Health Research Authority

PuntoTest Research Protocol

PuntoTest: PuntoTest: Speech-based cognitive screening tool (v1.0)
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	STFC-UKRI: NHSPOC01

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirements.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest, accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: 

Date: 24/07/2026

.....

Name (please print):

Anna Muñoz-Farré

Position: CEO & Co-founder

Chief Investigator:

Signature: 

Date: 24/07/2026

.....

Name: (please print):

Dr Latha Velayudhan

LIST of CONTENTS

SIGNATURE PAGE 1
LIST of CONTENTS 2
KEY STUDY CONTACTS 4
STUDY FLOW CHART 8
1 BACKGROUND 9
2 RATIONALE 11
3 THEORETICAL FRAMEWORK 11
4 RESEARCH QUESTION/AIM(S) 12
4.1 Objectives 12
4.2 Outcomes 13
5 STUDY DESIGN, METHODS of DATA COLLECTION and DATA ANALYSIS 13
5.1 Study Design 13
5.2 Methods of data collection 14
Study Procedures 14
PuntoTest Assessment 14
5.3 Data analysis 15
6 STUDY SETTING 16
7 SAMPLE AND RECRUITMENT 16
7.1 Eligibility Criteria 16
7.1.1 Inclusion criteria 16
7.1.2 Exclusion criteria 17
7.2 Sampling 18
7.2.1 Size of sample 18
7.2.2 Sampling technique 18
7.3 Recruitment 18
7.3.1 Sample identification 18
7.3.2 Consent 18
8 ETHICAL AND REGULATORY CONSIDERATIONS 19
8.1 Assessment and management of risk 19
8.2 Research Ethics Committee (REC) and other Regulatory review & reports 20
8.3 Peer review 21
8.4 Patient & Public Involvement 21
8.5 Protocol compliance 22
8.6 Data protection and patient confidentiality 22
8.7 Indemnity 23

8.8 Access to the final study dataset 23
9 DISSEMINIATION POLICY 24
9.1 Dissemination policy 24
9.2 Authorship eligibility guidelines and any intended use of professional writers 24

KEY STUDY CONTACTS

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	Science and Technology Facilities Council (STFC), UK Research and Innovation (UKRI) Reference: NHSPOC01
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Committees	Details of the Research Ethics Committee (REC) will be confirmed following IRAS submission and booking.

STUDY SUMMARY

This is a multi-site feasibility study designed to assess the feasibility of implementation of PuntoTest within NHS primary and secondary care settings, with the aim of supporting early detection of cognitive impairment and improving referral pathways. This includes embedded health economic assessments, as well as exploratory comparison with the current gold standard.

Study Title	PuntoTest: PuntoTest: Speech-based cognitive screening tool (v1.0)
Internal ref. no. (or short title)	PuntoTest_NHS_v1.0
Study Design	Multi-site feasibility study with an embedded health economics evaluation
Study Participants	Adults aged ≥50 years with subjective cognitive decline (SCD), mild cognitive impairment (MCI), or mild dementia, recruited through NHS primary and secondary care settings
Planned Size of Sample (if applicable)	150
Follow up duration (if applicable)	No formal follow-up; assessments conducted at a single time point within routine care. Optional additional PPIE workshop.

Planned Study Period	Planned Study Period: approximately 20 months from site activation (indicative end: December 2027). The end of study is defined by completion of data collection rather than a fixed date.
Research Question/Aim(s)	Can PuntoTest, a speech-based AI screening tool, be feasibly implemented in NHS primary and secondary care settings, and what is its potential diagnostic performance for detecting early cognitive impairment?

FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON FINANCIAL SUPPORT GIVEN
NIHR i4i FAST (NIHR510914)	Financial support for study delivery and research activities
Science and Technology Facilities Council (STFC), UK Research and Innovation (UKRI)	Financial support for study delivery and research activities
Punto Health Ltd (Sponsor)	Provision of in-kind support, including PuntoTest platform access (licences), platform maintenance, technical support, and project management

ROLE OF STUDY SPONSOR AND FUNDER

Punto Health Ltd is the study Sponsor and manufacturer of the PuntoTest app. Punto Health is responsible for overall study oversight, including protocol development, study management, regulatory compliance, and ensuring that the study is conducted in accordance with applicable regulations and standards.

The Sponsor will ensure appropriate governance, monitoring, and reporting arrangements are in place throughout the study. As well as providing technical support and product expertise.

