

Rehabilitation Exercise and Psychological Support after COVID-19 Infection: The REGAIN Study



This information sheet explains the REGAIN study and what taking part will involve. Before you decide if you want to take part, please read the information carefully. Talk to others about the study if you wish and please feel free to ask any questions.

Why are we doing this study?

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.

For people who are still struggling months after being ill with COVID-19, we want 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

Why have I been asked to take part?

We are asking you to take part in this study because you were treated in hospital with COVID-19. We will be asking around 535 people from across the UK, to take part.

Who is eligible for the study?

To be eligible for the study you need to:

- be a UK resident
- have been treated in a UK hospital for COVID-19,
- have been discharged from a UK hospital more than three months ago,
- still have health problems due to COVID-19,
- not be taking part in a similar COVID-19 exercise and support programme
- have an email address and access to a device for video calls like a smartphone, laptop or tablet.

Please note, only one person per household can take part in the study.

Do I have to take part?

It is up to you to decide if you want to take part. If you agree to take part, we will ask you to complete a consent form. Even after completing the consent form, you can withdraw at any time without giving a reason. If you don't take part, or you withdraw, the standard of care you receive will not be affected.

If you decide to withdraw, we will keep the information about you that we have already collected. We will also continue to collect information about your health from your GP, if you have consented to this. If you do not want this to happen, please tell us and we will stop.

What does taking part in this study involve?

Check you are eligible

If you are interested in taking part, please follow the Suitability Check link on the study website www.warwick.ac.uk/regain where you will be asked to complete some questions to check that the study is right for you. Here you will be able to register your interest and provide your contact details. After this, a member of the study team will telephone you to confirm if you are eligible to take part in the study and to answer any questions you might have.

Consent to taking part

You will then be sent a web link to complete an online consent form. Once you have done this, we will ask you to complete an online questionnaire.

Online questionnaire

You will be asked about the impact COVID-19 has had on your physical and mental health and your quality of life. There are a number of questions, and some may appear similar, but your answers are really important. We appreciate the time you spend completing the questionnaire which should take about 20-30 minutes to complete. You can take a break and return to the questionnaire at any time. A member of the study team may contact you if any of your responses are unclear or missing. You can contact us by phone or email (details on last page) if you are having any problems with the questionnaire or the website.

You will be asked to complete this questionnaire again at three months, six months and twelve months. If we have any questions for you during the study, we will get in touch.

If you received an invitation letter from an NHS hospital, they will provide the study team with information about the length of your hospital stay and the type of care you received. This information will be linked to the information you provide, to help us to understand how your stay in hospital affects your ongoing COVID-19 symptoms and any other health problems.

Study groups

After you have completed your first questionnaire you will be assigned by chance (randomised) to one of two groups:

- 1) A single online session of exercise advice and support
- OR**
- 2) An 8 week online exercise and support programme

You or the research team will not be able to choose which group you are in. This will be decided by a computer at random, just like tossing a coin or drawing lots.

With your permission, we will contact your GP to let them know you are taking part in the study and to let them know how you answered questions about your mental health. If you do not want us to tell your GP, you will not be able to take part. There may be times when the study team need to act upon confidential information for safeguarding reasons. If our questionnaires or conversations with you highlight any health problems (physical or mental) that may require further treatment, we may refer you to your GP or other healthcare staff.

What will I have to do next?

Depending on which group you are assigned to, we will ask you to do different things:

Group 1: Single online session of advice and support

You will be invited to have a video or telephone call with a REGAIN exercise specialist. During the call you will be given information on how to safely increase the amount of activity and exercise you do at home. The call will last about 30 minutes. You will also receive a 'Your Covid Recovery Guide' by email which provides a summary of online programmes published by NHS England and directs you to websites where more information and support can be found. You will have the chance to ask questions about your recovery from COVID-19. With your consent, we will record this session. This is for quality control purposes and to provide the REGAIN team with an understanding of the topics and issues that generate discussion.

Group 2: Online exercise and support programme

This 8 week programme has three parts:

1. Online appointment

You will start by having a video or telephone call with a REGAIN exercise specialist who will tell you what to expect from the programme and discuss your health needs. Together you will work out an exercise plan that is suitable for your level of fitness. The video call will last up to 60 minutes. You will also be directed to websites where more information can be found. You will have the chance to ask questions about your recovery from COVID-19.

2. Online exercise sessions

We will ask you to exercise at home 2-3 times a week. There are a couple of ways of doing this:

- Join a **live online group exercise class** at least once a week. These will last 40 minutes. All classes will be led by a REGAIN exercise specialist and will include exercises to improve your fitness, strength, balance, co-ordination and mood. You will exercise at a level agreed by you and the specialist. You will be in groups of between 6 and 10 people who are also taking part in the research study. We will ask you brief online questions before and after each session to find out how you are

feeling and if you have had any problems. Where possible, some groups will be single sex (if you would prefer this).

