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Effectiveness and cost-effectiveness of a personalised self-management support intervention for non-hospitalised people living with long COVID

Submission date
26/01/2022

Recruitment status
No longer recruiting

Registration date
27/01/2022

Overall study status
Completed

Last Edited
08/05/2025

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
Individuals with long COVID experience a wide variety of ongoing problems such as tiredness and difficulty with everyday tasks and means they can struggle to return to their former lives. This is then made worse by uncertainty and a lack of understanding by some healthcare professionals.
The LISTEN project is developing, delivering and evaluating an intervention which is a package of self-management support, to see if this helps individuals with long COVID to live their normal lives. The intervention is co-designed with individuals living with long COVID and a large patient and public panel from diverse backgrounds to ensure that the intervention can be personalised to individual needs.

Who can participate?
Adults over 18 years, with long COVID.

What does the study involve?
We will recruit individuals with long COVID and randomly allocate them to an intervention or control group. The control group will receive NHS usual care; the intervention group will receive the co-designed LISTEN resources and up to six coaching sessions from the trained practitioners. We will estimate the cost of the intervention and test its effect on how participants feel and cope with everyday activities. We will record healthcare resource use, expenses, and time of work to understand the economic impact of long COVID and our intervention on society and individuals. We will explore ways in which the intervention can be used across the NHS and broader communities.

What are the possible benefits and risks of participating?
At this stage of the research, the direct health benefits for you are unknown, but by being involved, you will help us to gather evidence about different methods that may help individuals living with long Covid.

There is a chance that you might find some topics sensitive or upsetting while taking part in the one-to-one support sessions or while answering the questionnaires. If you are participating in a focus group discussion, there is a risk that you might disagree with others. If disagreements occur, the interviewer will invite you both to put your point of view forward.

Where is the study run from?
Cardiff University (UK)

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

Who is funding the study?
National Institute for Health Research (NIHR) (UK).
UK Research and Innovation

Who is the main contact?
Prof Monica Busse, busseme@cardiff.ac.uk
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Contact information

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Scientific

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Type(s)
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
306220

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 51386, COV-LT2-0009, IRAS 306220

Study information

Scientific Title
Long COVID PersonalIsed Self-managemenT support EvaluatioN (LISTEN)

Acronym
LISTEN

Study objectives
To investigate the effectiveness and cost-effectiveness of a personalised self-management support intervention for non-hospitalised people living with long COVID

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/12/2021, Wales REC 7 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 2920 230457; Wales.REC7@wales.nhs.uk), ref: 21/WA/0368

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Long COVID-19

Interventions
Once consented, the participant will be able to access the baseline questionnaires on the LISTEN website. These will ask question about their Long COVID symptoms and how they are coping with them. We will specifically ask for:
1) Name, age, contact details, including postcode so we can make sure that they are connected to the correct a local site team
2) Information about their COVID (and long COVID) history
3) Information about how they manage day-to-day and their use of health and social care services.

Once the baseline questionnaires have been completed, the Trial management team will randomise the participant.
The participant will then be contacted to let them know if they will receive the LISTEN intervention or stay on usual care.
If they are offered the LISTEN intervention, they will receive up to 6, one to one sessions with a clinical practitioner through video call. These sessions will take place over a 10 week period to help self-manage long COVID. They will also have access to resources developed to help self-management, such as information booklets and online help.

After 6 weeks, we will ask participants to complete an interim assessment (ED-5D and health services resource questionnaire).

After 3 months, we will ask all participants (both arms) to complete the same forms as completed at baseline. We expect that filling out those forms will take roughly 45 minutes to complete on each occasion.

Data collections:
Outcome data will be collected at baseline and 3 months after randomisation (primary outcome timepoint) for both control and intervention participants. Interim data collection primarily focussed on health care resources will be undertaken. Data collection will be achieved via electronic case report forms, self-reported by participants and accessed using a purpose-developed online database. For participants who have issues accessing the database or have difficulties using a computer, the central CTR team will be available to provide IT support by telephone. If participants do not have access to a computer or are unwilling to use the internet, paper case report forms can be sent by post and the central CTR team will ring the participant to record the answers to the questionnaires.

At the end of the trial, we will ask some participants about their experiences of the trial. They might be invited to be interviewed by a researcher individually or in a group (focus group) using an online platform or telephone depending on what is most convenient for them. We would like to audio-record the interviews and will ask permission before the interview starts. Then we may also ask those who received the LISTEN intervention to complete some additional questionnaires which will help us to assess whether the intervention is acceptable, feasible, and appropriate for managing long COVID.

The interviews will take about 30 min to 1 hour – some may be shorter, some longer (but this depends on your group).

Intervention Type
Behavioural

Primary outcome measure
The impact of the LISTEN intervention on routine activities is assessed using the routine activities scale domain of the Oxford Participation and Activities Questionnaire (Ox-PAQ) at baseline and 3 months.

