PARTICIPANT INFORMATION SHEET

PROTECT sub-study:

Exploring how the menopausal transition influences brain health and disease

Thank you for taking part in the PROTECT Study. We would like to invite you to take part in the above sub-study led by and sponsored by the University of East Anglia.

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 friends and relatives if you wish. We recognise 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 ask you to read and sign the declaration on the next page of the website.

This study has been granted full ethical approval from University of East Anglia.

What is the purpose of the study?

This study aims to understand how the menopause transition influences brain health and mental health. In addition to this we want to explore how certain genes and lifestyle factors may modify this further. Women make up nearly two-thirds of all Alzheimer's disease cases, but we still do not fully understand why. This research will help identify the factors that increase women's risk and could lead to better ways to protect brain health and prevent dementia.

Why have I been invited to take part?

You have been invited to take part because you have previously consented to take part in the PROTECT Study.

We are inviting all active female PROTECT study participants

In order to participate you will also need to:

- Have experienced or be experiencing menopausal symptoms

- Have completed at least one wave of cognitive assessment

Do I have to take part?

It is up to you whether or not to join this sub-study. The purpose of this information sheet is to describe the study in detail and help you make your decision. If you agree to take part, you will need to read and sign a consent form on the website. You are free to withdraw at any time, without giving reason. A decision to withdraw at any time, or a decision not to take part, will not affect your participation in the PROTECT Study. If you withdraw from the study, we will keep all anonymised information about you that we have already obtained.

Why are we doing the study?

Women are more likely than men to develop dementia. This is especially true for women who carry a gene called ApolipoproteinE4 (APOE4), which increases the risk of Alzheimer's disease. Researchers think that changes during menopause (a time when the body and brain go through significant changes) may partly explain this increased risk, but this is not yet fully understood.

By exploring data already collected by the PROTECT study (e.g. cognitive assessments, measures of anxiety and depression and APOE status) in combination with the data we will gain from our questionnaires that explore fertility and the menopause transition we hope to better understand how certain aspects of the menopause (e.g. menopause length, severity of symptoms etc) might influence brain health and whether this is further influenced by our genes.

It is therefore envisaged that this research will help identify the factors that increase women's risk and could lead to better ways to protect brain health and prevent dementia.

What will happen if I take part?

If you choose to take part in the sub-study:

1) You will be asked to sign the online study consent form on the website.

2) You will be asked to fill in a short questionnaire (the questionnaire is related to your menstrual, reproductive and menopausal history), and will take approximately 10-15 minutes to complete.

Your response to these questions will then be added to your already collected responses as part of the main PROTECT study, which will help us to analyse how factors of the menopause transition influence mental health and cognitive ability.

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, cross-sectional** study, which means we will only collect information from you at a single point in time. Although this study presents minimal risk, there is a possibility that you may find some of these questions which relate to menopause, fertility, reproductive history or pregnancy to be personal or emotionally sensitive. You should only answer those questions that you feel comfortable answering. You do not need to answer any questions that you are not sure about, or you do not feel comfortable answering.

The main advantage of this research is that participants will be taking part in an important study that could provide valuable new knowledge about how the menopause transition influences health and cognition as people age.

What will happen to the data I provide?

The University of East Anglia is the sponsor for this sub-study and is based in the United Kingdom. The University of Exeter also based in the United Kingdom will act as the data controller. This means that the University of Exeter 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.

The University of East Anglia has a data sharing agreement with the University of East Anglia for the purpose of this sub-study. The University of Exeter will collect and securely store the new data generated as part of this study. The University of Exeter will then provide the University of East Anglia research team with the newly generated data, together with previously collected data relating to cognition, mental health, and demographic characteristics. All data shared with the University of East Anglia will be pseudonymised, meaning that participants will not be directly identifiable.

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 University of Exeter 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. The University of East Anglia research team will only have access to your pseudonymised data.

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.

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. 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 before they are shared with other researchers, and it will not be possible to identify you. .

All study data will be stored securely according to Data Protection Laws* and the security procedures in place at the University of Exeter.

For further information on how your personal information will be processed please visit our privacy policy on the study website.

*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 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 your information is used

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 Academy of medical science and is sponsored by the University of East Anglia. You will not receive payment for participating in this study.

Who has reviewed and approved this study?

The sub study has been reviewed by the University of East Anglia ethics committee

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 on 01392 725010 or email us on support.protect@exeter.ac.uk. Alternatively you can also speak to representatives at the University of East Anglia listed below:

University of East Anglia Sponsor Representative

Tel: 01603 591366

Email: researchsponsor@uea.ac.uk

(University of East Anglia) Research Team Contact (Study Helpline)

Email: m.pontifex@uea.ac.uk

Tel: 01603 597176

(Exeter) 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 to take part, please register for the study at 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 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 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 as your data are collected for research purposes only.

Thank you for your interest in taking part.

Consent to Take Part

- I confirm that I have read and understand the Information Sheet for Participants dated 17/07/2026 (v2) 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 consent to the processing of my personal information for the purposes explained to me via the Participant Information Sheet. I understand that such information will be handled and stored in accordance with the General Data Protection Regulation (GDPR) and other Data Protection Laws.
- 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 University of East Anglia as described in the Participant Information Sheet
- I give my consent for the researchers at the University of East Anglia to have access to relevant pseudonymised data of mine already collected from the main PROTECT Study.
- If I choose to withdraw, I understand that all anonymised data 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 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 this sub-study: “Exploring how the menopausal transition influences brain health and disease”