The funders, NIHR i4i FAST Programme and STFC-UKRI, provide financial support for the study but will have no role in the design of the study, data collection, analysis, interpretation of results, or decision to publish.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

Study Governance

The study will be overseen by a Study Steering Committee, which will meet monthly to provide strategic oversight and ensure appropriate conduct of the study. This committee is composed of key members from the study, including the Chief Investigator, Site Principal Investigators, Site Research team members, UCLP representatives (i.e. for PPIE), and Punto Health project members. Where relevant, individuals from the lived experience advisory panel will also join steering committee meetings.

Operational oversight will be conducted on a monthly basis to monitor study progress, recruitment, and data collection across sites.

Punto Health (Intervention Provider and Study Sponsor)

Punto Health is responsible for the overall sponsorship, coordination, and management of the study. This includes:

- Provision and maintenance of the PuntoTest platform
- Ensuring compliance with applicable regulatory, ethical, and governance requirements
- Oversight of study design, protocol development, and regulatory documentation
- Coordination of study activities across sites, including project management and monitoring of study progress
- Management of data collected via the PuntoTest platform, including secure storage in line with data protection requirements
- Support for interpretation of study findings and dissemination of results

UCLPartners (Subcontractor)

UCLPartners will support the study through:

- Health economics analysis to inform future economic evaluation
- Coordination of Patient and Public Involvement and Engagement (PPIE) activities
- Support for usability and acceptability evaluation
- Contribution to inclusion and accessibility strategies

NHS Sites

Participating NHS sites will be responsible for:

- Identification and recruitment of participants through routine clinical pathways

- Collection of clinical data, including ACE-III assessments
- Integration of study procedures within existing care pathways
- Support for consent and study procedures

Site Delivery

Each participating NHS site will be supported by a research assistant/nurse responsible for study delivery, participant coordination, and data collection.

PPIE (Patient and Public Involvement and Engagement)

Patient and Public Involvement and Engagement (PPIE) is embedded throughout the study and has informed the development of the study design, materials, and procedures. Ongoing PPIE activities will continue throughout the study to ensure that the research remains informed by the perspectives and experiences of people with lived experience of cognitive impairment and their carers. These activities will be facilitated by UCLPartners.

During the protocol development phase, PPIE input was obtained through two in-person workshops, with 8 (23rd March) and 6 (30th March) participants respectively, involving individuals with lived experience as outlined below.

PPIE Structure

PPIE input has been obtained from diverse groups to ensure representation, including:

- People with mild dementia and/or their carers
- Older adults serving as healthy controls
- People with mild cognitive impairment (MCI)

PROTOCOL CONTRIBUTORS

The study protocol was developed by Punto Health Ltd (Sponsor) in collaboration with the Chief Investigator and NHS site investigators.

UCLPartners contributed to the development of the health economics framework and Patient and Public Involvement and Engagement (PPIE) strategy.

The protocol and participant-facing materials were reviewed by individuals with lived experience through PPIE activities, and feedback was incorporated into the final study design.

Clinical input was provided by participating NHS clinicians to ensure the protocol aligns with routine care pathways and clinical practice.

KEY WORDS: Cognitive impairment, mild cognitive impairment (MCI), dementia, speech-based assessment, artificial intelligence, digital health, cognitive screening, feasibility study, memory services

STUDY FLOW CHART

Key Milestones:

- Months 0–3 (April–July 2026) 4 months: Regulatory approvals, site setup, research nurse recruitment and training
- Months 4–15 (August 2026–July 2027) 12 months: Participant recruitment and data collection
- Months 16–20 (approximately 5 months following completion of data collection): Data analysis, model development, reporting and dissemination

STUDY PROTOCOL
PuntoTest: Speech-Based AI Cognitive Screening in NHS Primary and Secondary Care

1 BACKGROUND

Dementia affects nearly one million people in the UK, yet only around 66% have a formal diagnosis, with variation in diagnosis rates across regions contributing to inequalities in access to care (NHS Digital, 2024).

Early detection of conditions such as mild cognitive impairment (MCI) and dementia remains a significant challenge in routine clinical practice. NHS memory services are under considerable pressure, with demand for services increasing substantially over time. National audit data indicate that referrals and service activity have risen markedly, with admissions increasing by over 130% since 2009 without a corresponding increase in staffing capacity (Royal College of Psychiatrists, 2024).

Waiting times from GP referral to first assessment frequently exceed 13 weeks, more than double the recommended 6-week benchmark, with diagnosis often delayed beyond several months (Alzheimer's Research UK, 2024; NHS England, 2023).

