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Does weight management improve Long COVID symptoms in people with Long COVID and obesity?

Submission date
21/10/2021

Recruitment status
No longer recruiting

Registration date
25/11/2021

Overall study status
Completed

Last Edited
10/01/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Around 10% of people with COVID-19 have symptoms that last for 12 weeks or longer – this is termed as having Long COVID. Long COVID symptoms are more likely to affect people with overweight/obesity compared to the rest of the population. Weight management programmes in adults with overweight/obesity can reduce symptoms such as fatigue, breathlessness and pain, however, it is not known how effective intentional weight loss is at reducing Long COVID symptoms. The aim of this study is therefore to test the effectiveness of a well-established professional weight management programme in people with Long COVID.

Who can participate?
People aged 18 or over with Long COVID symptoms persisting for more than 3 months before first recruitment contact, not currently hospitalised, with body mass index (BMI) above 27 kg/m² (>25 kg/m² for South Asians)

What does the study involve?
Participants will be randomly allocated (by a computer programme) to one of two groups:
1. Immediate entry to a remote structured weight management programme, which includes an initial period of total diet replacement (soups and shakes), followed by carefully managed food reintroduction and then weight loss maintenance to enable participants to manage their weight in the long term
2. “Delayed entry”, after 6 months, to the structured weight management programme
This study is entirely “remote”: there is no need to travel to a research centre or a hospital, and participants can remain at home for the duration of the study. They will receive a set of scales and a blood pressure monitor, and will be asked to report measurements of weight, height, blood pressure and physical activity. They will also be asked to complete questionnaires to name and rate their Long COVID symptoms, as well as questionnaires to assess demographics, medical history, medications, health, and overall enjoyment of life.
Following this, participants will be randomly allocated to receive 12-months treatment on the Counterweight-Plus/DiRECT diet weight management programme, which is delivered online by Counterweight Ltd with personal video/telephone support contact. Around 100 participants will

start the programme immediately following their first appointment, with the remaining 100 participants being offered access to the programme after a 6-month delay.
When participants start the weight management programme, they will be asked to stop eating their usual food and meals and instead start a Total Diet Replacement Plan of soups and shakes for 12 weeks, with the aim of achieving their maximum potential weight loss. The soups and shakes will be provided free of charge as part of the study. Participants will be provided with the Counterweight app, for recording measurements, e.g. weight, blood pressure etc, and provided with weekly educational content. During this 12-week period, they will also be supported and given advice by a specialist Counterweight dietitian, with monthly online/telephone appointments. There will also be an option of additional support via an app, through a chat function.
After 12 weeks on the soups and shakes, participants will be helped to reintroduce normal foods into their diet gradually over the next 8 weeks. During this time, they will continue to record measurements and will be provided with weekly educational content. Also, they will continue to have monthly online/telephone appointments with their specialist Counterweight dietitian. There will also still be an option of additional support via an app through a chat function.
The initial two phases of the programme aim to achieve at least 15-20 kg (2-3 stones) weight loss. Once the food re-introduction phase is completed, participants will enter the weight loss maintenance programme to learn how to maintain their new lower weight while enjoying a variety of foods. Participants will continue to be supported by their specialist Counterweight dietitian and offered monthly online/telephone appointments for up to 12 months. They will continue to be provided with educational content/advice to help maintain their weight loss which will include goal-setting, self-monitoring, physical activity, relapse prevention if their weight tends to rise again, and nutrition education.

What are the possible benefits and risks of participating?
There are very few health risks from following this weight management programme. Some people may experience some of the symptoms listed below during weight loss. These are usually temporary and go away once body weight is stable at a lower level.
1. Constipation (the researchers advise taking Fybogel to overcome this)
2. Dizziness is possible when standing up suddenly. This is due to the body adjusting to a healthier, lower blood pressure and happens mainly in those who are taking medication to control their blood pressure. If this occurs, take more time standing up, and aim to remain well hydrated by drinking plenty of water.
3. Gallstones – this is unusual and is most often a consequence of existing gallstones. The diet in this study contains some fat, which further minimises the risk of gallstone problems.
4. Taking part will involve a change in lifestyle and substantial time commitment. The weight management programme is challenging but participants will be given full support throughout the study.
While the researchers anticipate that participants in the study will lose weight, there is no guarantee of improvement in health or success of the intervention. Others living with Long COVID and overweight/obesity in the future, but who are not participating in this study, may benefit from the results of this study.

