

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/11/2020	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/11/2024	Condition category Infections and Infestations	<input type="checkbox"/> 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

Contact information

Type(s)

Scientific

Contact name

Ms Sharisse Alleyne

Contact details

REGAIN Trial Manager

Warwick Clinical Trials Unit

Warwick Medical School

University of Warwick

Gibbet Hill Road

Coventry

United Kingdom

CV4 7AL

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regain@warwick.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

288362

Protocol serial number

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

Study type(s)

Treatment

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.

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.

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Intervention Type

Other

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

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

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

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?
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	07/02/2024	09/02/2024	Yes	No
Results article	Intervention development v1	31/10/2024	01/11/2024	Yes	No
Protocol article	protocol	06/01/2021	07/01/2021	Yes	No
HRA research summary	Intervention development v2		28/06/2023	No	No
Other publications	Participant information sheet	23/02/2023	13/03/2023	Yes	No
Other publications		14/07/2023	26/10/2023	Yes	No
Participant information sheet		11/11/2025	11/11/2025	No	Yes

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes