Participant Information Sheet

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PROTECT Study: Platform for Research Online to investigate Genetics and Cognition in Ageing

Invitation to take part in a research study

We would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you.

Please take time to read the following information carefully and discuss it with family or friends if you wish. We recognise that there is a lot of information contained within this document. If you have any further questions, please contact a member of the study team (details are at the end of this information sheet).

It is important that you understand that you do not have to take part in the study and that if you do take part you are free to withdraw at any time. If you decide to take part we will ask you to read and sign the declaration on the next page of the website.

What is the purpose of the study?

This study aims to understand how the functioning of the brain, and our health and wellbeing, change as we age. In particular the study will look at how certain genes and lifestyle factors (such as exercise or education) affect the way our brain ages and influence our health as we get older. This will provide valuable information about the brain and could inform future research to prevent conditions such as dementia. The study is being led by the University of Exeter and run in partnership with King's College London and the South London and Maudsley NHS Foundation Trust.

Why have I been invited?

We are inviting adults over 40 from across the UK to take part in this study. We are looking for 50,000 people to join the study for the next 25 years.

In order to participate, you will also need to

- Have a good working understanding of the English language
- Have the ability to use a computer or touchscreen device with internet access.

Do I have to take part?

It is up to you whether or not to join the study. The purpose of this information sheet is to describe the study in detail to help you make your decision. If you agree to take part, you will then need to read and sign a consent form on the website. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive through your own General Practitioner or local NHS services. This study does not replace those services and if you feel less well during the time you are part of this study it is important that you seek help from your doctor or local health professionals in the usual way.

Why are we doing the study?

As we get older our brains also begin to age, resulting in a 'slowing down' of abilities such as memory or reasoning. However, we do not fully understand how or why these changes occur. Studies have indicated that certain genes might govern these mental processes, collectively known as 'cognition', and how it changes throughout our lives. To date there have been no large studies examining how these genes affect cognition in older adults over the long term. Furthermore, there is some evidence to show that lifestyle factors such as exercise and smoking status could also affect cognition but these links are still unclear and we need to understand more about how genes and lifestyle interact.

It is important to understand what affects our cognition as we age and why it affects people differently. This information could also provide vital knowledge about who is most at risk of dementia, which currently affects 850,000 people in the UK. In order to develop better prevention and treatment for this devastating condition, it is essential to understand cognitive decline and the factors that govern it.

This study will address these important issues by measuring cognition in 50,000 adults over 40 over 25 years through an online study. Participants will complete a series of tests each year and we will compare their performance with their genes to see how they affect their performance. By combining this work with information about each individual's lifestyle and medical status this study will provide valuable new knowledge about how genetics influence cognition in older adults. This information will also allow us to explore how overall health and wellbeing change with age, and what factors are involved.

What will happen if I take part?

If you decide to take part the following steps will happen:

1. During registration you will be asked to provide some basic personal details including your name, address, email address, date of birth, NHS number, GP details, and if you are already involved in an affiliated research study such as the Exeter 10,000 cohort or CODEC. These details allow us to contact you for research purposes and to send you important information.
2. You will be asked to sign the online study consent form on the website.
3. Once you have registered and signed the consent form you will be asked to provide some basic demographic information including gender (including an expanded question for inclusivity), marital status, ethnicity, employment and education.
4. You will be asked to complete a series of online cognitive assessments, for example to test your memory, reasoning and attention. These will take around 45 minutes to complete in total. There are some similarities in some of these tests, which allow us to detect subtle changes in your performance. These tests are designed to challenge you and some of them get harder as you move through them, so they can be difficult and tiring. This ensures we can gather the best quality data about your brain function. There is a short practice version of the tests before the main test session to help you understand how the tests work.
5. You will then be asked to complete a series of questionnaires on the website. Some of these are optional so you can choose which you would like to complete. The mandatory questionnaires are:

a. A medical history questionnaire, including your Body Mass Index, sleep quality, any pain, current diagnoses or prescriptions for any conditions you may have. We will only ask you about conditions that are relevant to this study.

b. Information on your current lifestyle habits, such as exercise, technology use and smoking.

c. A questionnaire about your diet and any dietary supplements you take. Information on any family history of dementia, including other brain conditions.

d. A questionnaire about how you feel you are performing day-to-day tasks.

e. A questionnaire about how you feel about your cognition.

f. A questionnaire about your behaviour and personality.

g. A questionnaire about your current mental health, including depression, anxiety and alcohol use.