In primary care, around 40% of general practitioners report limited confidence in conducting cognitive assessments, and currently used screening tools demonstrate limited sensitivity for early-stage impairment (Alzheimer's Society, 2022; Tsoi et al., 2015).

PuntoTest is a speech-based artificial intelligence (AI) cognitive screening tool designed for use in primary care and community settings. It analyses acoustic, semantic, lexical and syntactic features of recorded speech to detect subtle cognitive changes. The tool can be self-administered or clinician-supported, offering a scalable and accessible approach to early detection.

PuntoTest has been evaluated in clinical and pilot settings across Spain and the UK. In Spain, validation studies conducted at Alzheimer Center Barcelona involving 526 participants (control, MCI, and dementia) demonstrated 90% sensitivity and 81% specificity. These studies received ethical approval from the relevant research ethics committees (Ref: PR099/24). In addition, a 1,512-participant pilot study supported feasibility and integration within clinical pathways (Ref: ICPS017/25). In addition, a large-scale pilot screening programme conducted in community pharmacy settings, involving over 1,500 participants, also received ethical approval (Ref: ICPS017/25) and supported feasibility and integration within clinical pathways.

In the UK, over 80 participants have engaged in an ongoing study at the University of Manchester, conducted as part of the COMFORTage project, confirming the practical applicability of the tool within NHS-relevant settings.The tool is progressing toward UK regulatory compliance, supported by a

MARRS-funded ISO certification project. UK-specific validation is now essential to support regulatory submission and NHS adoption.

The development of PuntoTest has been informed by extensive Patient and Public Involvement and Engagement (PPIE), including co-design with NHS clinicians, patients, Age UK, and NHS Oxleas and NHS Enfield memory services and the University of Manchester, ensuring accessibility, acceptability, and appropriateness across diverse populations and workflows.

Together, this body of work provides a strong foundation for further evaluation. However, robust UK-specific evidence within NHS clinical pathways is required to determine feasibility, diagnostic performance and real-world applicability in primary and secondary care settings.

2 RATIONALE

Despite promising results from previous studies, further evidence is required to evaluate the performance and implementation of PuntoTest within NHS clinical pathways, particularly to support UK-specific validation.

To enable adoption, commissioning, and regulatory progression, evidence must be generated within the NHS context, reflecting real-world patient populations, clinical workflows, and comparator tools such as the Addenbrooke's Cognitive Examination-III (ACE-III), a widely used cognitive assessment tool in NHS memory services assessing multiple cognitive domains including attention, memory, language, and visuospatial function.

This study is therefore necessary to determine whether PuntoTest can be feasibly implemented within NHS primary and secondary care settings, and to evaluate its diagnostic performance in relation to established clinical assessments and referral decisions. In addition, the study will generate early evidence on usability, acceptability, and potential health economic impact, including effects on referral patterns, service capacity, and resource use.

If effective, the use of PuntoTest has the potential to reduce inappropriate referrals and unnecessary administrative burden, thereby supporting more efficient use of NHS resources. By improving case-finding in primary care, it may also contribute to increased service capacity and more timely access to specialist assessment.

This study also addresses prior feedback highlighting the need for strengthened study design, enhanced patient and public involvement, and the generation of UK-specific evidence. By addressing these questions within NHS services, the study will provide the evidence required to inform future

commissioning decisions, support regulatory approval, and enable progression to a definitive evaluation of clinical and cost-effectiveness.

3 THEORETICAL FRAMEWORK

This study is underpinned by a clinical and service delivery framework in which earlier identification of cognitive impairment can improve patient pathways and optimise the use of NHS resources.

This approach aligns with current NHS strategic priorities, including the NHS 10-Year Health Plan, which emphasises earlier diagnosis, prevention, and the delivery of care closer to home through digitally enabled solutions. Dementia is recognised as a priority condition, with national ambitions to improve diagnosis rates and reduce delays in accessing assessment and care.

Within current NHS pathways, delays in assessment and variability in referral appropriateness contribute to inefficiencies and increased pressure on specialist services. Waiting times from GP referral to initial assessment frequently exceed recommended NHS targets, often extending substantially beyond this in practice. Earlier and more accurate identification of individuals with potential cognitive impairment in primary care has the potential to support more appropriate referrals, reduce unnecessary demand on memory clinics, and improve timeliness of diagnosis.

