Trialling a blood test for Alzheimer's disease in UK memory services

Submission date	Recruitment status	[X] Prospectively registered
04/12/2024	Recruiting	<pre>Protocol</pre>
Registration date	Overall study status	Statistical analysis plan
11/02/2025	Ongoing	Results
Last Edited	Condition category	Individual participant data
18/09/2025	Nervous System Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

This study aims to find out whether plasma p-tau217 helps to diagnose Alzheimer's disease more quickly at an early disease stage when added to standard UK memory clinic assessments.

Who can participate?

Individuals will be eligible to participate if they are aged 50 years or older, referred by their GP to an NHS memory service, are being seen for their first appointment, have a progressive cognitive complaint reported by themself or their study partner (family member/friend/carer) and are judged by their assessing memory service clinician to have objective impairment with a presentation of either mild cognitive impairment or dementia (mild or moderate, such that they are able to provide informed consent to participate at baseline). Individuals are asked to nominate a study partner who has at least weekly contact with them (family member/friend /carer) who will also be asked to provide informed consent to participate. Individuals who have the capacity to consent at baseline and lose capacity over the course of the study will be eligible to continue participating if they and their study pattern are willing.

What does the study involve?

The location of the study will be sites where patients would normally be referred for assessment of memory problems and would occur at the same time as their normal clinical visits. Individuals will be seen face to face three times over a year (at the start, at 3 months and at 1 year) and will have two telephone-based assessments at 6 and 15 months. As this is part of the normal NHS assessment, no additional travel costs will be incurred. Individuals will be encouraged to attend with a family member, friend or carer as they would do for a normal memory clinic appointment. After the first clinic visit, individuals and their family members/friends/carers will be invited to join the study by their clinicians. Those who consent will donate a blood sample and information about them and their health will be collected. this will add no more than 75 minutes to the standard memory clinic assessment. Individuals and their family members/friends/carers will return to see their doctor to receive a diagnosis at 3 months. At this visit the blood test result will be available to the doctor for half of the patients seen. after the clinic visit the patient and their family member/friend will be invited to be asked some questions about their experience, adding 30 minutes to the assessment. At 6 months the participant and the family member/friend /carer will be contacted by telephone and asked a series of questions, with each call taking no

more than 60 minutes. At 12 months individuals and their family member/friend/carer will return for a clinic visit and the blood test result will be available to the clinician for the remaining half of the individuals seen. After the clinic visit, the individual and their family member/friend/carer will be asked some questions, taking no longer than 30 minutes. at 15 months they will have a telephone call similar to that undertaken at 6 months and lasting no more than 60 minutes.

What are the possible benefits and risks of participating?

Participation will mean that the memory service clinician responsible for making a diagnosis has access to the blood test result, which may aid the diagnosis as part of their assessment. There are known risks associated with blood sampling (local pain, bruising, infection) which are managed in accordance with standard clinical practice and local standard operating procedures. There is a risk of psychological distress related to the diagnosis being changed on the basis of the blood test either to or from Alzheimer's disease. Change of diagnosis is also a possible outcome through clinical follow-up alone (whether or not the blood tests contribute to that change) and so the psychological distress associated with diagnosis or change of diagnosis would be managed according to the standard of care provided by the memory service, which includes referral for post-diagnostic psychological support where deemed appropriate.

Where is the study run from?

The study sponsor is the UCL Comprehensive Clinical Trials Unit (UK). The study will be delivered by the NIHR research delivery network in partnership with NHS trusts across the UK in which memory services are located.

When is the study starting and how long is it expected to run for? April 2024 to March 2029

Who is funding the study?

- 1. Alzheimer's Research UK
- 2. Alzheimer's Society (UK)
- 3. National Institute for Health and Care Research (UK)
- 4. People's Postcode Lottery (UK)
- 5. Gates Ventures

Who is the main contact?
Trial manager, cctu.adapt@ucl.ac.uk

Contact information

Type(s)

Contact name

Mr Tanjil Nawaz

Contact details

Comprehensive Clinical Trials Unit Institute of Clinical Trials and Methodology 90 High Holborn 2nd Floor London United Kingdom WC1V 6LJ cctu.adapt@ucl.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

332672

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CPMS 57904, Grant Code: ARUK-BBC2023-002

Study information

Scientific Title

ADAPT: Alzheimer's disease Diagnosis And Plasma P-Tau217: a multi-centre diagnostic randomised controlled trial of disclosure of results of plasma p-tau217 to community memory clinic patients and clinicians in the UK

Acronym

ADAPT

Study objectives

The study hypothesis is that disclosure of the plasma p-tau217 result will increase the proportion of Alzheimer's disease diagnosis in comparison to non-disclosure at 3 months after blood sampling.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 08/01/2025, Health and Social Care Research Ethics Committee B (HSC REC B) (Meeting held by video-conference via Zoom, +44 (0)28 9536 1400, recb@hscni.net), ref: 24/NI/0149

Study design

Randomized; Interventional; Design type: Diagnosis, Process of Care, Device, Management of Care

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Alzheimer's disease

Interventions

At the start of the study, consenting individuals will provide one blood sample to be sent to UCLH for analysis. Basic information including age, sex, and ethnic group will be collected. The medical records will be checked and information including any medical problems, medications, and test results (including memory tests and renal function) will be recorded. This will allow for accurate interpretation of the blood test.