The optional questionnaires include:

a. An in-depth questionnaire about your history of mental health, including depression, anxiety, stress and psychosis and information about your previous alcohol and drug use

b. A questionnaire about your views on ageing

c. A series of fitness tests and a questionnaire about your balance

d. A questionnaire about your quality of life

e. A questionnaire set about Autistic Spectrum Disorder symptoms

f. A questionnaire about loneliness and your social networks

g. A questionnaire about Covid-19 if you have had it

6. If possible we will ask you to nominate an 'informant'. This should be someone who knows you well and spends time with you frequently, such as a spouse, child or close friend. If your nominated informant agrees to take on this role, they will be contacted with information on the study and asked to complete a consent form on the PROTECT website. Your informant will be asked to answer questions about you once a year for the duration of your participation. For confidentiality purposes, we will not be able to share these answers with you. If you decide you would like to continue participating in the study without their support, we will contact them to let them know and thank them for their participation. Nominating an informant is optional.

7. We will send a saliva sample kit to the address you provided with clear instructions on how to use it. We will ask you to provide a saliva sample to allow us to have samples of your DNA for the study. This is a very simple, quick and painless procedure. A pre-addressed envelope will be provided for you to post your sample back to us. If you are unable to provide a saliva sample you may be able to provide a blood sample instead. Unless you opt to take part in additional research studies this information will be for research purposes only and will not be made available to research participants. This is because the medical value of this information is not yet sufficiently understood to give people clear guidance. Your DNA samples will be stored anonymously in the Clinical Research Facility at the University of Exeter, and processed by our genetic analysis partner, deCODE Genetics Ltd (see below). If you have already provided a DNA sample through an affiliated cohort (such as the Exeter 10,000 study) you will not need to provide another one.

8. With your permission we will contact your GP to request a confidential copy of your medical notes. These will only be used for information that is directly relevant to the PROTECT study. The medical notes help us to have a more accurate picture of your medical status.

9. You will be asked if you would like to be contacted about taking part in future research into ageing and brain health including treatment studies. It is difficult to know exactly what new treatments will emerge and be assessed in clinical trials, but studies are likely to look at different ways of preventing cognitive decline in people in middle and later life. Studies may look at a variety of different treatment approaches such as lifestyle approaches (e.g. brain training or exercise) as well as drug therapies. This is entirely optional and you are not obliged to take part in any future studies if you do not wish to. By signing this part of the consent form you are only agreeing to receive information about future studies and you are under no obligation to take part. For any potential future study you would receive details about the study and it would be your choice whether to take part or not. In order to assess your suitability for future studies we, or our collaborators, may look at the anonymised data you have already provided in your assessments, including your scores on the cognitive, mental health and other tests. You can tell us if you would like us to check your suitability based on your anonymous DNA data, when you complete your consent form. You will only ever be contacted by a PROTECT study member regarding involvement in other studies. None of your personal details will be passed on to any other researcher, institution or company without your specific consent. You will be asked to complete a separate consent form for any additional study you are involved in. New studies are expected to be made available around three times each year.
10. Each year we will contact you by email and/or SMS and ask you to repeat the cognitive assessments and to update your answers to the other questionnaires (with the exception of questionnaires that ask about events in the past). We will also keep you up to date with the study and its findings through a newsletter and the website and may contact you by post (no more than once a year) or SMS/text message (no more than three times per year).
11. Once you have completed your demographic information and your first set of cognitive tests you will have access to a set of brain training games from your dashboard. These games have been shown to help maintain brain function in a large clinical trial. They are freely accessible to all PROTECT participants and you can play them as often as you wish.
12. There is a very small chance that people taking part in this study may develop cognitive impairment or dementia over the 25-year period. In the unlikely event we detect a clinically significant drop in your performance in the study tests we will contact you by email to let you know our concerns and give you the opportunity to discuss them with one of our study doctors. We will also write to your GP to recommend they arrange an appointment with you to carry out further tests. Your involvement in the study would not be affected by this process and it is your decision as to whether you wish to continue to take part.
13. We may also ask if you would be willing to discuss your experience of the PROTECT study and any related studies with one of our researchers through an interview over the telephone. There is no obligation to take part in this, and you would receive a separate information sheet and consent form about this part of the study if you did choose to take part.
14. At the end of the 25-year study we will contact you to let you know the findings of the research.

How will we use information about you?

We will need to use information from by you for this research project. This information will include your:

- Name and Initials
- Date of Birth
- 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.

What will happen to the data I provide?

The University of Exeter is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Exeter will keep identifiable information about you for ten years after the study has finished. Anonymised information, such as your assessment, brain training and DNA data, may be kept indefinitely and up until the study objectives have been achieved.

In 2018 regulatory changes in the way that data is processed came into force, with the EU General Data Protection Regulation 2018 (GDPR) and the Data Protection Act 2018 (DPA 2018). Since the UK left the EU, the key principles of EU GDPR have been adopted in the UK GDPR (a 'UK-only' version) and the DPA 2018 still applies.