In this context, PuntoTest is conceptualised as a pre-screening and triage tool that can be deployed in primary care and community settings. By providing an objective, rapid, and accessible assessment, it may support clinicians in identifying patients who require referral to memory services or further diagnostic testing.

This model of care has the potential to contribute to NHS priorities of improving diagnostic timeliness, increasing service capacity, and reducing unwarranted variation in access to care. In addition to clinical benefits, it may also generate health economic value by reducing inappropriate referrals, streamlining assessment pathways, and enabling more efficient allocation of healthcare resources.

This study will evaluate the feasibility of implementing this approach within NHS primary and secondary care settings, and explore its potential to contribute to more timely diagnosis, improved service delivery.

4 RESEARCH QUESTION/AIM(S)

Can PuntoTest, a speech-based AI screening tool, be feasibly implemented in NHS primary and secondary care settings, and what is its potential diagnostic performance for detecting early cognitive impairment?

4.1 Objectives

Primary Objective

To assess the feasibility of implementing PuntoTest within NHS primary and secondary care settings. This includes:

- The ability to recruit the target number of participants across sites
- Participant completion rates of the PuntoTest assessment
- The feasibility of recruitment pathways from both primary and secondary care

Secondary Objectives

- To compare performance of Punto test with current gold standard cognitive assessment, ACE-III (Addenbrooke's Cognitive Examination-III) and further develop the model.
- To assess variation in performance across demographic groups, including age, sex, and education
- To explore participant experience and acceptability of the PuntoTest assessment through qualitative interviews
- To generate preliminary health economics data to inform future NHS commissioning decisions and grant applications

4.2 Outcomes

Primary Outcomes (Feasibility Measures)

Feasibility will be assessed using the following measures:

- Recruitment rate (number of participants recruited per site per month) and proportion of target sample achieved within the study period
- PuntoTest assessment completion rate (proportion of participants completing study assessments)
- Recruitment pathway distribution (proportion of participants recruited via primary vs secondary care)

Secondary Outcomes

- Exploratory comparison of PuntoTest outputs with ACE-III results
- Variation in PuntoTest outputs across demographic groups, including age, sex, education, and living status
- Qualitative insights on participant experience and acceptability of PuntoTest, derived from thematic analysis of interview data

Exploratory Outcomes (Health Economics)

- Healthcare resource use, service activity, and staff time associated with the implementation of PuntoTest within the memory assessment pathway
- Service capacity indicators, including measures such as time to assessment, triage activity and triage duration
- Implementation and staff-related costs associated with the introduction of PuntoTest
- Data to inform future health economic evaluation of PuntoTest within NHS memory services

5 STUDY DESIGN, METHODS of DATA COLLECTION and DATA ANALYSIS

5.1 Study Design

This is a multi-site feasibility study designed to assess the implementation of PuntoTest within NHS primary and secondary care settings. This includes an embedded health economic evaluation and an exploratory comparison with the Addenbrooke's Cognitive Examination-III (ACE-III), a widely used cognitive assessment in NHS memory services

The study design has been informed by Patient and Public Involvement and Engagement (PPIE) activities, including structured workshops and feedback from individuals with lived experience, to ensure acceptability and relevance to patients and carers.

End of study definition

The end of study is defined as the point at which all required data from all participants across all participating sites have been collected and all data queries resolved, enabling the dataset to be locked for primary analysis. This corresponds to the completion of all participant assessments, the receipt and reconciliation of all ACE-III comparator data, and the finalisation of the dataset required to answer the primary feasibility research questions. Anticipated date of study completion is December 2027, but this date is indicative only and does not define the end of the study.

5.2 Methods of data collection

Study Procedures

Following informed consent, participants will complete the PuntoTest assessment within a controlled clinical environment as part of routine care pathways. The assessment includes the collection of basic demographic information (in-app) at the start of the session, followed by speech-based cognitive tasks. No additional study visits are required.

PuntoTest Assessment

PuntoTest is a speech-based AI cognitive screening tool designed for primary care and community use. It analyses recorded speech to extract acoustic, semantic, lexical, and syntactic features, which are used by AI models to detect subtle cognitive changes.

Participants will complete a ~10-minute PuntoTest assessment (approximately 5 minutes of testing and 5 minutes of explanation) using an iPad. Basic demographic information is collected at the start of the session, followed by the speech-based cognitive tasks.

ACE-III Assessment (Reference Standard)

The Addenbrooke's Cognitive Examination-III (ACE-III), a widely used cognitive assessment routinely employed in NHS memory services, will be used as the clinical reference standard. The ACE-III is a clinician-administered assessment of multiple cognitive domains and typically takes approximately 15–20 minutes to complete in clinical settings (Hsieh et al., 2013).

