Health Research Authority

# PuntoCare Research Protocol

**PuntoCare: Digital support platform for MCI and dementia (v1.0)**

**Version:** 3.0 **Date:** 14 August 2026 **IRAS Number:** 367218

**SPONSORS Number:** PuntoCare_UK_01

**FUNDERS Number:** NIHR Reference: NIHR510915

## 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: 21/08/2026

Name (please print):

Anna Muñoz-Farré

Position: CEO & Co-founder

**Chief Investigator:**

Signature: 
.....

Date: 21/08/2026

Name: (please print):

Dr Latha Velayudhan

## LIST of CONTENTS

SIGNATURE PAGE 2
LIST of CONTENTS 3
KEY STUDY CONTACTS 5
STUDY FLOW CHART 9
1 BACKGROUND 10
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 14
5.1 Study Design 14
5.2 Methods of data collection 14
Study Procedures 14
Data Collection Schedule 15
Data Collection Measures 15
5.3 Data analysis 16
6 STUDY SETTING 16
7 SAMPLE AND RECRUITMENT 17
7.1 Eligibility Criteria 17
7.1.1 Inclusion criteria 17
7.1.2 Exclusion criteria 18
7.2 Sampling 19
7.2.1 Size of sample 19
7.2.2 Sampling technique 19
7.3 Recruitment 19
7.3.1 Sample identification 19
7.3.2 Consent 19
8 ETHICAL AND REGULATORY CONSIDERATIONS 20
8.1 Assessment and management of risk 20
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 23
8.7 Indemnity 24

8.8 Access to the final study dataset 24
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

| | |
|---|---|
| Chief Investigator | **Dr Latha Velayudhan**<br>Clinical Reader in Ageing and Dementia Studies, Consultant Old Age Psychiatrist<br>King's College London and South London & Maudsley NHS Foundation Trust<br>*Email: latha.velayudhan@kcl.ac.uk* |
| SPONSOR<br>Study Co-ordinator | PuntoHealth<br>**Anna Muñoz-Farré**<br>CEO & Co-founder<br>*Email: anna@puntohealth.com*<br><br>**Maria Rollano**<br>Project Manager<br>*Email: maria@puntohealth.com* |
| Site Investigators | **Dr Monica Crugel**<br>Consultant Psychiatrist, Memory Service<br>Oxleas NHS Foundation Trust – Memory Service (Greenwich)<br>*Email: monica.crugel@nhs.net*<br><br>**Dr Reshad Malik**<br>Consultant Psychiatrist, Memory Service<br>North London NHS Foundation Trust – Enfield Memory Service<br>*Email: reshad.malik@nhs.net* |
| Funder(s) | **National Institute for Health and Care Research (NIHR)**<br>i4i FAST Programme<br>Reference: NIHR510915 |
| Key Protocol Contributors | UCLPartners (Subcontractor)<br>**Luis Tojo**<br>UCLPartners Lead / Programme Oversight<br>*Email: luis.tojo@uclpartners.com*<br><br>**Nicholas Swart**<br>Health Economics Lead<br>*Email: nicholas.swart@uclpartners.com*<br><br>**Jyoti Sharma**<br>Health Economics Analyst<br>*Email: jyoti.sharma@uclpartners.com*<br><br>**Choja Macarthy**<br>Patient and Public Involvement and Engagement (PPIE) Lead<br>*Email: Choja.Macarthy@uclpartners.com* |

| | |
|---|---|
| Committees | Details of the Research Ethics Committee (REC) will be confirmed following IRAS submission and booking. |

## STUDY SUMMARY

This feasibility study evaluates the implementation of PuntoCare, a digital post-diagnosis support platform for individuals with mild cognitive impairment (MCI) and early dementia, within NHS memory services, including participants referred from primary and secondary care pathways. The study aims to assess feasibility, usability, acceptability, and engagement, as well as explore potential impact on service utilisation and preliminary health economic outcomes.

| | |
|---|---|
| Study Title | PuntoCare: Digital support platform for MCI and dementia (v1.0) |
| Internal ref. no. (or short title) | PuntoCare_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 memory services, including participants referred from primary and secondary care pathways. Named carers will be invited to participate where available, although participation of a carer is not mandatory. |
| Planned Size of Sample (if applicable) | ~90 patient-carer dyads |
| Follow up duration (if applicable) | 24 weeks |
| Planned Study Period | Approximately 20 months from site activation (anticipated completion: December 2027). The end of the study is defined as the date on which the last participant has completed all protocol-defined follow-up assessments and all study-related data collection required to meet the study objectives. |
| Research Question/Aim(s) | Can PuntoCare, a digital post-diagnosis support platform, be feasibly implemented within NHS memory services, and what is its potential impact on usability, acceptability, and service utilisation, including preliminary health-economic outcomes? |

## FUNDING AND SUPPORT IN KIND

| FUNDER(S) | FINANCIAL AND NON FINANCIAL SUPPORT GIVEN |
|---|---|
| NIHR i4i FAST (NIHR510915) | Financial support for study delivery and research activities |

| | |
|---|---|
| Punto Health Ltd (Sponsor) | Provision of in-kind support, including PuntoCare platform access (licences), platform maintenance, technical support, and project management |

## ROLE OF STUDY SPONSOR AND FUNDER

Punto Health Ltd is the study Sponsor and 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.