Secondary outcome measures
1. To evaluate the impact of the LISTEN intervention on emotional well-being as assessed by the relevant domain sub-scale of the Ox-PAQ, at baseline and 3 months.
2. To evaluate the impact of the LISTEN intervention on social engagement as assessed by the relevant domain sub-scale of the Ox-PAQ, at baseline and 3 months.
3. To evaluate the impact of the LISTEN intervention on health-related quality of life as assessed by the Short Form (12) Health Survey, at baseline and 3 months.
4. To evaluate the impact of the LISTEN intervention on fatigue as measured by the Fatigue Impact Scale (FIS) at baseline and 3 months.
5. To assess health-related quality of life expressed as utility using the EQ-5D-5L questionnaire, at baseline, 6 weeks and 3 months.
6. To gather information on healthcare resource use using an adapted client service receipt inventory at baseline, 6 weeks and 3 months.
7. To assess the cost-effectiveness of the LISTEN intervention using an adapted client service receipt inventory at baseline, 6 weeks and 3 months.
8. To explore key anticipated mediators of intervention outcome (namely self-efficacy in the context of COVID-19) using the generalised self-efficacy scale (GSES) with additional context-specific questions at baseline and 3 months
9. To conduct a theory-driven detailed process evaluation within the trial using validated implementation scales to assess intervention acceptability, appropriateness and feasibility (through use of the AIM, IAM and FIM questionnaires, respectively) for a selection of intervention users at 3 months and providers at 3 months and 6 months into recruitment.

Overall study start date
01/08/2021

Completion date
31/07/2023

Eligibility

Key inclusion criteria
1. Age ≥18 years, AND
2. English or Welsh speaker or have access to someone who can act as a translator
3. Consulted with their GP to rule out serious complications or the need for further investigation in relation to persistent symptoms following COVID-19 infection, AND
4. Experience persistent illness (at least one long COVID symptom for 12 weeks or longer, AND
4.1 Positive SARS-CoV-2 PCR or antigen test (positive COVID19 test) during the acute phase of illness, OR
4.2 Positive SARS-CoV-2 antibody test (positive COVID-19 antibody test) at any time point in the

absence of SARS-CoV-2 (COVID-19) vaccination history, OR
4.3 Loss of sense of smell or taste during the acute phase in the absence of any other identified cause, OR
4.4 Symptoms consistent with SARS-CoV-2 (COVID-19) infection during the acute phase and high prevalence of COVID-19 at time and location of onset, OR
4.5 At least one symptom consistent with SARS-CoV-2 (COVID-19) infection during the acute phase AND close contact of a confirmed case of COVID-19 around the time of onset

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 558; UK Sample Size: 558

Total final enrolment
554

Key exclusion criteria
1. Any co-morbidities which are progressive or requiring palliative treatment.
2. Have been hospitalised for treatment of COVID-19 symptoms, during the acute phase of COVID illness.
3. Are currently participating in any COVID intervention trial (including contributing to the LISTEN co-design activities).

Date of first enrolment
01/03/2022

Date of final enrolment
28/02/2023

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff Locality - Cardiff & Vale University Lhb
Trenewydd

5 Fairwater Road
Cardiff
United Kingdom
CF5 2LD

Sponsor information

Organisation
Kingston University

Sponsor details
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Sponsor type
University/education

Website
http://www.kingston.ac.uk/

ROR
https://ror.org/05bbqza97

Funder(s)

Funder type
Government

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

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
As part of our Pathway to Impact, we will produce the LISTEN manual, including a clinical delivery and implementation guide (for services). We will provide service user-facing materials (including podcasts and blog posts from individuals with long Covid), a LISTEN briefing document and an infographic for DHSC/SAGE, namely a two-page summary with what we found, what it means and how to scale it. In the last 3 months, we will hold a knowledge mobilisation event to discuss and debate the findings and consider implementation at scale.

Intention to publish date
01/09/2024

Individual participant data (IPD) sharing plan
Data will be made available for sharing after reporting of the main trial results (anticipated to be 12 months after end of study date). Prior to the “end” of study, the protocol will define data that is available and analyses which are deemed appropriate. Participants will have been approached for their consent/dissent in line with these analyses. Prior to approved analyses being undertaken verification of consent or staged withdrawal of consent will be undertaken. All data sharing will adhere to regulatory requirements and in particular General Data Protection Regulation. Professor Fiona Jones is the data custodian (Co-chief investigator of the LISTEN project). Requests for data access should be made to Professor Monica Busse at CTR@cardiff.ac.uk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3.0	13/12/2021	26/01/2022	No	Yes
Protocol file	version 2.1	20/12/2021	26/01/2022	No	No
Protocol article		03/02/2023	03/02/2023	Yes	No
HRA research summary			26/07/2023	No	No
Other publications	An exploration of the experiences and self-generated strategies used when navigating everyday life with Long Covid	13/03/2024	14/03/2024	Yes	No
Results article		31/01/2025	14/04/2025	Yes	No
Results article	Process evaluation secondary measure	05/05/2025	08/05/2025	Yes	No