Where an ACE-III assessment has been conducted within the previous 3 months as part of routine clinical care, this will be used and will not be repeated.

If no recent ACE-III assessment is available, or if the most recent assessment is older than 3 months, the ACE-III will be administered as part of the study by trained clinicians.

Integration with Clinical Pathways

Assessments will be embedded within existing clinical workflows, with no additional study visits required.

In memory services, ACE-III is typically part of standard clinical care and will be used where available. In primary care settings, where ACE-III is not routinely performed, trained clinicians (e.g. Dr James Rogers) will administer the assessment as part of the study.

The PuntoTest assessment will be administered in person by a trained member of the research team (e.g. research nurse or research assistant), who will support participants in completing the assessment as required.

Optional Qualitative Interviews

Participant Interviews

Approximately 15 patients and/or carers who have completed the PuntoTest study and agreed to be contacted will be invited to take part in a one-to-one qualitative interview. Interviews will be conducted by telephone call, last up to 60 minutes, and follow a semi-structured topic guide exploring participants' experiences of PuntoTest, the tablet-based speaking task, the ACE-III assessment, usability, acceptability, and suggestions for improvement.

Participation will be voluntary, and participants may skip questions, take breaks, or stop the interview at any time and will not affect their regular NHS care. With consent, interviews will be audio recorded and transcribed and notes may be taken. Interview data will be pseudonymised, stored securely, and accessed only by authorised study team members.

Health Care Professionals Interviews

Clinicians and NHS staff involved in administering or supporting PuntoTest will be invited to take part in one-to-one qualitative interviews by telephone call, lasting up to 60 minutes. Interviews will follow a semi-structured topic guide and explore staff experiences of delivering PuntoTest, including ease of administration, training and support needs, fit with clinical workflow, technical or operational issues, acceptability, and potential use in NHS memory assessment pathways.

Participation will be voluntary, and staff may decline to answer questions or stop the interview at any time. With consent, interviews will be audio recorded and transcribed and notes may be taken. Interview data will be pseudonymised, stored securely, and accessed only by authorised study team members.

Data Collection Measures

The following data will be collected:

- PuntoTest assessment outputs (speech-derived features and model outputs)
- ACE-III scores as the reference standard
- Optional PPIE qualitative interviews

- Basic demographic data will be collected, including age (date of birth), sex, highest level of education, language background (including whether English is a first language), and living status (e.g. living alone).

5.3 Data analysis

Data analysis will include descriptive and exploratory components, consistent with the feasibility nature of the study, while also supporting ongoing model development.

Feasibility, usability, and engagement outcomes will be summarised using descriptive statistics. This will include recruitment rates, assessment completion rates, and recruitment pathways.

Exploratory analyses will be conducted to examine the relationship between PuntoTest outputs and results from the Addenbrooke's Cognitive Examination-III (ACE-III), a widely used cognitive assessment in NHS memory services. ACE-III data will be used as a clinical reference to support interpretation of results and ongoing model development. Analyses will be conducted overall and across relevant demographic subgroups.

Data collected in this study will also be used to support ongoing development and refinement of the PuntoTest model. Cross-validation approaches will be used, whereby different portions of the data are used at different stages of model development, to ensure appropriate use of the data, avoid overlap, and support robust results. The final modelling approach may be refined based on recruitment outcomes and dataset characteristics.

Qualitative data from participant interviews will be analysed using thematic analysis to explore participant experience, usability, and acceptability of the PuntoTest assessment.

Health economic analyses will be exploratory and descriptive, focusing on healthcare resource use, staff time, and service activity to inform future economic evaluation.

6 STUDY SETTING

This is a multi-site study conducted across NHS primary and secondary care settings in England. The participating NHS organisations are:

- Oxleas NHS Foundation Trust (Site Investigator: Dr. Monica Crugel)
- North London NHS Foundation Trust (Site Investigator: Dr. Reshad Malik)
- South London and Maudsley NHS Foundation Trust (Site Investigator: Dr. Latha Velayudhan)

- Greenwich GP Practice (Site Investigator: Dr. James Rogers)

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

The eligibility criteria for participation in the study are outlined below.