- Take part in **on-demand exercise classes** which will be available online for you to choose from. There will be sessions suitable for everyone ranging from light exercise to harder exercise.

You will not need any special exercise equipment to take part in the sessions.

Although there is only a very small risk of becoming unwell during exercise, we recommend that you have another person nearby at home when you are doing your first few exercise sessions.

3. Online support group

You will also be invited to attend six online group support sessions with the same people who are in your exercise group. Each session will be led by a REGAIN specialist and will last about an hour. During the sessions you will be able to talk with the people in your group who are all recovering from COVID-19.

You will be provided with a workbook which includes general information about the REGAIN study. There will also be guidance on the exercise and support sessions, space to record the dates and times of your sessions, and some worksheets to use during the support sessions.

With your consent, we will observe and record your online appointment, exercise sessions and support sessions. This is for quality control purposes and to provide the REGAIN team with an understanding of the topics and issues that generate discussion in the sessions.

OPTIONAL: *You do not have to agree to any of the following:*

- 1. GP follow-up:** If we do not receive a response from you to the online questionnaire at 12 months, with your consent, we will contact your GP to access your medical records to collect details of your health, medication and any health services you have received during the study.
- 2. Photographs and short video clips:** With your consent, we may take photographs or short video clips of the exercise and support sessions to be used for conference presentations and publicity. If you agree to this, we will get in touch and arrange a suitable time to do this.
- 3. Interview:** With your consent, we may invite you to take part in an interview to explore your experience of being in the study and how it made you feel. If you tell us you are interested in this, we will send you a separate invitation email where you will be directed to the interview information sheet to help you decide.

Do I need a computer to take part in the study?

You will need internet access, an email address and use of an electronic device to fill in the questionnaires, and make video calls and receive text messages. This can be a smartphone, tablet, laptop or computer. The device needs to have a camera that faces you, so we can see you during the video call.

We will use video call for the first appointment and if you are assigned to the exercise and support programme, for the exercise and support sessions. The study team will be available to help you with the use of computers, tablets, phones and other devices for video calls.

What should I expect from an online group exercise session?

The online group exercise and support group sessions will take place via a third-party online video platform which uses Zoom. If you are allocated to the 8 week exercise and support programme, the REGAIN specialist will provide you with a link to this website and ask you to register an account. The website will ask you to read and agree to the terms and conditions, then register an account using your name and email address.

During the online group sessions you will be visible on screen to the REGAIN specialist and the other people in the group. You can choose to remain anonymous by creating a nickname to be displayed in place of your real name. You will be asked to complete some brief online questions before and after each group exercise session. This will allow the REGAIN specialist to collect information on your health. Any data collected in this way will be encrypted and stored safely to NHS Digital and UK Government standards.

How long does the study last?

Although the programme only lasts one week (group 1) or eight weeks (group 2), you will be asked to remain in the study for 12 months so you can do the online questionnaires at three, six and 12 months.

What are the benefits of taking part?

Although this research study may not offer you any direct benefit, the findings may help people recovering from COVID-19 in the future.

What are the risks of taking part?

We do not anticipate any serious risk to you. There is always a very small chance that exercise can make you feel unwell. You will be advised and monitored by specialist staff. Exercise may cause tiredness, breathlessness and sore muscles, but this should get a bit easier each time you exercise. Although unlikely, if you are unwell during the live exercise sessions, a REGAIN specialist will contact you immediately online or by telephone and send emergency medical help if needed.

Although there is only a very small risk of becoming unwell during exercise, we recommend that you have another person nearby at home when you are doing your first few exercise sessions.

Sometimes, people can find the support sessions upsetting. Our specialist staff are fully trained and will provide appropriate support and assistance if needed.

Expenses and payments

There are no payments for taking part in this research study.

What are the alternatives to the REGAIN programme?

In some places in the UK it may be possible to join exercise and support groups provided by the NHS. These programmes have not yet been tested in research studies for people recovering from COVID-19.

What if new information becomes available?

Sometimes during a research study, new information becomes available about the treatment we are studying. If so, someone from the REGAIN team will contact you to discuss your involvement in the study. If you decide to withdraw from the study, you should discuss your care with your doctor. If you continue in the study, you may be asked to complete an updated consent form. In addition, we will contact you directly by letter and/or email to keep you updated. New information will also be available here:

www.warwick.ac.uk/regain

What if something goes wrong?

If you have any concerns about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you are still not happy and want to make a complaint, you can do this through the NHS complaints procedure. Please write to:

Complaints Manager
University Hospitals of Coventry and Warwickshire NHS Trust
Clifford Bridge Road
CV2 2DX
Email: feedback@uhcw.nhs.uk
Or phone: 02476 965 198

In the unlikely event that you are harmed by taking part in this study, compensation may be available. If you suspect that the harm is the result of someone's negligence, you may be able to take legal action, but you may have to pay any costs involved and you should get legal advice about this.

