

# Non-randomised controlled trial of the Hope programme for people living with long COVID

<b>Submission date</b> 10/02/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 18/02/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/11/2022	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Long COVID is a term to describe the effects of COVID-19 that continue for weeks or months beyond the initial illness. Research and patient testimonies highlight the impact of living with long COVID and the associated uncertainty of symptoms. Clinical guidelines suggest that long COVID symptoms should be managed pragmatically with holistic support. Symptoms of long COVID differ from person to person and can also come and go over time. Owing to these fluctuations, patients often feel that their symptoms are dismissed or not believed. Research findings highlight the negative impact of disbelief from medical professionals, self-stigma and stigma from others, and the need to have long COVID experiences validated. Peer support is seen as an accessible and engaging way to gain advice, support and validation. Indeed, research shows that since the first wave of the pandemic, people living with long COVID have sought peer support.

NHS long COVID clinics are overwhelmed, and patients are going online for peer support. The long COVID Hope Programme project takes a proactive, preventative approach to addressing the most urgent public health crisis in a generation. This project will co-develop and test the digital Hope Programme, combining peer-delivered support with evidence-based techniques for self-managing psychosocial, physical and cognitive challenges in long COVID.

### Who can participate?

Any adult (aged 18 years or over) who is living with long COVID. The funding prioritises courses for people living in the local community (Coventry, Warwickshire and Rugby), but the courses are open to people from across the UK. Residents of Coventry, Warwickshire and Rugby are given priority access to the Hope Programme, and vacancies are opened up, or waiting lists created, for individuals from other areas of the UK.

### What does the study involve?

Everyone who signs up for the Long COVID Hope Programme will be invited by email to take part in this study. Taking part in the study is entirely voluntary, and those who do not wish to take part can still join the Long COVID Hope Programme. The study will require participants to complete a set of health and wellbeing questionnaires at the start of the study and again 8 weeks later. All study documents and questionnaires are presented online.

What are the possible benefits and risks of participating?

The digital Hope Programme has been shown to be helpful for groups of people living with Long COVID in a study that did not have a control group. Participants may find the course helpful and /or may have suggestions for how it could be improved before it is put into a full-scale clinical trial. Participants will receive a £10 Amazon gift voucher for completion of all study questionnaires.

There are no direct risks of taking part in this study. Whilst the researchers do not anticipate the questionnaires will cause any distress to participants, some of the questions will ask about their health, which may touch on topics that some participants may find sensitive. Participants are informed that they do not have to answer any questions that they are uncomfortable with. If participants do experience any distress from completing the questionnaires, they are encouraged to contact their GP or the Samaritans.

Where is the study run from?

The evaluation research study takes place completely online and is run by Coventry University (UK). The Long COVID Hope Programme is run by Hope For The Community (H4C) Community Interest Company (UK).

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

July 2021 to April 2022

Who is funding the study?

NHS Charities Together (UK)

Who is the main contact?

1. Dr Faith Martin, [martinf8@cardiff.ac.uk](mailto:martinf8@cardiff.ac.uk)

2. Dr Anna Lynall, [hope@h4c.org.uk](mailto:hope@h4c.org.uk)

## Contact information

### Type(s)

Principal Investigator

### Contact name

Dr Faith Martin

### ORCID ID

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### Contact details

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# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

283172

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

106036, IRAS 283172

# Study information

## Scientific Title

Are there improvements in mental wellbeing following a digital peer-supported self-management intervention versus a wait-list control group, for people living with long COVID? A non-randomised pre-post study

## Study objectives

Compared to a non-randomised wait-list control group, are there improvements in positive mental wellbeing, self-efficacy, fatigue, depression, anxiety and loneliness following an 8-week digital peer-supported self-management intervention, for people living with long COVID?

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 22/12/2021, Coventry University Research Ethics Committee (Priory Street, Coventry, CV1 5FB, UK; Tel: not available; ethics.uni@coventry.ac.uk), ref: P106036

## Study design

Pragmatic non-blinded non-randomized wait-list controlled pre-post trial

## Primary study design

Interventional

## Secondary study design

Non randomised study

## Study setting(s)

Community

## Study type(s)

Quality of life

## Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

## **Health condition(s) or problem(s) studied**

Supporting people living with long-term symptoms of COVID-19 ('long COVID')

## **Interventions**

Current intervention as of 24/08/2022:

The Long COVID Hope Programme is an 8-week programme that combines positive psychology and cognitive behavioural approaches and is delivered by trained facilitators with lived experience of Long COVID. Symptoms of Long COVID differ from person to person and can also come and go over time. However, the most commonly reported symptoms are fatigue, breathlessness and brain fog. Prioritisation and goal setting are core elements of pacing, which is vital for fatigue management in Long COVID (Greenhalgh et al., 2020). These important evidence-based tools and techniques are included in the Long COVID Hope Programme.

People who signed up to join the Long COVID Hope Programme through Community Interest Company, Hope For The Community (H4C), gave their permission to be contacted by Coventry University (CU). CU invited them to take part in the research (pre/post) study. Participants who signed up for the January 2022 course formed the intervention group, and those who signed up to join the later course in March 2022 formed the non-randomised control group.

Previous intervention:

The Long COVID Hope Programme is an 8-week programme that combines positive psychology and cognitive behavioural approaches and is delivered by trained facilitators with lived experience of Long COVID. Symptoms of Long COVID differ from person to person and can also come and go over time. However, the most commonly reported symptoms are fatigue, breathlessness and brain fog. Prioritisation and goal setting are core elements of pacing, which is vital for fatigue management in Long COVID (Greenhalgh et al., 2020). These important evidence-based tools and techniques are included in the Long COVID Hope Programme.

People who signed up to join the Long COVID Hope Programme through Community Interest Company, Hope For The Community (H4C), gave their permission to be contacted by Coventry University (CU). CU invited them to take part in the research evaluation (pre/post) pilot study. Participants who signed up for the January 2022 course formed the intervention group, and those who signed up to join the later course in March 2022 formed the non-randomised control group.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Positive mental wellbeing measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS), at baseline and 8 weeks later

## **Secondary outcome measures**

1. Self-efficacy measured by the Self-Efficacy for Managing Chronic Disease 6 item scale (SEMCD6) at baseline and 8 weeks later
2. Fatigue measured by the Fatigue Severity Scale (FSS), at baseline and 8 weeks later
3. Loneliness measured by the UCLA Loneliness Scale, Version 3 (UCLA3) at baseline and 8 weeks later

4. Depression measured by the Patient Health Questionnaire 9 item scale (PHQ9) at baseline and 8 weeks later
5. Anxiety measured by the Generalised Anxiety Disorder 7 item scale (GAD7) at baseline and 8 weeks later
6. Long COVID symptoms reported via the COVID-19 Yorkshire Rehabilitation Screening Tool (C19-YRS) at baseline and 8 weeks later

**Overall study start date**

01/07/2021

**Completion date**

30/04/2022

## Eligibility

**Key inclusion criteria**

1. Adults aged 18 years and over
2. Self-reported or diagnosed long COVID symptoms
3. UK-based

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

120

**Total final enrolment**

94

**Key exclusion criteria**

No access to an internet-enabled device to engage with the intervention

**Date of first enrolment**

13/01/2022

**Date of final enrolment**

19/01/2022

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Coventry University**

Priory Street

Coventry

United Kingdom

CV1 5FB

## **Sponsor information**

**Organisation**

Coventry University

**Sponsor details**

Priory Street

Coventry

England

United Kingdom

CV1 5FB

+44 (0)2476657688

ethics.uni@coventry.ac.uk

**Sponsor type**

University/education

**Website**

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

**ROR**

<https://ror.org/01tgmhj36>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

NHS Charities Together

# Results and Publications

## Publication and dissemination plan

Planned publication in high-impact peer-reviewed journal

## Intention to publish date

31/10/2022

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to not having prior ethical approval for this.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		07/09/2022	29/09/2022	Yes	No
<a href="#">Protocol file</a>	version 2.1	15/08/2022	03/11/2022	No	No