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Participant Information Sheet

Study title:
Prevalence of subjective cognitive impairment in healthy older adults.

We would like to invite you to take part in our research study. Before making an informed decision, it is important to understand the aims of the study and what it will involve. Please take your time to thoroughly read the following information and feel free to ask us any questions if there is something that is not clear. We also recommend discussing with your friends and family if you wish.

What is the purpose of the study?

- Subjective cognitive impairment (SCI) is defined as the self-reported experience on worsening cognitive abilities e.g., worsening memory and thinking, without any difficulties being evident on objective tests of memory and thinking.
- SCI brings many concerned older adults to their GPs, however, it is unclear if SCI is a useful indicator of early changes in memory and thinking that could be related to disorders such as dementia. The types of questions and questionnaires that are used to assess SCI are not always comprehensive and can often be as limited as asking a single question such as “Do you think your memory and thinking is worse than it used to be?”.
- We want to investigate the most useful way to ask someone about changes in their everyday memory and thinking, and the best way to identify someone with SCI. We have identified a number of novel questionnaires that could help.
- We will also take a sample of saliva to test for the presence of the APOE e4 genotype. APOE is as a component of lipoproteins, which are the transporters of fats, such as cholesterol, around the body. APOE has recently been found to also be involved in processes other than fat metabolism, such as regulation of the immune system, and cognitive processes within the brain. Everyone inherits two APOE genes, one from each parent, either as APOE e2, e3 or e4. Some research suggests that people who have the APOE e4 genotype are at an increased risk of decline in their memory and thinking later in life. We will investigate if there is a link between the presence of APOE e4 and self-reported experience of changes in everyday memory and thinking. Some further information about APOE can be found at the end of this document.

Who can take part in this study?

You can take part in the study if:

- You are 50-80 years old
- You do not have a medical condition that might interfere with your ability to undertake tests of thinking and memory.

What does participation in this research involve?

You will be invited to the Whiteknights Campus at the University of Reading. The assessment will last **3 hours** in total and will include:

1. Questionnaires about your own self-reported (subjective) feeling of change in your everyday memory and thinking. Questions will ask about how well you are still able to

recall everyday tasks and navigate routes, and how well you are engaging in hobbies and socialising.
2. Memory and thinking tests will be administered to test how well you can remember words, your use of language, your attention to detail and your drawing skills. Some tests may be audio-recorded to help to better analyse your performance later. If you would prefer no audio-recording of any assessment, then please let the research team know. Your decision will not affect your participation in any way.
3. Questionnaires about your health and wellbeing. We will ask about your mood, everyday behaviours such as sleeping, and about your personality.
4. APOE genotyping. We will collect a saliva sample from you by swabbing the inside of your mouth. The saliva sample will be stored in a receptacle and taken to the School of Pharmacy, University of Reading for analysis.

Do I have to take part in this research study?

Participation in any research is entirely voluntary. It is important to remember that you are free to withdraw at any time without giving a reason and without any repercussions.

What are the possible benefits of taking part?

While there are no immediate benefits to taking part in this study, your participation will aid ongoing research into brain health and early diagnosis of conditions like Alzheimer's disease on a national and international scale. Although there is no payment for participation, reasonable travel expenses will be reimbursed.

What are the possible risks of taking part?

- *Questionnaires and assessments: Some of the assessments may raise concerns about your cognitive health. We cannot give medical advice based on the assessments and so we would encourage you to take any concerns to your GP for discussion. You can also discuss questions and concerns regarding your participation at any time after the assessment with the research lead, Dr Samrah Ahmed, in person or by emailing* samrah.ahmed@reading.ac.uk.
- *APOE testing:* There are no known risks involved with the collection of the saliva sample. Although the sample will indicate which version of APOE a person has, it cannot predict who will and will not develop memory and thinking difficulties later in life as this gene has only been explored at a population level. Therefore, your APOE status will **not** be revealed to you.

Will my taking part in this study be kept confidential?

