Participant Information Sheet

Longitudinal Validity Cohort

Title of Project: Establishing the validity and acceptability of remote finger prick blood sampling techniques for detection of Alzheimer-related and health-related blood biomarkers in older adults (VITAL)

Researcher name: Professor Anne Corbett, Professor Clive Ballard, Dr Byron Creese, Professor Nicholas Ashton

Invitation and brief summary:

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 at the end 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 invite you to read and sign the declaration on the next page of the website/app.

Purpose of the research:

We know that our brains age as we get older, and many conditions can affect how healthy our brains are. As our population ages there are an increasing number of people living with Alzheimer's Disease and other conditions such as Mild Cognitive Impairment. There are treatments available to slow the development of these conditions but very few people with early symptoms are in touch with medical services to assess and treat them. One of the most important steps is to make sure we can detect early brain health changes so we can treat them. Over the last few years there has been rapid progress in developing blood tests that can measure the proteins involved in the development of Alzheimer's Disease. These tests will start to become more routinely available in medical clinics over the coming years but this will still require people to be seen in a medical clinic to take a blood test.

Our team has developed a blood test that people can complete from home. The test can be delivered through the post and includes clear instructions that guide people through the simple process of pricking their thumb and putting a drop of blood onto a testing card that can then be posted back to us for analysis. This could potentially provide an easy way for people to take an initial test to see whether further assessment for memory problems is needed. Since it can be done from home it could be available widely to everyone with concerns about their memory.

We are conducting this study to find out whether this at-home blood testing kit is accurate at detecting the very early changes in brain health and how the test results align with changes in brain function over time. We also want to find out whether people feel comfortable providing blood samples at home using a specially designed test kit.

This will provide valuable information to help us in our work to detect changes in brain health earlier and to support people who are worried about their memory.

Why have I been approached?

We are inviting adults over 50 from across the UK to take part in this study. We are looking for 3500 people to join the study. We are particularly hoping to involve people who have some concerns about their memory, and we are recruiting people from the PROTECT-UK study because we have already collected information from you about your health and brain function.

What would taking part involve?

This is a three-year study but it will run in parallel with your usual PROTECT-UK study assessments. It involves providing blood samples on one occasion only, and then completing your PROTECT-UK assessments as you normally would. If you decide to take part the following steps will happen:

1. **Register:** The VITAL study will be available on your PROTECT-UK dashboard. You can enter this area, read this Participant Information Sheet and decide if you would like to take part. We will save your basic personal details including your name, date of birth, address and email address that are held by the PROTECT study. If you have any questions about the study you can contact the study helpdesk using the contact details at the end of this information sheet.
2. **Consent:** You will be asked to sign the online study consent form on the PROTECT website. This will include providing consent for us to access your PROTECT data, including data collected for the next three years, and check your location in the UK. If you are within two hours of Exeter you may be eligible for a separate part of this study which involves traveling to Exeter to give a blood sample. If this is the case we will contact you separately and you will be provided with a separate information sheet and consent form.
3. **Receive blood tests in the post:** We will send you two finger-prick blood test kits in the post.
4. **Complete the blood test kits:** You will be asked to complete the test following the instructions provided in the test kits. This will take around ten minutes. Detailed instructions are provided in the kits but these are outlined here so you know what to expect:
    a. Wash your hands, sit down and hang your hands to your sides.
    b. Open the test kit. Clean your finger with the disinfectant wipe.
    c. Gently press your thumb/finger onto the test lancet to fill the fingertip with blood.
    d. Let a large drop of blood fill the test area.
    e. Stop the bleeding with the gauze and apply a plaster.
    f. Close the test kit and seal.
    g. Use the stamped, addressed envelope to return your test to us for analysis
5. **Let us know about any problems:** If you experience any issues at any time as a result of taking part in this study you can let us know about these by completing a safety report form on the VITAL study section of your PROTECT dashboard, or by contacting the study helpdesk using the details provided in this information sheet.
6. **Provide feedback to us:** We will ask you to complete an anonymous survey to let us know about your experience of being part of the VITAL study, and how you felt about completing the at-home blood testing kits. The survey should take less than ten minutes to complete.

7. **Find out how the study went:** At the end of the study we will send you a report containing the findings of the research. Unfortunately we cannot provide you with detailed personal results of your blood test because these are still being investigated as part of the research study.

What are the possible benefits of taking part?

There aren't any immediate benefits resulting from your participation in this study. The study will provide valuable new knowledge about tests for Alzheimer's disease and Mild Cognitive Impairment that could make a major difference to the early diagnosis of these conditions in the future. There are no direct medical benefits in participating in this study.

What are the possible disadvantages and risks of taking part?

This study holds a low risk to you as a participant. However, blood sampling can result in some bruising, bleeding and discomfort at the site that the blood was taken from. You will be able to let us know about any issues that you experience in three ways. Firstly, you can complete a safety reporting form to report any major medical concerns. Secondly, you can contact the study team using the contact details on this information sheet. Thirdly, you can give us more general feedback by emailing us at support.protect@exeter.ac.uk using the subject header "VITAL Feedback".