7.1.1 Participant inclusion criteria

- Adults aged ≥50 years
- Capacity to provide informed consent
- Individuals in one of the following groups, as determined through routine clinical assessment:
    - Subjective Cognitive Decline (SCD; also referred to as Subjective Memory Complaints, SMC):
      The following criteria will be used to define SCD (Jessen et al., 2014):
        (1) Self-experienced persistent decline in cognitive capacity compared with a previously normal status
        (2) Normal performance on standardised cognitive assessments
        (3) No significant impairment in activities of daily living
        (4) Absence of mild cognitive impairment or dementia
    - Mild Cognitive Impairment (MCI):
      An individual meeting the following diagnostic criteria will be identified as having MCI (Albert et al., 2011):
        (1) Concern regarding a change in cognition, whether reported by the self, informant, or clinician.
        (2) Objective evidence of impairment in one or more cognitive domains, typically including memory.
        (3) Preservation of independence in functional abilities.
        (4) Absence of dementia.
    - Mild dementia:
      An individual meeting the following diagnostic criteria will be identified as having mild dementia (DSM-5, 2013):
        (1) Evidence of cognitive decline from a previous level of performance, reported by the individual, an informant, or a clinician
        (2) Objective impairment in one or more cognitive domains (e.g. memory, attention, language, executive function)
        (3) Interference with independence in everyday activities (e.g. requiring

assistance with complex tasks)
(4) Not better explained by delirium or another mental disorder

- Healthy controls:
  An individual meeting the following diagnostic criteria will be identified as a healthy control:
  (1) No self-reported cognitive concerns
  (2) Normal performance on a standardised cognitive assessment, defined as a score of ≥27 on the Mini-Mental State Examination (MMSE) (Molloy & Standish, 1997)
  (3) No clinical diagnosis of mild cognitive impairment or dementia
  (4) Independent in activities of daily living
- Availability of a recent ACE-III assessment (within the previous 3 months), or ability to complete the assessment as part of the study procedures
- Sufficient proficiency in English to complete the study procedures and digital assessment

7.1.2 Participant exclusion criteria

- Moderate or severe dementia, or any condition associated with lack of capacity to provide informed consent
- Inability to complete the ACE-III assessment required for study participation
- Severe sensory, motor, or cognitive impairments that would prevent completion of the study procedures, including use of the digital assessment tools, even with support
- Acute or unstable physical or mental health conditions that, in the opinion of the clinical team, would make participation inappropriate

7.1.3 Healthcare Professional Inclusion Criteria

- Healthcare professionals directly involved in the delivery of the study at participating NHS sites.
- Aged 18 years or over.
- Able and willing to provide informed consent.
- Able to participate in English.
- Willing to provide feedback regarding the feasibility, usability and implementation of PuntoTest.

7.2 Sampling

7.2.1 Size of sample

Approximately 150 participants will be recruited across NHS primary and secondary care settings.

The sample size was determined primarily based on recruitment feasibility within the study timeframe, taking into account estimated patient volumes at each participating site and expected sign-up rates.

This sample size is also considered appropriate for a feasibility study, allowing estimation of key feasibility parameters (including recruitment rates, completion rates, and acceptability), while also enabling exploratory assessment of results in relation to ACE-III.

7.2.2 Sampling technique

Participants will be recruited using a consecutive sampling approach through routine clinical pathways within NHS memory services and primary care settings.

Eligible participants will be identified by clinical teams during standard care and invited to take part in the study.

This approach is appropriate for a feasibility study, as it reflects real-world clinical practice and allows assessment of recruitment and implementation within NHS settings.

7.3 Recruitment

7.3.1 Sample identification

Eligible participants will be identified by clinicians or members of the research team during routine clinical care within participating NHS sites. Individuals meeting the inclusion and exclusion criteria will be approached and provided with information about the study.

Healthy controls will comprise cognitively healthy adults aged 50 years or over with no subjective cognitive concerns, no diagnosis of mild cognitive impairment (MCI), and no diagnosis of dementia.

Healthy controls may be identified through several routes, including participants involved in other ongoing studies at participating centres, partners, family members, or friends of patients attending participating services, responses to study advertisements displayed in participating clinics and primary care settings, and self-referred volunteers.

Where participants are identified through non-clinical routes, eligibility will be verified through eligibility assessment.

7.3.2 Consent

All participants will provide written informed consent before inclusion.

Participants will be provided with the Patient Information Sheet (PIS) by their treating clinician/ GP or sent by post. The cooling off period will be of minimum 24 hours duration and they will have the opportunity to ask questions before seeing the researcher.

