

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 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 changes 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. 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 King's College London.

Why have I been invited?

We are inviting adults over 50 from across the UK to take part in this study. We are looking for 5000 people to join the study for the next ten 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 with internet access.

If you have an established diagnosis of dementia from your doctor then unfortunately you will not be eligible for this study.

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 800,000 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 5000 adults over 50 over ten 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.

What will happen if I take part?

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

1. You will be asked to sign the consent form on the next page of the website (a copy of this is at the bottom of the downloadable information sheet).
2. Once you have registered and signed the consent form you will be asked to provide the following information on the website:
 - a. Some general information, such as your age, gender and education
 - b. Your address and contact details to enable us to send you important information and materials.
 - c. Your GP's contact details and NHS number
 - d. Information about your current medical status, for example, current diagnoses or prescriptions for any conditions you may have. We will only ask you about conditions that are relevant to this study.
 - e. Information on your current lifestyle habits, such as exercise, diet and smoking, and information about your previous alcohol and drug use. Questions about alcohol and drug use are not mandatory.
 - f. Information about your history of mental health, including depression, anxiety, stress and psychosis.
3. You will then be asked to complete two series of online cognitive assessments, for example to test your memory, reasoning and attention. These will take around one hour to complete in total. There are some similarities in some of these tests, which allows us to detect subtle changes in your performance. If possible we would encourage you to complete the tests three times in one week to give us the best quality data.
4. An additional test will ask you about how you have been performing day-to-day tasks. 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. They will be asked to complete questions about you as well. This part of the study is optional.

5. We will send two saliva sample kits to the address you provided with clear instructions on how to use it. We will ask you to provide two samples 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 samples back to us. 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 at the Bioresource (Biobank) for Mental Health, which is a government-funded research facility (see below for details).
6. 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.
7. You will be asked if you would like to be contacted about taking part in future research including treatment studies, as part of the BioResource and the PROTECT study. 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 the full details and it would be your choice whether to take part or not. In order to assess your suitability for future studies we may look at the data you have already provided in your assessments, including your scores on the cognitive, mental health and other tests. None of your personal details will be passed onto 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.
8. Each year we will contact you by email and ask you to repeat the cognitive assessments three times in one week, and to update your medical, lifestyle and mental health information. We will also keep you up to date with the study through a newsletter and the website.
9. At the end of the ten-year study we will contact you to let you know the findings of the research.

All the information we collect will be kept anonymous and confidential. Anonymised data may be provided to researchers running other studies in King's College London 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. It will not be used to make decisions about future services available to you, such as insurance.

We will keep all data for 10 years after the study has finished. We will then destroy it.

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.

All the information we collect will be stored confidentially, 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. Participants will also be part of the national Bioresource for Mental Health, which supports wide-ranging research into dementia and other conditions. If you agree to be contacted you will have the opportunity to take part in future important research into the brain, and how we can prevent conditions like dementia.

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 King's College London.

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 website or by contacting us on the study helpline. If you opt to withdraw from the PROTECT study you will be automatically withdrawn from the NIHR Bioresource, and any saliva sample you have provided will be destroyed. 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, GP details, NHS number) or whether you would like us to destroy that information. For legal reasons we will retain the name 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 point you withdraw. This includes all anonymised data from assessments and questionnaires, anonymised genetic data and extracted DNA, which is also entirely anonymised.

There is a very small chance that people taking part in this study may develop cognitive impairment or dementia over the ten year period. Based on the existing evidence this may occur in 5% of people over 60, although the risk of cognitive decline increases with age. In the unlikely event we detect a clinically significant drop in your performance in the study tests we will contact your GP to recommend they arrange an appointment with you to carry out further tests. If you do receive a diagnosis from a medical professional we ask that you let us know through the website or by calling the study helpline. The website will provide information, links and useful contacts that may be helpful to you if this situation arises. However, the study helpline cannot provide detailed or medical support and advice.

If someone develops dementia and loses the capacity to make decisions independently about their involvement in the study, they would then be withdrawn from the study. If this happens we would like to keep the information you have already provided up until that date. However, if you would prefer data collected up to this date to be removed from the study you can indicate this on the consent form. You can change your mind about this at any time by following the link on the website or contacting the study helpline.

Will my taking part in this study be kept confidential?

Research data will be collected online through the study website over the ten year period. All data will be stored securely according to *Data Protection Laws and the security procedures in place at King's College London and the NIHR Bioresource. The study database will not include your name, just a study number. Your data will be completely anonymised and it will not be possible to identify you.

During the study we will collect some limited personal information including your address. This information will be stored in a secure separate database. A secure list will link your name, study number and personal details so that we can send and receive your DNA samples and make sure it is linked to information about you. The information will only be available to a small number of researchers on the study team for analysis. We will not pass any information on to any third party.

***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 ten 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 publications.

What is the Bioresource Project?

The Bioresource is part of national NHS project to build up a central library of information (or "BioBank") about people's health. It will be used in scientific/medical research to help us better understand why different mental illnesses happen and how we can develop better treatments for them. They aim to collect:

- Biological samples – blood and/or urine, hair, saliva for genetic and biochemical testing.
- Clinical data - Examinations by doctors, family information, your response to treatment etc.
- Neuroimaging data – X-rays and brain scans.

For your involvement in the PROTECT study we are only collecting saliva samples. In the unusual circumstance where someone is unable to give a saliva sample the Bioresource will offer a cheek swab or blood sample (50 ml, or ten teaspoons) as an alternative option.

Some of this data will only be kept locally while some information and samples from this resource may also be made available to other scientists working in biomedical and healthcare research that may include the participation of commercial companies, subject to full ethical approval. The Bioresource may also invite you to take part in other research studies based of the information we collect. If you are contacted for any follow-up studies, it is up to you to decide whether you would like to participate or not.

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 by calling 0207 848 8183.

For independent advice and information you can contact the South London and Maudsley Patient Advice and Liaison Service (PALS):

T: 0800 731 2864

W: www.pals.slam.nhs.uk

E: pals@slam.nhs.uk

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 <http://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 at King's College London by ringing the study help and information line 0207 848 8183.

Please note that this helpline 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.