias, an independent person will carry out participant randomisation. Due to the nature and length of the intervention, it is not possible to blind either the researcher nor the participant to the treatment allocation.

Control group: Standard care
Participants allocated to the control group will receive that care usually provided to patients with long COVID. No fixed standard care is yet available and patients are managed symptomatically while following NICE guidelines.

Intervention group: LC-OHP
The long COVID OHP will be provided to participants allocated in the intervention group after the receipt of their baseline data. The OHP is a person-centred model and focuses on health as defined by consumers. It aims to support people with mental or physical illness by using a multidisciplinary collaborative therapy and self-efficacy intervention. The program addresses psychological and physical dimensions of health and is flexible to be delivered by a range of practitioners. It can also be delivered at all stages of the care trajectory; in inpatient and outpatient settings, at homes, or by video conferencing, and to groups or to individuals consumers.

In this trial, recognising that fatigue is a core component, the OHP for long COVID will be delivered in five sequential sessions. The program's key elements include goal setting, problem solving, identifying social supports and developing plans to cope with daily stressors, and responding to an episode of illness

Delivery of the five sessions will be weekly, with the first session held after collecting baseline data and the last completed prior to collecting data at three months. An additional booster session will be held three months after the last session and will target reviewing health plans and reflecting on achievements made towards health-related goals. Sessions will be held either in a 1:1 encounter with the facilitator, or in groups (a maximum of eight participants per group), or using a mixture of both, depending on participants' preferences. The 1:1 sessions will last up to one hour, with breaks provided upon participant's request, and if necessary, the session can be completed at another time. Group sessions will last up to 90 min and breaks will be provided upon request. Sessions will be held online (using a convenient platform such as Zoom, Skype or Microsoft Teams). Those who do not have access to online facilities will be given the option to have the sessions delivered by telephone. Sessions will be audio recorded to be checked by another member of the research team to confirm fidelity with delivering the program.

Intervention Type
Behavioural

Primary outcome measure

Feasibility and acceptability measured by:
1. Recruitment and retention rates measured by identifying the number of participants taking part in the study (from start to end) and number of participants who withdraw from the study at any point.
2. Acceptability and satisfaction of the LC-OHP measured by:
2.1. Conducting a telephone interview with a sample of participants in the intervention group at the end of the trial
2.2. Asking participants in the intervention group to complete the Course Experience Questionnaire (CEQ) at the end of the trial
Participants who decide to withdraw from the trial will also be invited to a short interview to assess their views of the LC-OHP and any changes that they may wish to suggest. Interviews will be held as soon after they withdraw
3. Acceptability of secondary outcome measures measured using telephone interview with a sample of participants in the intervention group at the end of the trial

Secondary outcome measures
Measured at baseline, and at 3 and 6 months post-randomisation:
1. Depression measured using the Patient Health Questionnaire (PHQ-9)
2. Anxiety measured using the Generalised Anxiety Disorder Assessment (GAD-7)
3. Self-efficacy measured using the General Self-Efficacy Scale (GSE)
4. Quality of life measured using the EQ-5D-5L questionnaire
5. Fatigue Assessment Scale (FAS)

Overall study start date
14/09/2021

Completion date
20/05/2023

Eligibility

Key inclusion criteria
1. Adult (18+ years with no upper age limit).
2. COVID-19 infection confirmed through PCR testing or clinical diagnosis from GP.
3. Experiencing post-COVID-19 syndrome (as defined by NICE 2020) 12 weeks or more following onset of symptoms / confirmed through testing.
4. Able to participate in telephone interview in English language (or with accommodated adjustments).
5. Able to consent to participate in study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Children and young adults (17 years and under).
2. Unable to consent to participate in study, despite reasonable adjustments being implemented.
3. Unable to participate in telephone interview in English language, where the research team have been unable to make adjustments to enable their participation.

Date of first enrolment
23/11/2021

Date of final enrolment
28/10/2022

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
University of Suffolk
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Sponsor information

Organisation
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Sponsor type
University/education

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http://www.ucs.ac.uk/home.aspx

ROR
https://ror.org/01cy0sz82

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Mental Health Alliance (East Suffolk, West Suffolk and North East Essex) Board

Results and Publications

Publication and dissemination plan
Planned publication in:
1. High-impact peer-reviewed journals
2. Abstracts submission to national and international conferences
3. Social media including Twitter, YouTube, LinkedIn

Intention to publish date
31/10/2024

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

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 (preprint)		21/01/2022	18/03/2022	No	No
Protocol article		24/02/2022	26/04/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article		01/08/2025	21/08/2025	Yes	No