If interested, a convenient date, time and venue will be discussed and scheduled for their visit followed by email or telephone confirmation and reminders. On the day of visit, a trained nurse/ researcher will explain the study, answer questions, and take formal consent.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

Participation in this study is considered low risk. The PuntoTest assessment involves short speech-based tasks delivered via a digital device, alongside the ACE-III assessment, which is part of routine clinical care.

The study design and participant procedures have been reviewed through Patient and Public Involvement and Engagement (PPIE) activities, with feedback indicating that the assessment is acceptable and not burdensome for participants.

There are no anticipated physical risks associated with participation. However, some participants may experience mild psychological discomfort, such as fatigue, frustration, or anxiety when completing cognitive assessments or when reflecting on memory difficulties.

To minimise potential distress:

- Assessments will be conducted in a supported clinical environment
- A trained member of the research or clinical team will be present throughout
- Participants will be reminded that they may pause or stop the assessment at any time without providing a reason

Participation is entirely voluntary, and withdrawal from the study will not affect the participant's clinical care.

If a participant becomes distressed or unable to continue, the assessment will be stopped and appropriate support will be provided by the clinical team.

There is no direct clinical feedback provided from the PuntoTest assessment, as it is a research tool. However, ACE-III results will be managed as part of routine clinical care. If any clinically relevant concerns arise during the study, these will be communicated to the appropriate healthcare professional in line with standard clinical practice.

Data-related risks are minimised through the use of pseudonymisation and secure data storage. Personal identifiers will be replaced with unique study codes, and all data will be stored on secure, encrypted systems with access restricted to authorised personnel only. Data will be processed in

accordance with applicable data protection regulations, including the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018. Appropriate data sharing agreements will be in place between participating organisations to ensure secure and compliant transfer of data.

Overall, the risk to participants is considered minimal and comparable to routine clinical assessment.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Regulatory Review & Compliance

The study protocol and associated documents have been reviewed by a UK Research Ethics Committee (REC) and the Health Research Authority (HRA). The study received a favourable opinion from the London–Stanmore Research Ethics Committee.

Prior to study initiation at each site, all necessary regulatory approvals will be obtained, including local Research & Development (R&D) approval from participating NHS organisations.

No site will begin participant recruitment until confirmation of local capacity and capability has been obtained.

The study will be conducted in accordance with applicable UK regulatory requirements and local site procedures.

The Chief Investigator (Dr Latha Velayudhan), in collaboration with the Sponsor, will ensure that all regulatory and governance requirements are met prior to study initiation and throughout the study duration.

Amendments

Any amendments to the study protocol or associated documentation will be reviewed by the Sponsor (Punto Health) to determine whether they are substantial or non-substantial.

Substantial amendments will be submitted to the Research Ethics Committee (REC), HRA, and relevant participating organisations for approval prior to implementation.

Non-substantial amendments will be managed in accordance with Punto Health procedures and communicated to relevant parties as appropriate.

All amendments will be documented, tracked through version control, and communicated to study sites and investigators as required.

8.3 Peer review

The study protocol has been reviewed by the Chief Investigator (Dr Latha Velayudhan) and developed in collaboration with NHS partners and UCLPartners, with input into clinical design, health economics, and patient and public involvement (PPIE).

8.4 Patient & Public Involvement

Patient and Public Involvement and Engagement (PPIE) is embedded throughout the study to ensure that the research is informed by the perspectives and experiences of people with lived experience of cognitive impairment and their carers.

PPIE Activities Throughout the Study:

Protocol Development Phase:

Structured PPIE activities were conducted in collaboration with UCLPartners, including a series of in-person workshops with individuals with lived experience of cognitive impairment and their carers.

Two workshops were conducted during this phase:

- Workshop 1: 23 March 2026 (11:00–12:00), attended by 8 participants
- Workshop 2: 30 March 2026 (11:00–12:30), attended by 6 participants

Participants included individuals with mild dementia, mild cognitive impairment, carers, and individuals experiencing memory difficulties without a formal diagnosis.

During these sessions, participants reviewed the study protocol, Participant Information Sheet (PIS), and consent form. Feedback highlighted the need to simplify participant-facing materials, including reducing length, improving clarity of language, and using more structured formats (e.g. bullet points) to support understanding. Participants also emphasised the importance of clearly explaining the purpose of the study, what participation involves (including time and procedures), and the consent process, particularly for individuals experiencing cognitive difficulties.

Accessibility was identified as a key consideration, including the development of an easy-read version of the PIS and consideration of alternative formats to support a wider range of participants.