The University of Exeter Medical School Research Ethics Committee has approved this research (Ref: 529634) 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 `Withdraw from Study' link on the VITAL study area or by contacting us on the helpdesk. If you withdraw from the study, you can choose for us to retain your personal information (email address, home address and full postcode) or for us to destroy that information for the VITAL study. This information will be retained in the PROTECT study. Please note we will retain your full name, partial postcode and participant ID number to ensure we have a record of your consent. We will keep all anonymised data you provide through our tests and surveys up to the time you withdraw.

How will my information be kept confidential?

The University of Exeter processes personal data for the purposes of carrying out research 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 informationgovernance@exeter.ac.uk or at Information Governance | Information Governance | University of Exeter

The University of Exeter is the sponsor for this study based in the United Kingdom.

We (the University of Exeter) will need to use information from you for this research project.

This information will include your:

- Full name
- Email address
- Home address
- Date of Birth
- Demographics (sex at birth, gender identity, marital status, ethnicity, employment, education) (from PROTECT-UK)

- Cognitive test results (from PROTECT-UK)
- Function of daily activities (from PROTECT-UK)
- Self-reported cognition (from PROTECT-UK)

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

You can find out more about how we use your information

- our privacy policy on the PROTECT website www.protectstudy.org.uk
- by sending an email to support.protect@exeter.ac.uk
- by ringing us on 01392 725010
- by viewing www.exeter.ac.uk/dataprotection
- by emailing dataprotection@exeter.ac.uk

We will keep all information about you safe and secure. Your coded blood samples will be kept and used for future academic research. No samples will be labelled with any personal details, and we will strictly adhere to all Data Protection requirements to ensure full confidentiality of your information. Anonymized samples may be given to academic collaborators to support new research and no samples will be shared or given to commercial organisations.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Will I receive any payment for taking part?

No, there are no payments available for taking part in this study. You will not be out of pocket as a result since all test kits in this study are provided with a pre-paid envelope to return the kit to us.

What will happen to the samples I give?

The samples you provide through the post will be received at our facility at the University of Exeter and processed in our laboratory to extract your blood sample. These will then be frozen and stored in our laboratory before being transferred to our collaborators at Gothenberg University for analysis. The samples will be fully anonymised so you will not be able to be identified from your sample.

What will happen to the results of this study?

At the end of the study period, 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 PROTECT website and will be communicated through the PROTECT newsletter. The information collected is totally confidential and no individuals will be identified in any reports/publications or presentations.

Who is organising and funding this study?

This study is being organised by a group of doctors and researchers at the University of Exeter (Prof Anne Corbett, Prof Clive Ballard) in collaboration with University of Gothenberg (Professor Nicholas Ashton) and Brunel University (Dr Byron Creese) and as part of the PROTECT-UK portfolio of research. The sponsor of the study is The University of Exeter and it is being supported by the University of Exeter National Institute of Health Research Biomedical Research Centre.

Who has reviewed this study?

This project has been reviewed by the University of Exeter Medical School Research Ethics Committee at the University of Exeter (Reference Number: 529634),

Contact for any questions or requests regarding your participation in this research

In the event of queries or requests you may contact me using the following contact information. Please email support.protect@exeter.ac.uk

To contact the Research Ethics Committee please email uemsethics@exeter.ac.uk

You can also contact the University Research Ethics and Governance Team if you wish to make a complaint or comment please email cgr-reg@exeter.ac.uk

or

Dr Antony Walsh
Head of Research Governance, Ethics and Compliance
University Corporate Services, University of Exeter
G14, Lafrowda House, St Germans Road, Exeter, EX4 6TJ
DD: 01392 726621 email A.Walsh3@exeter.ac.uk

Thank you for your interest in this project.

Consent to Take Part

- I confirm that I have read the information sheet dated 07/05/2024 (version no 4.0) for theabove project. I have had the opportunity to consider the information, ask questions and havehad these answered satisfactorily.
- I understand that my participation is voluntary and that I am free to withdraw at any timewithout giving any reason and without my legal rights being affected.
- I understand that relevant sections of the data collected during the study may be looked at by members of the research team, individuals from the University of Exeter and the University of Gothenberg, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
- I understand that taking part involves completing identifiable blood samples at home and anonymous feedback surveys which will be used for the purposes of research and included in an archive for up to 10 years
- I understand that taking part involves completing identifiable blood samples at home and anonymous feedback surveys which will be used for the purposes of research and shared with other researchers for use in future research projects
- I understand that taking part involves completing identifiable blood samples at home and anonymous feedback surveys which will be used for the purposes of research and included in reports published in an academic publication, project website and media publication in an anonymised format
- I understand that the study team will access existing and future (three years) data from the PROTECT-UK study . I give permission for the study team to have access to this 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 the capacity to consent as described above, I understand that all anonymised data and biological samples will be retained in the study, and that I will have the choice to destroy all identifying data about me that is held in the study with the exception of my name, partial postcode and consent form.
- I understand that taking part in this study will not result in any medical benefit to myself and that the results of the study are for research purposes only
- I understand that the data will be stored in a way complying with the provisions of the UK General Data Protection Regulation (2018), Data Protection Act (2018) and other Data Protection Laws.
- I agree to take part in the above project.