

REGAIN Eligibility Form

All fields required.

- **Name of person completing this form**

Drop down field displaying names of staff allocated the Eligibility responsibility as from delegation log. Required field. Should be editable.

Hello, my name is X I'm calling from the University Hospitals Coventry and Warwickshire. Am I able to speak with X please?

I'm a member of the REGAIN Study team. I'm calling today because you've completed our online check to see if you're suitable for the REGAIN study and it's indicated that you may be suitable. What I'd like to do on the phone today is go through some further questions with you to see if I can confirm that the study is suitable for you. It should take about X minutes, is that ok?

(If not ok, arrange time to call back)

Can I confirm that you've read our information leaflet on our website?

So you understand then that we're interested in helping people who are still struggling 3 months after being ill with COVID-19. What the study hopes to find out is which of two treatments is better for helping people recover. People who are suitable and consent to take part in the study will be allocated at random to one of two treatments- you do not get to pick which treatment you receive. You'll either be invited to an online rehabilitation exercise and support programme that lasts 8 weeks or, you'll be invited to take part in a single online session of exercise advice and support. So people in the first group will need to have a device like a smartphone or tablet that they can use to take part in live exercise classes or support classes via video call. People in the second group will also need a phone or tablet but for the single session of exercise advice and support done via video call. People in both groups will be asked to complete 4 online questionnaires over a year.

Do you have any questions about the study or what it would involve for you before I move onto the eligibility questions?

- **Is the patient able to understand spoken and written: English or Punjabi or Gujrati or Urdu or Mandarin or Bengali by themselves or with support from family/friends?**

Yes/No

If Yes, please specify which language:

English, Punjabi, Gujrati, Urdu, Mandarin, Bengali

Eligibility criteria, must be answered Yes to be deemed eligible and to proceed to next question

If No, move to Ineligible page

- **On our website, which version of the Participant Information Sheet did you read? The versions are written on the top of the first page, they're a shape and a colour. For example 'blue circle version'**

Drop down field to show list of PILs e.g. Blue circle version DATE, Red triangle version DATE. Team will put in IT helpdesk request to add an option to the drop down when needed. Ask SA for the first PIL version - the date of it is yet to be finalised.

Caller Prompts:

The PILs on the website have a shape in a colour in the top right hand corner. This is to help us know which version patients have read.

Ask the participant what the shape and colour on the PIL was when they read it on the website.

If they are unsure, look at the version date of the PILs available in the drop down list for this question. Ask the patient if they viewed the PIL before or after the date of the most current version to determine which version they read.

- **What is your date of birth?**

Date field.

Is the patient aged 18 years old or over?

Yes/No *Can the system answer this question based on the DOB given above? If not, the system should flag those that aren't 18 or over so the caller can answer No here.*

Eligibility criteria, must be 18 years old or over to be deemed eligible and to proceed to next question

If No, move to Ineligible page

Please conduct a duplication check here using DOB and postcode to check this person hasn't already been randomised into the study. Flag duplications here.

- **Have you already taken part in this study?**

Yes/No

Eligibility criteria, must be answered No to be deemed eligible and to proceed to next question

If Yes, move to Ineligible page

Caller prompts:

This applies to previous randomisation in the REGAIN study only

- **Can you provide the date that you first came out of hospital following your COVID-19 infection?**

Date entry box dd/mmm/yyyy.

Validation in place to check that this date is at least 3 months from today's date.

Flag on screen those that don't meet this validation

Caller Prompts:

It is time since **first** discharge following a COVID infection that we are interested in, not any subsequent re-admissions

Participants must have been first discharged at least 3 months ago.

If the patient has not yet reached 3 months, ask them to return to the website when they reach 3 months and try again.

If the patient does not know their discharge date, ask for the number of weeks/ months since they were discharged and count back from today's date. Use the date you land on.

Has it been at least 3 months since the patient was first discharged from hospital following COVID-19 infection?

Yes/No

Eligibility criteria, must be answered Yes to be deemed eligible and to proceed to next question

If No, move to Ineligible page

If pt fails eligibility due to not being discharged at least 3 months ago, the caller should be able to come back to the website and try again when 3 months has elapsed.

- **Can I confirm the main hospital responsible for your care when you were treated for COVID? I have that recorded as XXX**

Pull through hospital as given at initial screen but allow for this to be edited if needed.

Caller prompts:

This doesn't have to mean the hospital you were discharged from or the one you were admitted to. It's whichever hospital was the **main** one responsible for your care during hospitalisation.

