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Reducing fatigue in Long COVID-19: A feasibility study of a self-help intervention to reduce fatigue-related symptoms among patients in general practice

Submission date
03/08/2022

Recruitment status
No longer recruiting

Registration date
09/08/2022

Overall study status
Completed

Last Edited
31/05/2023

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
We know many people who have COVID-19 can feel fatigued and that this doesn't always go away. Our study aims to test a treatment already used with patients who have chronic fatigue syndrome (ME/CFS) to see if it could help.

Who can participate?
Adults aged 18 years or over can participate, who received a positive COVID test between July 2020 and February 2022. Entry into this Phase 2 intervention trial is via initial screening through our original Phase 1 online survey. Invitations to this Phase 1 survey are sent by email or text to patients who volunteered to join the Research for the Future database OR to patients with a GP in Greater Manchester who invite them to take part.

What does the study involve?
One of our research practitioners will telephone or email you if you are eligible and have provided your contact details when you completed the Phase 1 survey. if you agree to take part they will go through a consent form over the phone or by email with you and answer any questions you might have, You will then be allocated at random to either receive the intervention treatment immediately or 12 weeks later. The intervention kits will be sent through the post to you at home.
You will be asked to follow a treatment plan over the next 12 weeks and have a tick list to monitor this. You will be provided with all you need to do this: a long handled massager, massage oil, hot water bottle, cold gel pack and instructions plus a link to video demonstration and a contact for our patient liaison advocate who can help answer any questions.
After 12 weeks all participants will be asked to complete the same short online survey.
Those without intervention packs will then receive theirs through the post.
You can choose to continue to use the pack if you wish after the initial 12 weeks.

Some participants will be asked to take part in an interview over the phone about their experiences of using the treatment.
We ask everyone to repeat the short online survey again at 24 weeks.

What are the possible benefits and risks of participating?
We hope using the treatment will help your fatigue and this has been used successfully for a number of years in people with fatigue. This study reduces the need to attend centres for treatment and we hope this along with the short survey will help reduce participant burden. The treatment takes around 30 minutes each day to complete though can be used more if you wish. In order to benefit from the hot / cold therapy we recommend wrapping the hot water bottle and gel cold packs in cloths to avoid any burning of the skin.

Where is the study run from?
The study is run from Salford Royal Hospital (UK) with colleagues from The University of Manchester and The Perrin Clinic also involved in the study.

Who is funding the study?
The study is funded by Fund into Osteopathic Research Into ME (FORME) (UK) a charity to help patients with chronic fatigue (ME/CFS) who also have an interest in underlying causes of fatigue and Long COVID.

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

Who is the main study contact?
Dr Lisa Riste
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
291940

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

IRAS 291940, Sponsor 21OTHER01-S, CPMS 51098

Study information

Scientific Title
In people with Long COVID related fatigue, is there a difference between participants using self-help lymphatic drainage vs. no intervention on fatigue (assessed using Chalder Fatigue Questionnaire (CFQ) score) at 12 weeks?

Study objectives
Self-help intervention techniques that promote lymphatic drainage will help reduce fatigue in patients with Long COVID more than those in the wait-lit control arm at 12 weeks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/01/2022, London - Chelsea Research Ethics Committee London Centre (2 Redman Place,
Stratford, London, E20 1JQ, UK; +44 (0)207 104 8029; chelsea.rec@hra.nhs.uk), ref: 21/LO/0809

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

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
Fatigue symptoms following Long COVID

Interventions
Following consent over the telephone by one of our research practitioners, participants will be randomised into the trial using sealed envelope (TM) 1:1 intervention to wait-list control. Randomisation will be stratified by gender and by recruitment site (RftF vs FARSITE GP invitation). Eligible participants will be allocated at random (1:1) in blocks of size 4, 6 or 8 (chosen at random and in equal numbers) to:
Intervention: This group will receive an intervention pack containing; patient instructions and

online video link, a long handled massager and massage oil, hot water bottle and gel pack for contract bathing and a tick sheet to monitor recommended exercises,
Wait-list control group: Will receive the same pack 12 weeks after randomisation.
Both groups will be asked to complete follow-up online surveys at 3 months (12 weeks) and 6 months (24 weeks) post RDZ.

Intervention Type
Behavioural

Primary outcome measure
1. The recruitment rate into our Phase 2 intervention will be recorded as the number of eligible participants who consented to participate in the study over the 4 month recruitment period.
2. The attrition rate in our Phase 2 intervention will be recorded as the number of eligible participants who consented to participate in the study but had not completed final 24 week follow-up measures.

Secondary outcome measures
1. Fatigue is measured using Chalder Fatigue Questionnaire (with participants completing online questionnaire using scoring 0,1,2,3) at 0, 12 and 24 weeks.
2. Physical functioning is measured using SF-12 at 0,12 and 24 weeks (online questionnaire) at 0, 12 and 24 weeks.
3. Quality of life is measured using EQ-5D at 0,12 and 24 weeks (online questionnaire) at 0, 12 and 24 weeks.

Overall study start date
12/03/2021

Completion date
30/11/2023

Eligibility

Key inclusion criteria
1. Adult aged 18 years or over
2. Tested positive for COVID (between July 2020 and February 2022)
3. Scored of 4 or more on Chalder Fatigue Questionnaire scored bimodally (0,0,1,1)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

100

Total final enrolment
100

Key exclusion criteria
1. Less than 18 years
2. Current or previous ME/CFS diagnosis
3. Current end-stage heart failure, cancer, sleep apnoea (or other major sleep disorders)
4. Major mental health diagnoses (eg. schizophrenia)
5. Pregnant and lactating women
6. Care home residents
7. Dementia

Date of first enrolment
01/08/2022

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northern Care Alliance NHS Foundation Trust
Salford Royal
Stott Lane
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
Northern Care Alliance

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Directorate Research & Innovation
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Sponsor type
Hospital/treatment centre

Website
https://www.northerncarealliance.nhs.uk/

Funder(s)

Funder type
Charity

Funder Name
Fund for Osteopathic Research into ME (FORME)

Results and Publications

Publication and dissemination plan
We will aim to have research outputs in the form of original research articles published in Open Access peer review journals and will seek to raise the profile of our work at conference presentations. All the study team will be invited to participate in the writing, reviewing and editing of papers and will conform to guidance issues by IJCME.

Results of the study will be disseminated by the Northern Care Alliance NHS Foundation Trust via their website: https://www.reserchforthefuture.org, newsletters and social media. This will ensure that volunteers who have participated in this research have access to the study findings

Intention to publish date
31/08/2024

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.
The database will be available as locked-read only CSV spreadsheet which will be uploaded alongside the manuscript submitted for publication. This will allow other researchers to access our feasibility data and show openness and transparency in our work.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 0.2	10/12/2021	09/08/2022	No	Yes
Protocol file	version 0.2	10/12/2021	09/08/2022	No	No
HRA research summary			26/07/2023	No	No