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

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

## 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
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London
United Kingdom
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# Additional identifiers

### Integrated Research Application System (IRAS)
332672

### Central Portfolio Management System (CPMS)
57904

### Protocol serial number
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

### Primary study design
Interventional

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

### 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
SS0 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, AlzResearchUK, AlzheimersResearch UK, 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