Participants' baseline blood samples will be processed locally and plasma will be transferred to UCLH for ptau217 analysis. Results will be provided to the diagnosing clinician along with a guide for interpretation (including the influence of renal function and body mass index both of which in extreme cases may influence the ptau-217 result). For 50% of participants, the result will be available to their clinician to share with them at the 3-month visit; the remaining 50% at 12 months. The primary outcome will be the difference in the proportion of AD diagnoses between the two arms at 3 months. The total number of study visits will be 5. The baseline, 3-month and 12-month visits will be in person, and the 6-month and 15-month visits will be by telephone. Differences between the two arms in management (including prescription of medication), quality of life and economic impacts will be captured (face-to-face at 3 and 12 months; by telephone assessments at 6 and 15 months) and analysed by economists at the LSE.

A small number of individuals taking part will be offered the opportunity to be interviewed (either as individuals or in groups) about their experiences and views of the study. This will be recorded and transcribed but kept anonymous.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Alzheimer's disease diagnosis, measured as clinician assignment of diagnosis at 3 and 12 months

Key secondary outcome(s))

- 1. Clinician confidence in diagnosis of Alzheimer's disease, measured on a Likert scale before and after consultation at 3 months and at 12 months
- 2. Change of diagnoses to or from Alzheimer's disease, measured by change in clinician assignment of diagnosis at 3 and 12 months
- 3. Clinician activities indicating Alzheimer's disease diagnosis: initiation of AD drug therapy, provision of AD post-diagnostic counselling, clinical trial referral, ascertained by collection of these data by case record forms from study clinicians and corroborated by local medication prescription records, at 3, 6, 12 and 15 months
- 4. Health-related quality of life, measured using the EQ5D-5L questionnaire at baseline, 3, 6, 12 and 15 months
- 5. Mean costs indexed by NHS and social care resource use and costs, measured using the Client Service receipt Inventory at baseline, 3, 6, 12 and 15 months

Completion date

31/03/2029

Eligibility

Key inclusion criteria

- 1. Age >=50 years
- 2. Referred to NHS memory service, being seen for first appointment
- 3. Presence of a cognitive complaint by the patient (and/or study partner)
- 4. History of progressive decline in the opinion of the investigator
- 5. Objective evidence for impairment as evidenced by any of MMSE <28, MOCA <28, ACE-III <90, RUDAS <28 in an appropriate language
- 6. Alzheimer's disease is a diagnostic consideration, with a presentation of either Mild Cognitive Impairment (MCI) or mild or moderate dementia
- 7. Able to nominate a study partner who has regular contact (at least weekly)
- 8. Willing and able to provide consent (including via a proxy)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

50 years

Sex

All

Key exclusion criteria

- 1. Normal cognition or subjective complaints that are not supported by cognitive testing
- 2. Amyloid status and/or plasma p-tau217 status already known to patient or referring clinician based on prior amyloid PET, CSF analysis or plasma biomarker
- 3. Lacks capacity to provide consent at recruitment visit

Date of first enrolment

28/08/2025

Date of final enrolment

31/03/2027

Locations

Countries of recruitment

United Kingdom

England

Scotland

Study participating centre Mid and South Essex NHS Foundation Trust

Prittlewell Chase Westcliff-on-sea United Kingdom SSO 0RY

Study participating centre Coventry and Warwickshire Partnership NHS Trust

Wayside House Wilsons Lane Coventry United Kingdom CV6 6NY

Study participating centre Leicestershire Partnership NHS Trust

Riverside House Bridge Park Plaza Bridge Park Road Leicester United Kingdom LE4 8PQ

Study participating centre Southern Health NHS Foundation Trust

Tatchbury Mount Hospital Calmore Southampton United Kingdom SO40 2RZ

Study participating centre Camden and Islington NHS Foundation Trust

St Pancras Hospital 4 St Pancras Way London United Kingdom NW1 0PE

Study participating centre Kent and Medway NHS and Social Care Partnership Trust

Farm Villa Hermitage Lane Maidstone United Kingdom ME16 9PH

Study participating centre Gloucestershire Health and Care NHS Foundation Trust

Edward Jenner Court 1010 Pioneer Avenue Gloucester Business Park Gloucester United Kingdom GL3 4AW

Study participating centre Derbyshire Healthcare NHS Foundation Trust

Trust Headquarters Kingsway Hospital Kingsway Derby United Kingdom DE22 3LZ

Study participating centre West London NHS Trust

1 Armstrong Way Southall United Kingdom UB2 4SD

Study participating centre

Grampian

Summerfield House 2 Eday Road Aberdeen United Kingdom AB15 6RE

Study participating centre Tayside

Ninewells Hospital Dundee United Kingdom DD1 9SY

Study participating centre Greater Glasgow and Clyde

Gartnavel Royal Hospital 1055 Great Western Road Glasgow United Kingdom G12 0XH

Study participating centre Lothian

Waverleygate 2-4 Waterloo PLACE Edinburgh City of Edinburgh United Kingdom EH1 3EG

Sponsor information

Organisation

University College London

ROR

https://ror.org/02jx3x895

Funder(s)

Funder type

Charity

Funder Name

Alzheimer's Research UK

Alternative Name(s)

Alzheimer's Research Trust, AlzheimersResearch UK, AlzResearchUK, ARUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

Alzheimer's Society

Funder Name

National Institute for Health and Care Research

Funder Name

People's Postcode Lottery

Funder Name

Gates Ventures

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet
Participant information sheet
11/11/2025 No Yes