ISRCTN16203689 https://doi.org/10.1186/ISRCTN16203689

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

Submission date
04/12/2024

Recruitment status
Recruiting

Registration date
11/02/2025

Overall study status
Ongoing

Last Edited
04/04/2025

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[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
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
332672

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/04/2024

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

Age group
Adult

Lower age limit
50 Years

Sex
Both

Target number of participants
Planned Sample Size: 1100; UK Sample Size: 1100

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

01/06/2025

Date of final enrolment
31/03/2027

Locations

Countries of recruitment
England

Scotland

United Kingdom

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

Sponsor details
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United Kingdom
WC1E 6BT
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jro.sponsorship@ucl.ac.uk

Sponsor type
University/education

Website
http://www.ucl.ac.uk/

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

Publication and dissemination plan
The results of the trial will be disseminated regardless of the direction of effect. Publication will comply with the UCL CCTU publication policies. A lay summary of the results will also be provided to be disseminated to those participants who took part who express an interest in the findings. A summary of results and end-of-trial report will be submitted to the Research Ethics Committee via the HRA and the MHRA, and published through an open-access mechanism in a high-impact peer-reviewed journal within 12 months of trial closure. Within one year of the end of the trial a public-facing plain language written summary, a short documentary and podcasts will be co-produced with the PPI group. These will summarise the findings and their potential impact. This information will be disseminated across health and social care organisations, charities, community groups, open days, festivals and other fora. This work will be conducted according to University of Kent policy and protocol regarding social media and the co-development/sharing of media content with patients and the public.

Intention to publish date
31/03/2030

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