- **During your hospital admission for COVID, were you ever admitted to a critical care unit? Critical care is a specialised ward and can be called intensive care unit (ICU) or high dependency unit (HDU).**

I stayed in an Intensive Care Unit (ICU) or High Dependency Unit (HDU)

No I did not stay in ICU or HDU

I don't know

Answers will be pulled through to the randomisation to inform a stratification variable.

'Don't know' is equivalent to 'Ward stay' for the purposes of stratification.

Caller prompts:

ICU or HDU is where patients receive critical care treatment if required

- **Can I confirm the health problems that you still have following COVID-19? I have those recorded as XXX**

Pull these through as from initial screen. Allow these to be edited if needed – we may need to add problems not brought through.

Caller prompts:

If you are not getting back to living your life as normal more than three months after you left hospital, then your problems are considered substantial by the study.

Does the patient still have substantial COVID-19 related health problems?

Yes/No

Eligibility criteria, must be answered Yes to be deemed eligible and to proceed to next question

If No, move to Ineligible page

- **Are you currently taking part in any other rehabilitation programmes or support programmes?**

Caller prompts:

Exclude active treatment programmes that involve exercise rehabilitation or more than 30 minutes contact.

The patient can take part in passive programmes, where only materials are provided and there is no active exercise engagement.

Ask the patient if they are able to postpone any conflicting programmes until after the REGAIN intervention has finished (12 weeks). If they are willing and able to do this, this will not be counted as a conflicting study.

Is the patient already engaging in, or planning to engage in a conflicting NHS delivered rehabilitation programme in the next 12 weeks?

No/Yes

Eligibility criteria, must be answered No to be deemed eligible and to proceed to next question

If Yes, move to Ineligible page

- **To take part in this study there are some things you will need.**

You will need an email address, a mobile phone and a device that you can use for making video calls and watching videos e.g. laptop, phone, tablet.

The email address is so we can email you links to complete our online forms. We will also send you a text message with a pin code to access those online forms.

We may text or email you to let you know other things for example we send messages confirming when you've joined the study and confirming when you've completed online forms.

If you are allocated to the exercise programme, you'll need an email address to access the website with all our online exercise videos. You'll need a device to watch the videos on and to join a live exercise class.

If you're allocated to the advice session, you'll need a device for a video call with an exercise specialist.

Some of these things require an internet connection.

Do you think you will have a problem with these study needs?

Caller prompts:

Do you have access to the internet on your chosen device?

Does your device have a front facing camera so you could watch the screen whilst the camera is pointing at you and recording you?

Do you have enough data allowance to be able to access internet 3-5 times per week for half an hour? That is a maximum based on if you were allocated to the exercise programme only.

Can a family member or friend help answer any of these questions?

If the patient needs to hang up and get an answer from a family member or friend, arrange to call them back to continue the eligibility call.

Does the patient have access to, and the ability/support to use, internet, email, video and audio?

Yes/No

Eligibility criteria, must be answered Yes to be deemed eligible and to proceed to next question

If No, move to Ineligible page

- **Do you have any health conditions that mean you should not be undertaking exercise?**

Caller prompts:

Has your doctor advised you against doing exercise? What is the problem that made them advise against exercise?

Conditions that would contraindicate exercise:

Unstable angina (unpredictable and/or at rest)

Untreated left main coronary stenosis

Severe symptomatic aortic stenosis

Severe symptomatic cardiac arrhythmias

Hypertrophic cardiomyopathy

Neuromuscular, musculoskeletal, or rheumatoid disorders that are severely exacerbated by exercise

Uncontrolled heart failure

Is exercise contraindicated? Yes/No

Eligibility criteria, must be answered No to be deemed eligible and to proceed to next question

If Yes, move to Ineligible page

Caller may use comments here to record what the contraindication was.

- **Are you happy to take part in group exercise and group support sessions if you are allocated to the exercise programme?**

Caller prompts:

****NOT TO BE READ OUT LOUD****: We are trying to establish if the patient has any severe mental health problems that would mean they couldn't take part in the study. If they couldn't make it through a live class, couldn't make it through the online questionnaires or couldn't make it through a group psychological support call without disrupting others, they should be excluded.

Does the patient have any severe mental health problems preventing engagement?

Yes/No

Eligibility criteria, must be answered No to be deemed eligible and to proceed to next question

If Yes, move to Ineligible page

- **Is anyone else in your household taking part in the REGAIN study?**

Yes/No

Eligibility criteria, must be answered No to be deemed eligible and to proceed to next question

If Yes, move to Ineligible page

Perform duplication check [here](#) to check that no one is randomised already from that postcode and house number. Flag if they are. Caller will want to go back and change the answer to this question to Yes if the pt answered No but were then flagged.