This feedback was incorporated into the final protocol and participant-facing materials prior to ethics submission, including revisions to improve clarity, structure, and accessibility.

During Study Implementation:

- Including lived experience representatives on the steering committee. Providing the opportunity for regular feedback.
- Co-design workshops with lived experience representatives to inform study delivery and participant materials, as necessary.
- Qualitative PPIE interviews, providing feedback on PuntoTest usability. These interviews are optional and opt-in for study participants, with participation compensated at a rate of £25 per hour.

This approach ensures people with lived experience are actively involved not only in shaping the initial protocol, but also in guiding study delivery, enhancing participant engagement, and ensuring the research remains responsive to participant and carer needs throughout the study period. We aim to ensure representation of older adults, racial minority communities, and socioeconomically deprived areas through targeted outreach.

8.5 Protocol compliance

The study will be conducted in accordance with the approved protocol.

All study personnel will be appropriately trained in the study procedures and their responsibilities prior to participation in the study.

Any deviations from the protocol will be documented and managed in accordance with Punto Health procedures.

The Chief Investigator (Dr Latha Velayudhan) along with the sponsor and research team will have overall responsibility for ensuring compliance with the protocol and for the conduct of the study across all sites.

Regular oversight will be maintained through study management processes, including monthly steering committee meetings, to ensure adherence to the protocol and applicable regulatory requirements.

8.6 Data protection and patient confidentiality

The study will be conducted in accordance with the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018. The NHS Trust at each participating site will act as the Data Processor, with Punto Health Ltd acting as Data Controller under formal data processing agreements.

Participants will be assigned a unique study identifier, and identifiable information will be stored separately from research data. Research data used for analysis will be pseudonymised to protect participant identity.

All study data, including audio recordings collected through the PuntoTest assessment, will be stored securely on encrypted servers with access restricted to authorised personnel only. Data will be protected both in transit and at rest in accordance with applicable security standards.

Personal data will not be shared outside the direct care and research team. However, authorised individuals from the study sponsor, regulatory authorities, or audit bodies may be granted controlled access to identifiable data for the purposes of monitoring, audit, or regulatory compliance. All such access will be strictly limited and subject to appropriate confidentiality obligations and data protection requirements.

Data will be retained in line with regulatory requirements and good research practice. Identifiable data will be retained for up to 3 years, and research data underpinning study findings may be retained for up to 10 years in accordance with sponsor and regulatory requirements, before secure deletion. Voice recordings, as identifiable biometric data, will be retained for a shorter period and will be securely destroyed 3 years after the end of the study.

All study personnel will comply with confidentiality requirements and data protection policies applicable to their organisation.

8.7 Indemnity

Participating NHS organisations will provide indemnity for clinical negligence and harm arising from the conduct of the study at site, in accordance with standard NHS indemnity arrangements.

Punto Health Ltd, as study sponsor, holds appropriate insurance to cover liabilities arising from the design, management, and conduct of the study, including non-negligent harm to participants.

In the event that a participant suffers harm as a result of participation in the study, appropriate procedures will be followed in line with NHS and Punto Health policies.

Punto Health has comprehensive insurance coverage provided by CFC Underwriting Ltd, including professional liability, cyber and privacy, general liability, and employers' liability.

8.8 Access to the final study dataset

Access to the final study dataset will be restricted to authorised members of the research team.

The sponsor (Punto Health) will have overall responsibility for access to and use of the final dataset.

Data shared with collaborators will be pseudonymised and limited to the minimum necessary for analysis purposes.

Any sharing of data outside the immediate research team will be subject to appropriate data sharing agreements and in accordance with UK data protection legislation.

No identifiable participant data will be shared in any publications or dissemination of study findings.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

The findings of this study will be disseminated through peer-reviewed publications, conference presentations, and reports to relevant stakeholders, including NHS partners and funders.

A summary of the study findings will be made available to participants upon request through the research team at participating sites.

Results will be reported in aggregate form only, and no individual participants will be identifiable in any publications or dissemination outputs.

The dissemination of findings will support future research, NHS service development, and potential implementation of PuntoTest within clinical pathways.

9.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship of study outputs will be determined in accordance with standard academic practice and based on substantial contributions to the conception, design, conduct, analysis, or interpretation of the study.

All contributors who meet authorship criteria will be appropriately acknowledged.

No professional medical writers will be used in the preparation of study outputs. If this changes, any involvement will be transparently declared in accordance with publication standards.