Informant Information Sheet

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PROTECT-UK: Platform for Research Online to investigate Genetics and Cognition in Ageing and Brain Health

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 throughout our lives. In particular the study will look at how genetic, lifestyle and medical factors (such as exercise or education) affect the way our brain functions. 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 several Maudsley NHS Foundation Trusts.

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?

Brain health is a very important part of our health and wellbeing. This includes our mental health such as our mood and feelings, as well as how our brain changes throughout our lives. Certain conditions such as depression, anxiety and dementia have long-lasting impacts for our health, and these can change as we mature and get older. They are closely linked to our overall health, as well as to our lifestyles and quality of life. We know that looking after our brain health is an important part of healthy living and can help us to avoid these long-term conditions. There is a need for large-scale research to understand how brain health is affected by different factors in our lives and how we can maintain good brain health throughout our adult lives.

As we get older our brains also begin to age, resulting in a 'slowing down' of abilities such as memory or problem-solving, and leading to changes in how our brains function. 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 adults over the long term. There is strong evidence to show that lifestyle factors such as exercise and smoking status could also affect cognition and mental health 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 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 and other mental health conditions such as depression which affects one in six adults in the UK, and autistic spectrum disorders such as ADHD, which is becoming increasingly common in UK adults. We need to gather large amounts of data, and track people's progress over time, to allow us to understand how these conditions develop and how they could be prevented, treated or managed. Online and digital technology allows us to gather data quickly and easily through computers and smartphones without people needing to visit a clinic. This approach to research means we can run very large research studies and understand brain health better than ever before.

This study will address these important issues by measuring cognition and brain health over 25 years in 50,000 adults over the age of 18, 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 three questionnaires 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 and brain health changes in 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 three online questionnaires about how your friend or family member's behaviour might have changed over the past ten years, how they have been performing day-to-day tasks, and personality and lifestyle. These will take up to a total of 30 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?

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.

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 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 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) but we will withdraw you from your role as their informant.

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 information collected in this study will be kept strictly confidential and stored either on an encrypted electronic database or a password protected computer 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 (10 years) and securely destroyed at the end of the study. For further information on how your personal information will be processed please visit our privacy policy https://www.protectstudy.org.uk/Home/PrivacyPolicy on the study website.

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 https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/
- 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, please 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 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

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 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 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 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.

Thank you for your interest in taking part.

Informant Consent to Take Part

- I am aged 18 or older, live in the UK and have access to a computer and the internet.
- I confirm that I have read and understand the 'Information Sheet for Informants' (v4) dated 30 AUGUST 2024 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 I lose capacity to consent during the period of this research I understand that I would immediately be withdrawn from the study.
- If I chose to withdraw, or lose capacity to take part in the study, I understand that all anonymised data will be retained in the study, and that I will have the option to destroy all identifying data about me with the exception of my name and consent form.
- Should my friend or family member withdraw from the study or opt to participate in the project without me, I understand that I would be removed from my role as their informant.
- 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 agree to take part in the PROTECT study as an informant.