The University of Exeter terms its lawful basis to process personal data for the purposes of carrying out research as being in the 'public interest'. The University continues to be transparent about its processing of your personal data and the participant information sheet should provide a clear explanation of how your data will be collected, processed, stored and destroyed. If you have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information can be obtained from the University of Exeter's Data Protection Officer via the web-link; https://www.exeter.ac.uk/about/oursite/dataprotection/dpo/

If you have any concerns about how your data is controlled and managed for this study, then please contact the Sponsor Representative **(Contact details at the end of the information sheet)**.

All information collected in this study will be kept strictly confidential and stored in an electronic database and on an encrypted password protected Microsoft Azure database system at the University of Exeter which can only be accessed by the research team. You will be allocated a unique participant number, to ensure your information will be protected and cannot be identified outside of the research team. Any personally identifiable information will be stored separately and securely from information obtained from the research, it will only be kept for a limited time for no more than 10 years after the study has finished and securely destroyed thereafter.

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 the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

When you agree to take part in a research study, the information about your health may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. The exception to this is in the event that your cognitive performance drops below the levels we would expect, as outlined in the section 'What if I don't want to carry on with the study.' It will not be used to make decisions about future services available to you, such as insurance.

What is deCODE Genetics and how will they handle my DNA sample?

deCODE are an international genetics company who work in partnership with the University of Exeter to process and analyse DNA samples for research under a Research Collaboration Agreement. Your saliva will be sent to deCODE as an anonymous sample for extraction of DNA and analysis as part of the overall PROTECT Study. The data will be returned to the University of Exeter for analysis. DeCODE may also receive anonymised data from the study (including results from cognitive tests and other questionnaires). However, we will never send your personal details to deCODE so your data will remain anonymous.

deCODE operate under the strict international regulations for genetics research and are bound by the Collaboration Agreement with the University of Exeter, which protects the confidentiality and usage of any samples and data processed within the PROTECT Study.

What are the possible benefits and risks of taking part?

This is not a clinical trial and there are no risks associated with any treatment or other intervention. This is an 'observational' study, meaning we only wish to observe how you progress over time. There is a small risk that some people may find certain questions difficult to answer or distressing. For example, some of the cognitive tests are designed to be very challenging, which may cause increased stress. In addition, some of the optional questionnaires include questions about traumatic events, mental health and abuse, which may be distressing for some participants. In these cases there is clear information on where to go for support.

All the information we collect will be stored securely, according to the law.

The main advantage of this research is that participants will be taking part in an important research study that could provide valuable new knowledge about how the brain works as we get older.

The London Bridge NHS Research Ethics Committee has approved this research (Ref: 13/LO/1578) and the research will be covered by normal insurance policies at the University of Exeter.

What will happen if I don't want to carry on with the study?

A number of situations may arise in which you may wish to withdraw from the study. These are outlined below.

1. You choose to withdraw: You can withdraw from the study at any time without giving a reason. You can do this through the website or by contacting us on the PROTECT helpdesk. If you withdraw from the study you can tell us whether you want us to retain any personal information that could be used to identify you (email address, home address and full postcode, GP details, NHS number) or whether you would like us to destroy that information. Please note we will retain the full name, partial postcode and participant ID of any withdrawn participants to ensure we have a record of your consent when you registered. We will retain all anonymised data that we have collected up to the time you withdraw. This includes all anonymised data from assessments and questionnaires, anonymised genetic data and extracted DNA, which is also entirely anonymised.
2. On the event of your death: If you were to die during the period of this study we would ask your informant, if you have one, to notify us about your death. They can do this either through their study page on the website or by contacting the helpdesk. Your account would then be closed and we would retain all anonymised information you have provided up until that date and will retain your personal information unless you have indicated otherwise, as stated in point 1 in this section.

Will my taking part in this study be kept confidential?

Research data, such as your answers to the questionnaires, will be collected online through the study website over the 25-year period. The study database will not include your name, just a study number. These data may be used by other researchers in the future, however they will be completely anonymised before they are shared with other researchers and it will not be possible to identify you. Authorised members of the study team who are not involved in research may contact you to invite you to additional studies but they will not see your study results.

During the study we will collect minimum required personal information such as your full name, contact details and GP address. This information will be stored in a secure separate database and will only be available to a small number of people on the PROTECT study team at the University of Exeter to support you should you contact the PROTECT helpdesk and to communicate study information such as alerting you to new assessments. A secure list linking your full name, study number and contact details will be made available to the University of Exeter Clinical Research Facility so that they can send and receive your DNA sample. We will never pass your personal information on to any third party without your written consent.

All study data will be stored securely according to Data Protection Laws* and the security procedures in place at the University of Exeter and the biomedical facility processing your saliva sample.

For further information on how your personal information will be processed please visit our privacy policy on the study website.

