

CONSENT FORM, V3.0 29Oct2020

Title of Project: Rehabilitation Exercise and Psychological Support after COVID-19 Infection: The REGAIN Study.

Chief Investigator: Dr Gordon McGregor

Please take the time to read each of the items on this consent form carefully and then select Yes or No for each item.

In order to take part in the REGAIN study, you must be happy to answer all of the essential items on this consent form as Yes. If your answer to any essential item is No that is not a problem and you can still submit the consent form, however you will not be able to continue and join the REGAIN study. Optional items can be answered as either Yes or No.

If you'd like to discuss the consent form with a REGAIN team member, please call 02476 151719. You can leave this consent form and revisit it at anytime by clicking the link you have been sent to access this form. Your answers will be saved when you leave the consent form.

1. I confirm that I have read the REGAIN Participant Information Sheet [___]. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

No/Yes

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

No/Yes

3. I understand that relevant sections of my NHS hospital records, medical notes, GP records and data collected during the study, may be looked at by responsible individuals from the University of Warwick, University Hospitals Coventry and Warwickshire NHS Trust, regulatory authorities, and NHS Trusts, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

No/Yes

4. I understand that the REGAIN intervention is delivered by a third party online video platform and that if I am randomised to the REGAIN intervention group I will be asked to register an account. Registering an account will require me to agree to the Terms and Conditions and to provide my name and email address.

No/Yes

5. I understand that appropriate personal identifying information will be collected, stored and used by authorised individuals from Warwick Clinical Trials Unit and University Hospitals Coventry and Warwickshire NHS Trust. This is on the understanding that any information will be treated with the strictest security and confidentiality.

No/Yes

6. For individuals who initially received a study invitation letter from a NHS hospital trust:

I understand that routinely collected data regarding my COVID-19 admission will be provided by my hospital. I agree for Warwick Clinical Trials Unit and University Hospitals Coventry and Warwickshire NHS Trust to hold and link this data to the data I provide for this study.

For other individuals:

I understand that my hospital will not provide data.

No/Yes

7. I understand that the anonymised information collected about me may be used to support other research in the future, and may be shared anonymously with other researchers. Any future research will be ethically approved where necessary.

No/Yes

8. I agree to my General Practitioner being informed of my involvement in the study, and for them to be provided with a summary report of the results from the questions I answered about my mental health and of any safeguarding concerns the study team have about my health.

No/Yes

9. I agree to be contacted by a member of the REGAIN team if there are any questions or queries for me during the study.

No/Yes

10. I agree to being sent text messages and/or emails by the REGAIN team. I understand that a third party service may be used to send text messages and agree to my contact details being provided to facilitate this.

No/Yes

11. I agree to take part in the above study.

No/Yes

12. **OPTIONAL** – If the study team do not receive a response from me to the online questionnaire at twelve months, I agree to my General Practitioner being contacted so the study team can access my medical records, to collect details of my health and any medication and services I have received during the study.

No/Yes

13. **OPTIONAL** – I agree to some of my sessions being observed and audio recorded to monitor quality. I understand that these recordings may be transcribed by a member of the REGAIN team or a third party transcription service contracted to work on the study. These transcripts will be made anonymous.

No/Yes

14. **OPTIONAL** – I agree to have photographs or short video clips taken during the live exercise sessions. I agree that these may be used for conference presentations and study publicity and understand that these videos will be stored securely at Warwick Clinical Trials Unit.

No/Yes

15. **OPTIONAL** – I agree to being contacted after 3 months' time to see if I would like to be interviewed by a researcher to discuss my experiences of being involved in this research

No/Yes

Perform a check when item 15 is answered- If No selected to any of the non optional items show the prompt:

You have answered No to a essential item on this consent form which is not a problem, however we would like to remind you that all essential items must be answered Yes in order to proceed in the study. If you click the Submit button now, remember you will be unable to take part in the REGAIN study.

If you'd like to discuss the consent form with a REGAIN team member, please call 02476 151719.

You are able to change your answers on the consent form at any point before clicking the Submit button.

Name of person completing the consent form (enter your full name):

Date consent form completed:

Thank you for submitting your consent form. You will receive a message shortly letting you know what the next step is. Please be sure to check your inbox and junk box for this message.

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