Caller prompts:

Has anyone in the household been *randomised* into REGAIN?

We can only accept one randomisation per household.

If one household member has already been randomised, the second will not be permitted to join the study.

The reason for this is because of the potential for 'cross contamination'. If each person receives a different treatment type, but they have access to both treatments because they are sharing a household, it becomes difficult to know if the treatment is working or rather which treatment is working. For that reason we can only take one person per household.

Patients must pick which person they would like to put forwards for randomisation if more than one person from the household have passed the initial screen but neither has yet been randomised. They must of course, meet all other eligibility criteria.

- **Does the patient have the ability to consent?**

Yes/No

Eligibility criteria, must be answered Yes to be deemed eligible and to proceed to next question

If No, move to Ineligible page

Caller prompts:

Is the patient able to understand the study and give informed consent by themselves?

Do they have the capacity to consent?

- **Ineligible page**

Has the patient met all the necessary eligibility criteria?

Database to answer Yes/No based on answers to the above eligibility criteria questions only

If they're on this page the patient has not satisfied all the necessary eligibility criteria.

Thank you for answering those questions. Unfortunately, I can tell you that you are **not** eligible for the REGAIN study. The study is only suitable for people who meet a certain set of criteria and from what we've discussed today you don't meet all of them. If you feel you have ongoing care needs, we ask that you please get in touch with your GP to discuss them if you haven't done so already.

What we *would* like to do, is direct you to an NHS website which focuses on supporting your recovery after COVID-19. It's called [yourcovidrecovery.nhs.uk](https://www.yourcovidrecovery.nhs.uk). Please feel free to visit that website and learn how it can support you in recovering from the long terms effects of COVID-19.

There's also a youtube video explaining more about the yourcovidrecovery website. If you type yourcovidrecovery into youtube you'll be able to find that.

Thank you again for your time on the phone today and for your interest in the study.

Take care

<https://www.yourcovidrecovery.nhs.uk/>

<https://www.youtube.com/watch?v=yhtsFQwFq90>

- **Eligible page**

Has the patient met all the necessary eligibility criteria?

If all the above questions have been answered the database should answer this question as Yes/No based on answers to the above eligibility criteria questions only.

If they're on this page, the patient should have satisfied all the necessary eligibility criteria.

Thank you for answering those questions, I can confirm that you are eligible to take part in the REGAIN study.

What happens next, if you're happy for us to do so, is we'll ask for you to read and complete a consent form that we will email over to you. The form is an opportunity for you to agree that you understand what taking part in the study involves. It checks that you're happy with the information we'll collect from you and how we'll use it.

Would you like me to email the consent form to you?

- **Can you confirm your email address for me please?**

Pull in the email address from the Contact Details page. Allow it to be edited if necessary

In the email you'll receive a link that will take you to the consent form. When you click on the link, it will ask for a pin code. The pin code will be automatically text to your phone. So just enter the pin code and the consent form will appear. We do that two-step process just so we know it is you completing the form and not someone else.

There's 13 statements on the consent form. Read each of them, and if you agree with them, select Yes for each. If you don't understand an item you can call us back so we can explain it, the phone number to ring will be on the screen. You'll be able to go back to the consent form without losing any of the answers you've already selected by clicking on the link again.

Do you feel like you understand what to do when you receive the link for the consent form?

If you don't receive the email from us within two hours, please check your junk or spam box in case it's gone in there. If it's not there, please email us with your name letting us know the problem and we'll get back in touch with you to fix the issue straight away. Our email address is on our website.

When you complete the consent form, if you've answered Yes to the necessary items you can proceed to the next step. The next step is completing our online baseline questionnaire. Again, you'd receive a link via email and a pin code via text. There are quite a lot of questions in the questionnaire, and some may appear quite similar to each other, but your responses are really important to us and we really appreciate the time you spend completing them. It should take about 20-30 minutes to complete in all. If you get tired, you can leave the questionnaire and come back to it a different day if you like, it'll save your answers and pick up where you left off.

After the questionnaire is completed that's when you'll receive a message letting you know that you've successfully joined the study and we'll get in touch again then by phone.

Thank you so much for your time on the phone today, we really appreciate it. If you have any problems with any of the forms just give us a call. The email with the link for the consent form will be sent to you when I hang up, so please check your inbox and junk box for it.

Thank you again, take care.

NOT APPROVED