PARTICIPANT INFORMATION SHEET

PROTECT sub-study:

Understanding the Psychological Impact of COVID-19 on Older Adults

Thank you for taking part in the PROTECT Study. We would now like to invite you to take part in the above sub-study which will be lead and sponsored by the University of Exeter. Before you decide whether to participate it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Please ask a member of the research team if there is anything that is not clear or if you would like more information. Take your time to decide whether or not you wish to take part. If you decide to take part, you may keep this information sheet.

What is the purpose of the study?

There are growing concerns over the possible impact of coronavirus (COVID-19) on people's brain health. It is currently unclear what symptoms are most common in people who have had COVID-19, and whether their day-to-day lives, such as their return to work, are affected. This information will be important to ensure we provide the best advice and support for people after they recover from COVID.

This study will collect data from people who have had COVID-19 to find out more about any mental health and physical health symptoms they have experienced, and to ask about what they do to cope with these symptoms. This will involve asking people to complete a set of questionnaires about their COVID-19 experience and other symptoms and experiences.

Why have I been invited to take part?

You have been invited to take part because you have previously consented to take part in the PROTECT Study. Participants will also be above 40 years of age without dementia, from any gender, all ethnicities, and able to complete a questionnaire.

Do I have to take part?

It is up to you to decide whether or not to take part in this sub-study. If you decide to take part, you will be emailed a copy of this information sheet and will be asked to sign an online consent form. If you decide to take part, you are still free to withdraw at any time, without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your participation in the PROTECT Study.

What will happen to me if I take part?

If you would like to take part in this study, you will be asked to fill in a consent form on the PROTECT Study website. You will then be able to access this study from your PROTECT Study dashboard. You will be asked to complete a brief confirmation of your demographic information and then six questionnaires, listed below:

1. Information about your COVID-19 experience: You will be asked if/how you were diagnosed with COVID-19 and what treatment you received
2. Mood and mental health: You will be asked to complete two questionnaires. One will ask about any symptoms of depression, and one will ask about symptoms of post-traumatic stress following COVID
3. Fatigue: You will be asked questions about how tired you feel and whether this affects your day-to-day life
4. Breathing difficulties: You will be asked about any breathing difficulties or symptoms you have
5. Employment: You will be asked about your employment (if relevant) and how it has changed since having COVID-19

The survey will be completed through your account on the PROTECT Study website. It will take approximately 20 minutes to complete.

We will also use data that you have already provided to the PROTECT study to support this study. **This will include demographic data, such as gender, date of birth, educational attainment, employment status and ethnicity.** Data will also be included from your annual cognitive tests. This will help us to analyse the impact of COVID-19 on cognitive health and ageing. **No data from PROTECT can be used to identify any individual. The shared data will be pseudonymised before being provided for this study.**

What are the possible benefits and risks of taking part?

There is an extremely small risk that some people may find certain questions difficult to answer. **Such that answering questions relating to mood/health may cause possible distress.** You should only answer those questions that you are comfortable with. You do not need to answer any questions that you are not sure about or you do not wish to.

The main advantage of this research is that participants will be taking part in an important study that could provide valuable new knowledge about the prevention of cognitive decline after COVID-19.

What will happen to the data I provide?

The University of Exeter is the sponsor for this study. In working with the PROTECT Study team we will be using information from you in order to undertake this study and will act as data controller. This means that we are responsible for looking after your information and using it properly. The PROTECT Study team will keep identifiable information about you and we researchers will have only the anonymised data. **Personal data will be deleted after 10 years**, whereas anonymised information collected as part of this study will be kept indefinitely in accordance with the PROTECT Study privacy policy. For more information about how the PROTECT Study uses your personal data, please see the PROTECT Study privacy policy.

To safeguard your rights, we will use the minimum personally identifiable information possible. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep all anonymised information about you that we have already obtained.

Individuals from the University of Exeter may look at your research records to check the accuracy of the research study. The only people in the University of Exeter who will have access to information that identifies you will be people who need to contact you to discuss issues directly relating to the study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

Will participation be kept confidential?

Your data will be processed in accordance with the General Data Protection Regulation (GDPR). All of the data collected as part of this project will be regarded as strictly confidential and will be held securely until the research is finished. No study data will be available in any identifiable format to anyone outside of the immediate research team. We may share anonymised data from this study with other researchers, within the remit of PROTECT Study policy and following necessary approvals.

All data for analysis will be anonymised. In reporting on the research findings, we will not reveal the names of any participants. All research staff are provided with training regarding GDPR and University of Exeter standards for handling data. Any data provided electronically will be stored on a database on a restricted server only accessible by specified members of the research team who have been given authorisation to access the database.

Questions, comments and requests about your personal data can be sent to

The Administrator
PROTECT Study
College House 1.23
St Luke's Campus
The University of Exeter
Exeter, EX1 2LU
United Kingdom

Or by emailing support.protect@exeter.ac.uk.

Alternatively, you may also contact the University of Exeter's Data Protection Officer who is responsible for monitoring compliance with relevant legislation in relation to personal data, by emailing dataprotection@exeter.ac.uk.You have the right to lodge a complaint with the Information Commissioner's Office at www.ico.org.uk/concerns.

What if I change my mind about taking part?

Your decision to participate in this study is voluntary. You can withdraw from the study at any time without giving a reason by logging into your PROTECT Study account and clicking on the Withdraw from Study option in the Manage Account section of the website. Alternatively, you can contact the PROTECT Study helpdesk by emailing support.protect@exeter.ac.uk or by telephoning 01392 725010. By withdrawing you are making the decision not to provide any further information or responses to the study questionnaire and you will not receive any further communications about it. However, if you withdraw from the study, we will retain all anonymised data that we have collected up to the time you withdraw. This includes all anonymised data from questionnaires.

Who is organising this study?

This sub-study is being led by the University of Exeter, nested within the main PROTECT Study, which is led collaboratively by the University of Exeter, King's College London and South London and Maudsley NHS Trust.

Contact for further information

If you have any questions or require more information about this study, please contact the PROTECT helpdesk by emailing support.protect@exeter.ac.uk.

What if there is a problem?

If you wish to complain or have concerns about any aspect of the way you have been approached or treated during the course of this study, you can contact the University of Exeter College of Medicine and Health Ethics Committee (cmhethics@exeter.ac.uk).

Additional information and Frequently Asked Questions are available on the PROTECT Study website. If this does not answer your query you can contact the PROTECT Study team by calling 01392 725010.

Thank you for reading this information sheet and for considering taking part in this research.

Consent to Take Part

- I confirm that I have read and understand the Participant Information Sheet version 1.2 dated 28.06.22 for the above sub-study, sponsored and led by the University of Exeter. I have had the opportunity to consider the information and ask questions, which have been answered satisfactorily.
- 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.
- I consent to the processing of my personal information for the purposes explained to me via the Participant Information Sheet. I understand that such information will be handled and stored in accordance with the General Data Protection Regulation (GDPR) and other Data Protection Laws.
- I give my consent for the researchers to access relevant information already being collected about me from the PROTECT Study.
- I understand that my information may be subject to review by responsible individuals from the University of Exeter on for monitoring and audit purposes.
- If I chose to withdraw, I understand that all anonymised data will be retained in the study up to the point of my withdrawal, and no further data will be collected.
- I agree to take part in the PROTECT sub-study: Understanding the Psychological Impact of COVID-19 on Older Adults.