***Data Protection Laws** *means (a) any law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding restriction (as amended, consolidated or re-enacted from time to time) which relates to the protection of individuals with regards to the Processing of Personal Data to which a Party is subject, including the Data Protection Act 1998 ("DPA") and EC Directive 95/46/EC (the "DP Directive") (up to and including 24 May 2018) and on and from 25 May 2018, the GDPR and all legislation enacted in the UK in respect of the protection of personal data; and (b) any code of practice or guidance published by the ICO (or equivalent regulatory body) from time to time.*

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our FAQ webpage at https://www.protectstudy.org.uk/Home/Faq
- by asking one of the research team
- by sending an email to Antony Walsh, Head of Research Governance (Contact details at the end of this information sheet), or
- by ringing us on 01392 725010.

Who is organising and funding the research?

The study is funded by the National Institute for Health & Care Research and is sponsored by the University of Exeter. You will not receive payment for participating in this study.

Who has reviewed and approved this study?

The study has been reviewed by a UK Health Department's NHS Research Ethics Committee (London Bridge), and the Health Research Authority who are the regulatory authority for research involving the NHS.

What will happen at the end of the study?

At the end of the 25-year study period you will complete your final annual assessments on the website. We will contact you to let you know the study has ended and to thank you for your contribution. The results of the study will be published in a scientific journal. We will provide you with a lay summary of our findings in the form of a newsletter. The findings will also be available on the study website. The information collected is totally confidential and no individuals will be identified in any reports/publications or presentations.

What if there is a problem?

If you have a concern about any aspect of this study, information and Frequently Asked Questions are available on the study website. If this does not answer your query you can contact the research team on 01392 725010 or email us on support.protect@exeter.ac.uk.

For independent advice and information you can contact the relevant Patient Advice and Liaison Services at the NHS Trusts that are associated with this study:

Patient Advice and Liaison Service (PALS)

North Devon & Exeter Patient Advice and Liaison Service (PALS):

T: 01271 314090

W: http://www.northdevonhealth.nhs.uk/contact/patient-advice-liaison-service-pals

E: ndht.PALS@nhs.net

South London & Maudsley PALS:

T: 0800 731 2864

W: https://www.slam.nhs.uk/patients-and-carers/advice-and-information

E: pals@slam.nhs.uk

University of Exeter Sponsor Representative

Dr Antony Walsh
Head of Research Governance, Ethics and Compliance
University of Exeter
Research Ethics and Governance Office
University Corporate Services
Lafrowda House, St Germans Road
Exeter, EX4 6TL

Tel: 01392 726621

Email: A.Walsh3@exeter.ac.uk

Generic Sponsor mailbox: res-sponsor@exeter.ac.uk

Research Team Contact (Study Helpline)

Email: support.protect@exeter.ac.uk

Tel: 01392 725010

Further Information

Thank you for taking the time to read the information about this study. If you would like to take part, please register for the study at https://www.protectstudy.org.uk. If you would like more information about the study before you decide whether or not to take part, you can contact a member of the study team by calling the study helpline on 01392 725010 or emailing your query to support.protect@exeter.ac.uk.

Please note that this helpdesk is for general information and support for the study. It will connect you to a member of the study team who will be able to talk about the study but will not be able to provide medical advice. Please also note that we are not able to give out information about your personal performance or progress in the study as your data are collected for research purposes only.

Thank you for your interest in taking part.

Consent to Take Part

- I am aged over 40 or older, live in the UK and have access to a computer or touchscreen device with internet access.
- I confirm that I have read and understand the Information Sheet for Participants dated 10/01/2024 (v24) for the above study. I have had the opportunity to consider the information, seek clarification and understand my involvement in the study.
- 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 understand that relevant data collected during the study may be looked at by individuals from the research team at the University of Exeter and King's College London or from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.
- In the event that a significant drop in my performance on the cognitive tests is detected during the study I give permission for the study team to contact my GP to recommend further testing.
- In the event that I lose capacity to consent during the period of this research I understand that I would immediately be withdrawn from the study.
- If I choose to withdraw or lose the capacity to consent, I understand that all anonymised data will be retained in the study, and that I will have the choice to destroy all identifying data about me that is held in the study with the exception of my name, partial postcode and consent form.
- I understand that the data will be stored in a way complying with the provisions of the General Data Protection Regulation (2018) and other Data Protection Laws.
- I understand that anonymous data from this study may be used by other researchers in the future.
- I understand that the storage of my DNA samples will be pseudonymous (labelled with an ID number instead of personally identifying information) and outcomes of the analysis are unlikely to have any implications for me personally.
- I agree to provide DNA (saliva) samples for genetic analysis as part of the PROTECT study
- I understand that my anonymised data may be analysed to check my suitability for future studies, and that I would be asked to complete a separate consent form before taking part in any new study.
- I give permission for the PROTECT study researchers to contact my GP to request a confidential copy of my medical notes.
- I agree to take part in the PROTECT study.