Hard copies of completed assessments will be stored in a locked filing cabinet in the Harry Pitt Building, accessible only by the research team. A unique participant ID number will be given to all participants and so your name will not be used in any further analysis or publications. When your data is transferred to a computer file for analysis, it will be securely stored on a University of Reading server and managed in accordance with University Information Compliance Policies. Hence, if for any reason you wish to withdraw your data from the study, you must do it before this point. Data will be made fully anonymous within one month of the completion of the study. After that point, we will not be able to link any data to you. Fully anonymised data will be retained indefinitely and may be shared with other researchers to allow further work in this important field of study.

The saliva samples will be labelled with your unique participant ID number to protect your identity. After analysis, your saliva sample will be discarded in a safe and appropriate manner.

What if I would I like to make a complaint?

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact the Lead investigator Dr Samrah Ahmed via email at samrah.ahmed@reading.ac.uk, or you can contact the Head of the School of Psychology and Clinical Language Sciences, Professor Carmel Houston-Price at carmel.houston-price@reading.ac.uk.

Who has reviewed the study?

This study has been reviewed by the University Research Ethics Committee at the University of Reading and has received a favourable ethical opinion for conduct. (UREC 22/34)

Where can I get more information?

Dr Samrah Ahmed is the Lead Researcher on this study. For further information, please contact at samrah.ahmed@reading.ac.uk

The APOE gene fact sheet

Genes contain the information to make all the proteins our body needs. Humans have around 25,000 genes, 99.9% of which are exactly the same in all people. There is much interest in the genes that differ between people and how they impact our health. In this study, we are interested in how these variations affect your thinking and memory in your everyday tasks. For this reason, we ask you to provide a saliva sample that we will use to determine if you have variations of a particular gene.

Your saliva sample will be tested for variations in APOE, and this factsheet is designed to explain what APOE does in the body and what impact variations in the APOE gene may have on your health.

What is APOE, and what does it do?

The primary role of APOE is as a component of lipoproteins, which are the transporters of fats, such as cholesterol and blood fats also known as triglycerides, around the body. APOE has recently been found to also be involved in processes other than fat metabolism, such as regulation of the immune system, and cognitive processes within the brain.

Does everyone have the same APOE gene?

The APOE code may differ from person to person. Three common versions of the gene exists, namely e2, e3 and e4, which differ in 2 protein building blocks (amino acids) at position 112 and 158 in the protein. These differences alter the activity of the protein and which lipoproteins it is associated with.

Everyone inherits two APOE genes, one from each parent. Therefore it is possible for you to have one of the following six combinations, e2/e2 (1%), e2/e3 (11%), e2/e4 (2%), e3/e3 (61%), e3/e4 (23%), e4/e4 (2%), with the figures in brackets indicating approximately what proportion of the UK population have that combination.

How does this affect me as an individual, and what can I do about it?

Research has shown that different gene combinations for APOE can influence an individual's predisposition towards future disease risk, in particular heart disease and changes in thinking and memory which may lead to Alzheimer's disease. Although the evidence is not fully consistent, it has been estimated that having the e3/e4 or e4/e4 combination is associated with an increased risk of these conditions. This is thought to be due to elevated cholesterol levels, lower antioxidant levels and inflammation. Keeping physically active and not being overweight and eating a healthy diet with wholefoods, fruit and vegetables will help to reduce risk. You can look at websites such as The British Heart Foundation website, www.bhf.org.uk for lots of tips on diet and exercise. What is good for your heart is good for your brain.

Implications for health insurance

The genotyping we do is what is called 'predictive testing' and so there is no need to disclose the results of these tests by you or the research team to your insurance company. This is true at present or at any time in the future.

Why are researchers interested in this gene?

We are interested to further determine if individuals of different APOE genotypes manage everday tasks differently, such as driving, having a conversation and managing your household. In future, if we know that some tasks become difficult for people with certain genotypes earlier in life, before the onset of heart or thinking and memory problems, it may be that support, medicines and advice could be offered earlier and with better effect.

Sources of further information

It must be emphasised that genotyping is a relatively new area which is still in the research stage, with information in this area far from complete. If you would like to read more on this topic, you may find the following web-site of the Human Genetics Commission useful, www.hgc.gov.uk

If you have any questions or would like further information please contact the Principal Investigator Dr Samrah Ahmed, at the School of Psychology and Clinical Language Sciences, University of Reading. Please email samrah.ahmed@reading.ac.uk.