ISRCTN11466448 https://doi.org/10.1186/ISRCTN11466448

A randomized trial to assess the effects of physical and mental health rehabilitation for people recovering from COVID-19

Submission date
20/11/2020

Recruitment status
No longer recruiting

Registration date
23/11/2020

Overall study status
Completed

Last Edited
01/11/2024

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
People recovering from COVID-19 can feel weak, breathless and tired. Some people are also worried and frightened. For most people, these problems will get better on their own, but for some people, they may continue for a long time after leaving hospital. A rehabilitation programme may help. For people who are still struggling months after being ill with COVID-19, the aim of this study is to find out which of two treatments is better for helping people recover: a single online session of exercise advice and support or an 8-week online exercise and support programme

Who can participate?
People who have been treated in a UK hospital for COVID-19 who were discharged more than 3 months ago and still have health problems due to COVID-19

What does the study involve?
After a questionnaire has been completed, participants will be assigned by chance (randomised) to one of the two treatments. Participants assigned to a single online session of exercise advice and support will have a 30-minute call with a REGAIN exercise specialist during which they will be given information on how to safely increase activity and exercise at home. They will also be directed to websites where more information and support can be found and will be able to ask questions about recovery from COVID-19.
Participants assigned to an 8-week online exercise and support programme will have a 60-minute call with a REGAIN exercise specialist during which they will be given an activity and exercise plan to follow at home. Participants will also be directed to websites where more information and support can be found and will be able to ask questions about recovery from COVID-19. They will also join a live online exercise (1 hour per week) and support (1 hour per week) group for 8 weeks, and will be able to access on-demand physical activity and exercise sessions as required.

What are the possible benefits and risks of participating?
Although this study may not offer any direct benefit, the findings may help people recovering

from COVID-19 in the future. The researchers do not anticipate any serious risk to participants. There is always a very small chance that exercise can make people feel unwell. Exercise may cause tiredness, breathlessness and sore muscles, but this should get a bit easier over time. All exercise will be advised and monitored by specialist staff. Sometimes people can find the support sessions upsetting. Fully trained specialist staff will provide appropriate support and assistance if needed.

Where is the study run from?
University Hospitals Coventry and Warwickshire NHS Trust (UK)

When is the study starting and how long is it expected to run for?
September 2020 to September 2023

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

Who is the main contact?
Ms Sharisse Alleyne
REGAIN@warwick.ac.uk

Study website
https://warwick.ac.uk/regain/

Contact information

Type(s)
Scientific

Contact name
Ms Sharisse Alleyne

Contact details
REGAIN Trial Manager
Warwick Clinical Trials Unit
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CV4 7AL
-
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
288362

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 46819, IRAS 288362

Study information

Scientific Title
Rehabilitation Exercise and psycholoGical support After covid-19 InfectioN (REGAIN): a multi-centre randomized controlled trial

Acronym
REGAIN

Study objectives
An intensive, online, supervised, group, home-based rehabilitation programme will be clinically and cost-effective, compared to best practice usual care, for people discharged from hospital (>3 /12) after COVID-19 infection

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/11/2020, East of England – Cambridge South REC (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)2071048065; cambridgesouth.rec@hra.nhs.uk), REC ref: 20/EE/0235

Study design
Randomized; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Physical, Rehabilitation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
https://warwick.ac.uk/fac/sci/med/research/ctu/trials/regain/regain_pis.pdf

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions

Current intervention as of 13/03/2023:
A multi-centre RCT testing the clinical and cost-effectiveness of an intensive, online, supervised, group, home-based rehabilitation programme that supports long-term physical and mental health recovery (REGAIN) vs. best-practice usual care for people discharged from hospital (>3 /12) after COVID-19 infection.

Patients will be identified via three routes:

1. Participant Identification Centres
Clinical care teams at UHCW NHS Trust and each PIC site (NHS hospital trust) will screen hospital discharge data and identify potential participants for contact by mail. The sites will send potential participants an infographic flyer and invitation letter which will direct potential participants to the study website to find out more information and to register their interest.

2. Self Referral
A REC-approved infographic invitation flyer will be used to promote the study. These infographic invitation flyers will be provided to relevant primary and secondary care NHS COVID clinics for staff to hand out to potential participants. The flyers will also be displayed and available at GP practices and pharmacies. The study will be promoted through local/national media/social media, relevant charities and on the study website. People suffering from ongoing COVID-19-related symptoms following hospital discharge will be able to self-refer and to register their interest via the study website.

3. NHS Digital screening
At the time of writing, the Secretary of State for Health and Social Care has issued NHS Digital with a Notice under Regulation 3(4) of the Health Service (Control of Patient Information) Regulations 2002 (COPI) to require NHS Digital to share confidential patient information with organisations entitled to process this under COPI for COVID-19 purposes. As such, whilst this COPI Notice is in effect, participants will be identified by NHS Digital for inclusion in the REGAIN study in support of the pandemic response.