Where is the study run from?
Dykebar Hospital (UK)

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

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

Who is the main contact?
Diann Taggart, diann.taggart@ggc.scot.nhs.uk

Study website
http://www.redirectstudy.co.uk

Contact information

Type(s)
Public

Contact name
Ms Diann Taggart

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
304075

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
GN21ME311, IRAS 304075, CPMS 51463

Study information

Scientific Title
Remote Diet Intervention to Reduce Long COVID symptoms Trial

Acronym
ReDIRECT

Study objectives

Previous research has shown multiple clinical and personal benefits from weight loss, including increased energy levels, improved general wellbeing and better quality of sleep. It is not clear, however, whether supported weight loss can improve symptoms of Long COVID.

The hypothesis being tested is that supported weight loss in adults with Long COVID and overweight/obesity can improve symptoms of Long COVID such as fatigue, breathlessness, pain and depression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending, South East Scotland REC01 (Waverly Gate, 2-4 Waverly Place, Edinburgh, EH1 3EG, UK; +44 (0)131 465 5473; sandra.wylie@nhslothian.scot.nhs.uk), REC ref: 21/SS/0077

Study design
Baseline randomized remote-delivered non-blinded wait-list controlled trial (with entry after 6 months) with mixed methods process and economic evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Quality of life

Participant information sheet
See additional files

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

Interventions
Following completion of baseline data participants will be allocated to one of the two groups using a mixed minimisation/randomisation approach. 80% of participants will be allocated according to minimisation algorithm or allocated at random, if neither allocation achieves lower imbalance and the remaining 20% will be allocated at random. Participants will be randomised at baseline in a 1:1 ratio to the intervention arm (Counterweight Plus/DiRECT diet) or the wait-list control arm.

Control - participants allocated to the control arm will be given access to the Counterweight Plus /DiRECT programme after 6 months

Intervention - Counterweight Plus/DiRECT diet programmes are delivered by Counterweight Ltd via an online platform with text chat, video or telephone support. Individuals will be allocated a named "Counterweight Coach" for personal support for regular appointments and to moderate

an online chat facility to enable peer support between participants. Counterweight coaches include many specialist dieticians, and professionals experienced in behaviour change (i.e. psychology graduates). Coaches receive formal competency-based training from a Counterweight specialist, then ongoing supervision and mentoring to maintain programme fidelity.

Intervention Type
Supplement

Primary outcome measure
The primary outcome will be a continuous measure derived from the symptom score for the most important Long COVID symptom reported by the participant at baseline, 3 and 6 months, with the 6-month measure the primary outcome. Participants will complete symptom scores at baseline and will nominate the symptom they would most like to improve:
1. Fatigue measured using the Validated Chalder Fatigue Scale (CFQ-11)
2. Breathlessness measured using the modified MRC Dyspnoea Scale
3. Pain measured using the P4 Numeric Pain Rating Scale
4. Anxiety and depression measured using the Hospital Anxiety & Depression Scale (HADS) questionnaire
5. Other - for other symptoms with no pre-specified scale, the researchers will use a Visual Analogue Scale (0 to 10)

Secondary outcome measures
Measured at baseline, 3 and 6 months:
1. The symptoms not nominated by each participant as their primary outcome measure (listed above) will become secondary outcomes
2. Quality of life measured using the EQ-5D-5L
3. Work productivity measured using the Work Productivity and Activity Impairment (WPAI) questionnaire
4. Weight in kg will be measured by self-reporting (participants will be sent their own weight scales)
5. A process evaluation will assess the implementation of the intervention in terms of dose, fidelity and reach and explore the experience of the intervention from the perspective of participants including acceptability, patterns of use, and barriers and facilitators to use. This will be done using semi-structured interviews.
6. Cost-effectiveness of the intervention assessed using an economic evaluation

Overall study start date
31/03/2021

Completion date
31/05/2024

Eligibility

Key inclusion criteria
1. People with Long COVID symptoms persisting >3 months before first recruitment contact, not currently hospitalised
2. People who are aged 18 or above
3. People with body mass index (BMI) above 27 kg/m² (>25 kg/m² for South Asians)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240

Key exclusion criteria
1. People who have had lengthy hospitalisations (>10 days) or intensive care unit (ICU) admissions related to COVID-19
2. People who are currently on insulin or anti-obesity drugs
3. People who have had a proven myocardial infarction within the last 6 months
4. People with severe mental illness (including severe depression and eating disorders)

Date of first enrolment
20/12/2021

Date of final enrolment
04/07/2022

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Glasgow
Institute of Health and Wellbeing
1 Horselethill Road
Glasgow
United Kingdom
G12 9LX

Study participating centre
NHS Ayrshire & Arran
PO Box 13 Boswell House
10 Arthur Street

Ayr
United Kingdom
KA7 1QJ

Study participating centre
NHS Borders
Newstead
Melrose
Roxbughshire
United Kingdom
TD6 9DB

Study participating centre
NHS Lanarkshire
14 Beckford Street
Hamilton
United Kingdom
ML3 0TA

Study participating centre
NHS Grampian
Summerfield House
2 Eday Road
Aberdeen
United Kingdom
AB15 6RE

Study participating centre
NHS Tayside
Kings Cross
Clepington Road
Dundee
United Kingdom
DD3 8EA

Study participating centre
NHS Fife
Springfield House
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United Kingdom
KY15 5UP

Study participating centre
NHS Greater Glasgow & Clyde
JB Russell House
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH

Study participating centre
NHS Highland
Reay House
17 Old Edinburgh Road
Inverness
United Kingdom
IV2 3HG

Study participating centre
NHS Orkney
Garden House
New Scapa Road
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KW15 1BQ

Study participating centre
NHS Lothian
Waverly Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre
NHS Forth Valley
33 Spttal Road
Stirling
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FK8 1DX

Study participating centre
NHS Western Isles
37 South Beach Street
Stornoway
United Kingdom
HS1 2BN

Study participating centre
NHS Dumfries & Galloway
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The Crichton
Bankend Road
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United Kingdom
DG1 4ZG

Study participating centre
NHS Shetland
Brevik House
South Road
Lerwick
United Kingdom
ZE1 0RB

Sponsor information

Organisation
NHS Greater Glasgow and Clyde

Sponsor details
Research & Innovation
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PA2 7DE
+44 (0)141 314 4012
maureen.travers@ggc.scot.nhs.uk

Sponsor type

Hospital/treatment centre

Website
http://www.nhsggc.org.uk/

ROR
https://ror.org/05kdz4d87

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
NHS Greater Glasgow & Clyde and the University of Glasgow are joint controllers of the data arising from this study.

Once the study has been completed, a final report will be prepared for publishing purposes and to feedback research results to both the Sponsor and REC. This will be provided to Sponsor/REC via email and will be made accessible to the wider research community on international study registry websites such as ClinicalTrials.gov or EudraCT. The CI will have the right to publish the study data. There are no sponsor review requirements on publications.

There are no plans to notify participants of the outcome of the study. The results will instead be used to provide evidence for future research proposals that will be subject to sponsor and the appropriate regulatory approvals. Participants will be provided with CI/PI contact details in the participant information sheet and will have the opportunity to request results from their PI if

they so wish. Participants will be advised upon requesting results that these will be made available once data analysis has been completed and/or the final study report has been compiled.

The main study documentation - study protocol and full study report - will be made accessible to the wider research community on international study registry websites such as ClinicalTrials.gov or EudraCT within 1 year of study opening. The protocol will be published at the end of 2021 /early 2022, and the statistical analysis plan will be available until 2022. The final protocol will be provided once ethics approval is received.

Intention to publish date
01/11/2024

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date. When publishing quantitative results the researchers will follow Office for National Statistics (ONS) guidance to ensure that presented data does not include any information that could be potentially identifiable. For qualitative results (from process evaluation) all participants will be anonymised and the researchers will ensure no quotations could be potentially identifiable.

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?
Participant information sheet	version 1.0	12/08/2021	09/11/2021	No	Yes
Protocol file	version 1.1	19/11/2021	15/08/2022	No	No
Protocol article		03/08/2023	26/10/2023	Yes	No
Participant information sheet	version 1.1	19/11/2021	28/06/2024	No	Yes
Statistical Analysis Plan	version 1.0	24/04/2023	28/06/2024	No	No
Other publications	Baseline Characteristics	05/03/2024	15/08/2024	Yes	No
Results article		08/01/2025	10/01/2025	Yes	No