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Using activity tracking and just-in-time messaging to improve adaptive pacing in people with long COVID: a pragmatic randomised control trial

Submission date
16/07/2021

Recruitment status
No longer recruiting

Registration date
08/11/2021

Overall study status
Completed

Last Edited
13/02/2025

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Long-COVID symptoms often get much worse after activity. Adaptive pacing (AP) is a way for people coping with long-COVID to manage their day-to-day activity so that they don't make their symptoms worse. AP means patients must balance what they plan to do with how much energy they feel they have. This is not always easy because the amount of activity that will cause symptoms to worsen is different for everyone. Also, individuals must keep track of their activity (perhaps for several days) which can also be challenging, particularly if poor memory is a symptom.

With help from people with long-COVID, we have developed an approach to make AP easier. We will track activity remotely and send alerts if they risk doing too much. This way, people managing with long-COVID might avoid over-exertion and prevent periods where symptoms worsen.

Who can participate?
Adults reporting persistent symptoms which have lasted for at least 8-weeks after initial infection with COVID-19 and which interfere with day-to-day activity and who have access to a smartphone.

What does the study involve?
We will ask a group with long-COVID to wear a Fitbit activity monitor and download a mobile phone app designed by us. We will use the information from the Fitbit to keep track of each participants activity level. We will then send alert messages if it looks like they might do too much. This way, each person will have their own AP plan. The activity and messaging support will last for 6-months. After this, we will see if our approach was effective by comparing how often symptoms worsened compared to a control group who only received standard AP advice. If this

approach works, we will see if the tracking and messages can be improved and offer an updated version to the control group so they can also benefit. We will also look for ways to scale up the process to help more people.

What are the possible benefits and risks of participating?
The researchers cannot guarantee any benefits from participating in this study. However, it is possible that participants will better manage their symptoms and avoid periods where their symptoms get worse. Participants will better understand how activities affect their heart rate. There are no anticipated risks. Messages to participants will suggest they take breaks and will not request participants do anything they would not normally do.

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

When is the study starting and how long is it expected to run for?
July 2021 to February 2024

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

Who is the main contact?
Prof. Nicholas Sculthorpe, nicholas.sculthorpe@uws.ac.uk
Dr Lawrence Hayes, lawrence.hayes@uws.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
COV-LT2-0010

Study information

Scientific Title
A randomised controlled trial of activity tracking and JITAI managed adaptive pacing for symptoms of post-exertional malaise in people with long-COVID

Acronym
ATJ-PEM

Study objectives
An activity tracking and personalised just-in-time adaptive intervention (JITAI) will reduce symptoms of post-exertional malaise (PEM) in people with long-COVID compared to usual care six months after ransdomisation.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 12/08/2021, University of the West of Scotland Health and Life Sciences Ethics Committee (Stephenson Place Hamilton International Technology Park Blantyre, Glasgow G72 0LH; no telephone contact provided ; gary.boyd@uws.ac.uk), ref:16638

Study design
Pragmatic single centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

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
Reducing frequency and severity of post-exertional malaise in people with long COVID.

Interventions
250 participants with long COVID will be randomised into intervention and control groups using a secure, independent online trial allocation service. Allocation will be stratified for age and sex.

125 Participants in the control group will receive standard advice on pacing and managing energy levels. Participants in the intervention group will receive an activity tracker and a bespoke mobile phone 'App'. Each day, using their activity tracking data intervention participants will receive individualised alert messages when they spend time above a specific HR determined activity threshold (eg. time above 130 bpm) and if they have not spent sufficient time at rest.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 13/02/2025:

Post-exertional malaise using the DSQ-PEM at baseline and 6 months

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Previous primary outcome measure as of 05/04/2024:

Post-exertional malaise using the PEM questionnaire at baseline and 6 months

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Previous primary outcome measure as of 07/03/2023:

Physical functioning assessed via the SF-36 at baseline and 6 months

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Previous primary outcome measure:

Post-exertional malaise using the PEM questionnaire at baseline and 6 months

Secondary outcome measures

Current secondary outcome measures as of 05/04/2024:

1. PEM trend using PEM questionnaire assessed monthly
2. Depression trend using PHQ-9 monthly
3. Depression change using PHq-9 assessed at baseline and 6 months
4. Fatigue trend using FSS monthly
5. Fatigue change using FSS at baseline and 6 months
6. Quality of life trend using SF12 monthly
7. Quality of life change using SF12 at baseline and 6 months
8. Self-efficacy trend using Self Efficacy Scale monthly
9. Cognitive function using a variation of the symbol digit modalities test monthly
10. Cognitive function using a variation of the symbol digit modalities test at baseline and 6 months.
11. Pain using Pain VAS assessed at baseline and 6 months
12. Pain trend using Pain VAS assessed monthly between months 0-6
13. Resting heart rate assessed daily using the activity tracker

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Previous secondary outcome measures:

1. PEM trend using PEM questionnaire assessed monthly
2. Depression trend using PHQ-9 monthy
3. Depression change using PHq-9 assessed at baseline and 6 months
4. Fatigue trend using FSS monthly
5. Fatigue change using FSS at baseline and 6 months
6. Quality of life trend using SF36 monthly
7. Quality of life change using SF36 at baseline and 6 months
8. Self-efficacy trend using Self Efficacy Scale monthly
9. Cognitive function using a variation of the symbol digit modalities test monthly
10. Cognitive function using a variation of the symbol digit modalities test at baseline and 6 months.
11. Pain using Pain VAS assessed at baseline and 6 months
12. Pain trend using Pain VAS assessed monthly between months 0-6
13. Resting heart rate assessed daily using the activity tracker

Overall study start date

16/07/2021

Completion date
28/02/2024

Eligibility

Key inclusion criteria
1. Adults reporting persistent symptoms which have lasted for at least 8 weeks after initial infection with COVID-19 and which interfere with day-to-day activity.
2. Participants should be recovering at home and have access to an Android (SDK16 or higher) or iPhone (iOS version 10 or higher) mobile phone.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned sample size is 172 with 86 participants per group. To allow for 30% attrition, we plan to recruit a total of 125 per group and 250 participants in total.

Total final enrolment
250

Key exclusion criteria
1. Currently receiving ongoing care for LC via primary or secondary care services.
2. Prior diagnosis with a comorbidity with similar symptoms (e.g. ME/CFS).
3. Currently receiving a therapy known to cause exacerbations.
4. Currently participating in another LC focussed intervention.
5. Impaired cognitive function which compromises comprehension of study information or messaging.
6. Insufficient English language for messaging to be effective.
7. No mobile phone access

Date of first enrolment
01/12/2021

Date of final enrolment
15/02/2023

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
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Sponsor information

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University/education

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ROR
https://ror.org/04w3d2v20

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

Results and Publications

Publication and dissemination plan
The researchers intend to publish a paper on the development of the intervention in scientific peer-reviewed journals, and will disseminate their findings at academic conferences, NHS events, and within our local research community.

Intention to publish date
28/02/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof Nicholas Sculthorpe (nicholas.sculthorpe@uws.ac.uk). Type of data: Pre and Post PEM data, Pre and Post cognitive function, Fatigue, and depression data and Interview transcripts. The researchers will be using the data to inform future studies, so envisage that it would be two years after the end of the study before they would be willing to share the data, and it will be available for four years thereafter. Only researchers who are undertaking intervention development studies using Just-In-Time adaptive interventions (JITAIs) and who wish to investigate appropriate adaptations for intervention acceptability by undertaking secondary analysis may access the data on request to the principal investigator. Consent will request participants agree to the statement “information about me may be used in other research, but the information will not use my name.” All transcripts will be anonymised with any identifying information removed. Participants will be able to agree to participate but opt out of data sharing. Data for those participants will not be available.

IPD sharing plan summary
Available on request