For independent advice on research, you can contact PALS (Patient Advice and Liaison Service) on: Freephone 0800 028 4203
Or you can email them at feedback@uhcw.nhs.uk.

How will we use information about you?

We will need to use information from you, from your medical records and from your GP for this research project.

This information will include your name, date of birth and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Will my taking part in this study be kept confidential?

University Hospitals Coventry and Warwickshire NHS Trust (UHCW NHS Trust) is the sponsor for the study. The study will be managed by Warwick Clinical Trials Unit at the University of Warwick (UoW). UHCW NHS Trust and UoW will use information you provide and information from your hospital and GP records to carry out this study, and will act as joint data controllers for the study. This means that, together, they are responsible for looking after your information and using it properly. UHCW NHS Trust and the UoW will keep identifiable information about you for 12 months after the study has finished and non-identifiable information about you for 10 years after the study has finished.

All information we collect about you during the study will be kept strictly confidential and will only be accessible to authorised people. The only reason we would break confidentiality would be in an emergency. If you are assigned to the 8 week online exercise and support programme, REGAIN practitioners at UHCW will keep paper records of your contact details and medical health information as per their safety protocol. These paper records will be stored securely in locked filing cabinets only accessible to study staff. These records will not be passed onto UoW. If your own health, or somebody else's health, was in danger, we may contact you, your GP, the emergency services or other healthcare staff.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can read the privacy statements on the UHCW NHS Trust and UoW websites:

www.uhcw.nhs.uk/privacy

<https://warwick.ac.uk/services/sim/privacynotices/research>

You can also find out more about how we use your information here:

<http://www.hra.nhs.uk/patientdataandresearch>

NHS sites, UHCW NHS Trust and UoW will use your contact details to contact you about the research study, to make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Your contact details will be disposed of securely 12 months after the study has finished or following withdrawal. Individuals from UHCW NHS Trust, the UoW, and regulatory organisations may look at your medical and research records to check the accuracy of the data collected during the research study.

NHS sites will pass these details to UHCW NHS Trust and the UoW, along with information collected from you and your medical records. The only people at the UoW and UHCW NHS Trust who will have access to information that identifies you, will be people who need to contact you about the study, exercise specialists leading the online groups, people who follow up on your progress or check questionnaires are completed, people who host the database where your information will be stored, or people who will audit the data collection process. If you are interested in taking part in the study but are later deemed ineligible, your contact details will be disposed of securely within 6 weeks.

The people who analyse study information will not be able to identify you and will not have access to your name or contact details. NHS sites will keep identifiable information about you from this study for a minimum of 10 years after the study has finished. If you agree to take part, and with your permission, your GP will be notified that you are taking part in this study.

With your consent, some of your contact information will be shared with third parties. If you agree to take part your name and telephone number will be shared with a third-party text and email messaging service so we can contact you about the study. If you are allocated to the REGAIN online exercise and support programme group you will also be asked to register an account with a third party online video platform using your name and email address. This will enable you to access the online exercise and support sessions via Zoom. This online video platform will collect and store information on your attendance at classes, time spent watching on demand videos and any answers to online questions completed prior and after the exercise sessions. This information will be stored alongside your name and email address. UoW and UHCW NHS Trust will be given access to this data to review your attendance and activity at sessions, use of online videos and your safety. The data collected will be encrypted and stored safely to NHS Digital and UK Government standards until 12 months after the study has finished. Personal identifiable data shared with or stored by third parties will be securely deleted when it is no longer needed.

With your consent, the UoW and UHCW NHS Trust will collect information about you for this research study from you and your medical records. This information will include ethnicity, and health information, which is regarded as a special category of information. If you agree to take part, we may use information collected for future research. Any future research will only proceed if approved by a Research Ethics Committee where necessary.

What will happen to the results of the study?

At the end of the study we will publish the findings in medical journals and at medical conferences. You will not be identified in any reports or publications. Once all participants have been followed up and the results have been analysed, we will make a copy of the study results available on the study website:

www.warwick.ac.uk/regain.

Who is organising and paying for the study?

This study is sponsored by UHCW NHS Trust and is being coordinated by the UoW. The study is funded by the National Institute for Health Research, COVID-19 Recovery and Learning programme (NIHR 132046).

Who has reviewed the study?

Any research that involves the NHS and patients is reviewed by an independent group of people called a Research Ethics Committee. This committee is there to protect your interests. This study has been reviewed and been approved by the Cambridge South REC. People who have had COVID-19 have also been involved in every part of designing and setting-up this study.

Contact for further information:

If you have any questions about the study, either now or in the future, do please contact us using the details below:

REGAIN Trial Manager
Warwick Clinical Trials Unit
Email: REGAIN@warwick.ac.uk
Tel: 02476 151 719

Thank you for taking the time to read this information and for considering taking part in this study.



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