Further to baseline assessment, a total of 535 participants will be randomised to the REGAIN intervention or best practice usual care.

The REGAIN Intervention: Eight-week, online, supervised, home-based, exercise rehabilitation programme with behavioural, motivational and mental health support.

Best-practice usual care consisting of a single online session of advice and support.

Outcomes will be assessed at baseline pre-randomisation, 3, 6 and 12 months (post-randomisation). The primary outcome will be HRQoL measured using the PROMIS® 29+2 Profile v2.1 (PROPr) at 3 months post-randomisation. Data will be collected directly from trial participants using online data collection.

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Previous intervention as of 19/03/2021:
A multi-centre RCT testing the clinical and cost-effectiveness of an intensive, online, supervised, group, home-based rehabilitation programme that supports long-term physical and mental health recovery (REGAIN) vs. best-practice usual care for people discharged from hospital (>3 /12) after COVID-19 infection.

Patients will be identified via two routes:

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Intervention Type
Other

Primary outcome measure
Health-related quality of life (HRQoL) measured using the PROMIS® 29+2 Profile v2.1 (PROPr) at 3 months post-randomisation

Secondary outcome measures
Measured at 3, 6 and 12 months post-randomisation:
1. Health-related quality of life (HRQoL) measured using PROPr
2. Dyspnoea measured using PROMIS dyspnoea severity Short Form
3. Cognitive function measured using PROMIS Neuro-QoL Short Form v2.0 - Cognitive Function
4. Health utility measured using Euroqol EQ-5D-5L
5. Physical activity participation measured using the International Physical Activity Questionnaire (IPAQ short-form)
6. PTSD symptom severity measured using the Impacts of Events Scale-Revised (IES-R)
7. Depressive and anxiety symptoms measured using the Hospital Anxiety and Depression Scale (HADS)
8. Work status measured using time lost from work (paid/unpaid) and patient-borne health costs
9. Health and social care resource use measured using participant self-report and NHS records
10. Death measured using GP data

Overall study start date
01/09/2020

Completion date
30/09/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 19/03/2021:
1. UK resident
2. Aged ≥18 years
3. ≥ 3 months after any UK hospital discharge related to COVID-19 infection, regardless of need for critical care or ventilatory support
4. Substantial, as defined by the participant, COVID-19 related physical and/or mental health problems

5. Access to, and ability/support to use, email, text message, internet video, including webcam and audio
6. Ability to provide informed consent
7. Able to understand spoken and written English or Bengali, Gujarati, Urdu, Punjabi, Mandarin themselves or with support from family/friends

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Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 535; UK Sample Size: 535

Total final enrolment
585

Key exclusion criteria
1. Exercise contraindicated
2. Severe mental health problems preventing engagement
3. Previous randomisation in the present trial
4. Patient already engaging in, or planning to engage in a conflicting NHS delivered rehabilitation programme in the next 12 weeks
5. A member of the same household has previously been randomised in the present trial

Date of first enrolment
30/11/2020

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital Coventry and Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation
University Hospitals Coventry and Warwickshire NHS Trust

Sponsor details
Research & Development
4th Floor Rotunda, ADA40007
Coventry
England
United Kingdom
CV2 2DX
+44 (0)2476 966198
ResearchSponsorship@uhcw.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.uhcw.nhs.uk/

ROR
https://ror.org/025n38288

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR132046

Results and Publications

Publication and dissemination plan
The study protocol will be published in a peer-reviewed journal. The researchers will publish papers in open-access journals describing the development and refinement of the REGAIN intervention, and the study protocol, as per recommended guidance for transparent reporting, the Consolidated Standards of Reporting Trials (CONSORT) guidelines (https://www.consort-statement.org), the NIHR standard terms, and Warwick SOP 22: Publication & Dissemination. The Warwick Clinical Trials Unit will publish the results of the trial on their website when these are available. Publication of the initial trial results, including the primary outcome, will take place as soon as possible (scheduled for January 2022).

Intention to publish date
30/09/2023

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.

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?
Protocol article	protocol	06/01/2021	07/01/2021	Yes	No
Other publications	Intervention development v1	23/02/2023	13/03/2023	Yes	No
Statistical Analysis Plan	version 2.0	25/10/2022	25/05/2023	No	No
Statistical Analysis Plan	Health economics analysis plan version 2.0	15/09/2022	25/05/2023	No	No
HRA research summary			28/06/2023	No	No
Other publications	Intervention development v2	14/07/2023	26/10/2023	Yes	No
Results article		07/02/2024	09/02/2024	Yes	No
Results article	Cost-effectiveness of an online supervised group physical and mental health rehabilitation programme for adults with post-COVID-19 condition after hospitalisation for COVID-19: the REGAIN RCT	31/10/2024	01/11/2024	Yes	No