University of East Anglia

UEA BAES - Participant Information Sheet (PIS)

Study Title

University of East Anglia Brain And Eye Study (UEA BAES)

Study Sponsor & Funding

Sponsor: University of East Anglia, Norwich, United Kingdom
Funding:
Norwich Medical School, University of East Anglia
School of Pharmacy, University of East Anglia

What is the study's purpose?

We are investigating ApoE, a gene that influences dementia risk. Our study will be looking at different ApoE genotypes and if it causes changes to the eye or brain. We will also be investigating if Artificial Intelligence (AI) can detect these changes.

Why am I being asked to take part?

You are being asked to participate because of your involvement in previous studies where your ApoE genotype was determined. Our study is investigating the differences between ApoE genotypes using images of the eye and brainwave recordings. To do this we are recruiting people with different genotypes that either increase or decrease risk.

What is involved?

This is an observational study; we will only be taking recordings of specific aspects of your health, we will not be administering any trial drugs or treatments.

These tests are:

- Two Cognitive health questionnaires, one called ACE-III, the other called RUDAS which are used in clinical settings to help diagnose dementia.
- An EEG, measuring your brainwave response. This will be taken whilst resting, looking at a flashing light source, and performing a reaction test.
- OCT scans and pictures of your eyes, this also involves flashing lights.
- We will also ask you some questions about your health history.

All tests are carried out during a single visit at the Norwich Medical School at University of East Anglia Research Park with a Postgraduate Researcher. We expect the session to take around an hour and a half.

Please note: We are unable to provide a personal diagnosis or assessment of your risk of dementia.

What are the possible benefits?

Whilst there are no immediate benefits for those participating in the study, it is hoped that the research being carried out will have a beneficial impact on the identification and treatment of those with dementia.

Do I have to take part?

- It is completely your decision to take part or not.
- If you decide that you would like to take part, you can keep this information sheet and you should contact the research team.
- You can withdraw from the study at any point and you do not have to give a reason.
- If you decide to withdraw after we have collected your data we will remove it from our database.
- Deciding not taking part in the study will have no impact on any care you may be receiving or any other studies you may be involved with.

Are there any risks?

- There are no known significant risks for any of the imaging procedures you will undergo.
- In rare cases, the flashing lights you will be shown during your EEG can cause seizures in those with certain types of epilepsy. **If you have a history of seizures or epilepsy**; please inform one of our study coordinators for advice.
- The **eye drops used to dilate your pupil for OCT (Tropicamide 1%)** can cause temporary blurring of your vision. The drops last for several hours; **do not drive yourself to your appointment**. In rare cases the drops can cause irritation, headache, hypotension, nausea, faintness.
- In the unlikely event that we discover anything of concern, we may give you a letter to take to your GP to discuss further investigation.

What if something goes wrong?

If you have any complaints about the study, you can contact any member of the research team. If you feel that the complaint has not been handled to your satisfaction, you can contact the University of East Anglia to take your complaint further. Contact details for both can be found at the end of this document.

How will my information be stored?

- All data collected with your consent during the study will be stored on a secure server at UEA in compliance with GDPR and UK Data Protection Act 2018 regulations. Your consent is the legal basis for processing your information.

- Personal information will be kept on record for 10 years for archival and scientific purposes.
- We will not include your personal details in any reports or publications as a result of this study. The only exception to this are the retinal photographs taken during this study. These are considered biometric data and therefore cannot be fully anonymised.
- We support open science, and aim to make our study data accessible to other researchers using an online platform.

Am I eligible to take part?

To take part in the study you should meet all of the eligibility criteria listed below. If you have any questions or uncertainty, please do not hesitate to contact us:

- You had your ApoE genotype recorded as part of a previous research study.
- You are a Fluent English speaker.
- You are able to travel to the study site at UEA.
- You have no history of visual impairment or eye disease.
- You have no history of neurodegenerative disorder.
- You have no history of diabetes.
- You have no history of cardiovascular disease.
- You have no history of vascular disease or sickle cell anaemia.
- You have no history of photosensitive epilepsy or seizures.

Travel

Please do not drive yourself to the study session unless you have an alternative method of onward travel. We have a small amount of funding that can be used to subsidise travel expenses incurred as part of this study.

Contacts

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You are welcome to contact us if you have any concerns or complaints:
Prof. Lee Shepstone, Head of Research, Norwich Medical School, l.shepstone@uea.ac.uk

Data Protection enquiries:
Ellen Paterson, UEA Data Protection Officer, dataprotection@uea.ac.uk.