

Informant Information Sheet

Version 1 Date: 01/10/2018

PROTECT UK 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 questions, please contact a member of the study team (details are on the last page 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 changes as we age. In particular the study will look at how genetic, lifestyle and medical factors (such as exercise or education) affect the way our brain ages. 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 through a collaboration with King's College London and the South London and Maudsley NHS Foundation Trust.

Why have I been invited?

You have been nominated by a friend or family member who is participating in this research study to answer some questions about him or her.

In order to participate, you will need to:

- Have a good working understanding of the English language
- Have the ability to use a computer or touchscreen device with internet access
- Have known the study participant for 10 years or more
- Be aged 18 or older and reside in the UK.

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. If you do enrol in the study, you are free to withdraw at any time, without giving a reason.

If you decide not to join the study as an informant, your name and email address (as provided by the study participant) will be removed from our database within a month of your receiving this invitation. You may also decline through the link provided in the email invitation, or cancel your registration up to the point of enrolment.

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 problem-solving. However, we do not fully understand how or why these changes occur. Studies have indicated that our genes, lifestyle and medical history 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 over 25 years in 50,000 adults over the age of 40, through an online study. Your friend or family member will complete a series of tests each year and we will compare their performance with their genes to see how it changes as they age. As their informant, you will help enrich their data by completing two tests each year on their behalf. By combining this work with information about each participant's genetics, lifestyle and medical status this study will provide valuable new knowledge about how cognition changes in older adults.

What will happen if I take part?

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

1. You will be asked to register your name and email address and tell us your relationship to the person who nominated you.
2. You will sign the consent form on the next page of the website.
3. Once you have registered and signed the consent form, we will let your friend or family member know you have accepted their invitation to become their study informant.
4. You will then be asked to complete two online questionnaires about how your friend or family member's behaviour might have changed over the past ten years and how they have been performing day-to-day tasks. These will take a total of 15-20 minutes to complete.
5. Each year we will contact you by email and ask you to repeat the questionnaires. This way we will be able to track any changes you may have observed in your friend or family member. We will also keep you up to date with the study through a newsletter and the website.
6. At the end of the 25-year study we will contact you to let you know the findings of the research.

What will happen to the data I provide?

All the information we collect will be kept anonymous and confidential. The study participant will not have access to any information you complete on their behalf. Anonymised data may be provided to researchers running other studies at the University of Exeter and King's College London, including 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. It will not be used to make decisions about future services available to you, such as insurance.

Due to recent regulatory changes in the way that data is processed (General Data Protection Regulation 2018 and the Data Protection Act 2018) the University of Exeter's lawful basis to process personal data for the purposes of carrying out research is termed as a 'task in the public interest'. The University will endeavour to be transparent about its processing of your personal data and this information sheet should provide a clear explanation of this. If you do have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing dataprotection@exeter.ac.uk or at www.exeter.ac.uk/dataprotection. If you have any concerns about how the data is controlled and managed for this study then you can also contact the Sponsor Representative, Pam Baxter, Senior Research Governance Officer, whose details are at the end of the information sheet.

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.

Unless you opt to destroy it, any personally identifiable information you submit as part of this study (for example, your name and email address) will be held for a period of 10 years after the study has ended. We will then destroy it. Anonymised information, such as your

assessment data, may be kept indefinitely and up until the study objectives have been achieved.

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 your friend or family member progresses over time.

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

The main advantage of this research is that participants and informants 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?

You can withdraw from the study at any time without giving a reason. You can do this through the ‘I wish to withdraw’ link on the study 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 or whether you would like us to destroy that information. Please note, we will retain your full name and unique study ID 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 point you withdraw. Once you have withdrawn, a notification email will be sent to your friend or family member who may choose to nominate a new informant.

If you withdraw from this role but you are already taking part in PROTECT as a study participant or as an informant for another friend or family member your participation will not be affected.

In the event that your role as an informant comes to an end before the study has finished, for example your friend or family member may choose to withdraw from PROTECT, we will contact you to inform you and ask if you would like to remain involved with the study (i.e. continue to receive our quarterly newsletter).

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 and it will not be possible to identify you.

During the study we will also collect some limited personal information such as your full name and email address. This information will be stored in a secure separate database and will only be available to a small number of researchers on the PROTECT study team. We will never pass your personal information on to a third party without your written consent.

All data will be stored securely according to Data Protection Laws* and the security procedures in place at the University of Exeter, King's College London and the South London and Maudsley NHS Foundation Trust.

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 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, please contact the research team on 01392 72 5010 or email us on support.protect@exeter.ac.uk.

For independent advice and information you can contact the Royal Exeter & Devon NHS Foundation Trust Patient Advice and Liaison Service (PALS):

T: 01392 402093

W: <http://www.rdehospital.nhs.uk/patients/help/pals.html>

E: rde-tr.PALS@nhs.net

Further Information

Thank you for taking the time to read the information about this study. If you would like more information 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 72 5010 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 the study team who will be able to tell you 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 friend or family member's personal performance or progress in the study.