The funder, NIHR i4i FAST Programme, provides 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 is sponsored and coordinated by Punto Health. It 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 study coordination and delivery of the intervention. This includes:

- Provision and maintenance of the PuntoCare digital platform
- Management of platform access, user accounts, and technical infrastructure
- 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 study data collected via the PuntoCare 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:

- Participant identification and recruitment through routine clinical pathways
- Integration of the intervention within existing care pathways
- Provision of clinical oversight to ensure participant safety

**Site Delivery**

Each participating NHS site will be supported by a research nurse/research assistant responsible for participant recruitment, onboarding, weekly contact during the first month, and periodic check-ins throughout the study.

## 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.

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

**KEY WORDS:** Dementia, mild cognitive impairment (MCI), digital health, post-diagnosis support, cognitive stimulation therapy (CST), feasibility study, memory services, NHS, carers, health economics, service utilisation, wellbeing

## 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, reporting and dissemination

**STUDY PROTOCOL**

**PuntoCare: Digital Post-Diagnosis Support Platform for MCI and Early Dementia**

## 1 BACKGROUND

Dementia affects nearly one million people in the UK and represents a significant and growing public health challenge, with an estimated annual cost exceeding £42 billion, including approximately £16 billion borne by the NHS. The burden of dementia extends beyond healthcare systems, with unpaid carers providing substantial support and experiencing high levels of psychological and emotional strain (Alzheimer's Society, 2024; Alzheimer's Research UK, 2025).

Following diagnosis, access to structured post-diagnostic support remains limited. Only a small proportion of individuals report receiving adequate support from memory services, primary care, or voluntary organisations. Many families experience a dementia-related crisis within the first year of diagnosis, highlighting gaps in ongoing care and support (Alzheimer's Society, 2024). While Cognitive Stimulation Therapy (CST) is widely recommended and offered by NHS services, access remains inconsistent, with variation in programme delivery, completion, and capacity across sites (NICE, 2018).

There is increasing evidence supporting multimodal interventions for cognitive health, combining cognitive stimulation, physical activity, and lifestyle support. For example, the Finnish FINGER trial demonstrated that integrated approaches can improve cognitive outcomes compared to standard care (Ngandu et al., 2015). NICE guideline NG97 recommends interventions that promote cognition, independence, and wellbeing through personalised and meaningful activities (NICE, 2018). However, delivery of these interventions at scale within NHS services remains challenging due to workforce constraints, limited capacity, and variability in service provision.

PuntoCare is a digital post-diagnosis support platform designed to address these challenges by providing structured, personalised support for individuals with mild cognitive impairment (MCI) and early dementia, as well as their carers. The platform integrates cognitive stimulation exercises, physical activity, educational content, and symptom tracking diary within a single digital environment, with the aim of supporting ongoing self-management and reducing reliance on resource-intensive services.

Despite the growing interest in digital health interventions, there remains limited evidence on the feasibility of implementing such approaches within NHS memory services and their potential impact on service delivery and patient outcomes.

## 2 RATIONALE

Preliminary evidence from service improvement initiatives within NHS settings has demonstrated that PuntoCare can be successfully integrated into routine clinical care. The platform has been deployed within standard care pathways in NHS memory services in North London (Enfield) and Oxleas (Greenwich), supporting individuals with cognitive impairment and their carers. To date, over 60 patients have used the platform across these sites as part of routine care delivery. These real-world implementations have provided early evidence of feasibility, usability, and acceptability, as well as insights into integration within existing clinical pathways. This study represents a more formal prospective evaluation of an intervention that is already in place and operational within NHS services.

In addition, PuntoCare has been implemented in service improvement and clinical settings in Spain. A prospective study is currently underway at the Consorci Sanitari Alt Penedès-Garraf (CSAPG), which has received ethics approval and is expected to recruit approximately 200 participants. Further deployments in Hospital de Granollers (n=98) and Hospital del Mar (n=53) have enabled testing of the platform in regulated clinical environments and generated substantial feedback from patients, carers, and clinicians. Insights from these implementations have informed iterative improvements to the platform and provide additional supporting evidence of its acceptability and potential utility within clinical pathways.

However, despite these promising developments, there remains a lack of formal prospective evaluation within the NHS context. In particular, evidence is needed to assess feasibility of recruitment and retention, integration within routine care pathways, usability and acceptability, and potential service-level impact.

This study is therefore designed as a multi-site feasibility study to generate the necessary evidence to inform a future definitive pilot trial and support potential wider implementation within NHS memory services.

## 3 THEORETICAL FRAMEWORK

This pilot study is underpinned by a service delivery and self-management framework in which structured, accessible post-diagnostic support can improve patient outcomes while reducing pressure on healthcare systems.

Current NHS memory service pathways often provide limited ongoing support following diagnosis, with many patients receiving intermittent follow-up and relying on voluntary services or informal care (Alzheimer's Society, 2024). While Cognitive Stimulation Therapy (CST) is widely recommended and offered across NHS memory services, access and delivery remain inconsistent. Although approximately 88% of services report offering CST, only around 44% deliver the full evidence-based

programme, reflecting constraints in workforce capacity and service resources (Royal College of Psychiatrists, 2024).

At the same time, demand for services continues to increase, contributing to capacity constraints and extended waiting times (NHS England, 2023; Royal College of Psychiatrists, 2024).

PuntoCare is conceptualised as a digitally enabled intervention integrated within routine care pathways, designed to provide continuous, personalised support outside of traditional clinical settings. By delivering structured daily care plans, including cognitive stimulation, physical activity, and educational content, the platform aims to extend access to evidence-based interventions such as CST beyond resource-limited face-to-face programmes.

In addition, the platform supports self-management and carer involvement through symptom tracking, personalised content, and ongoing engagement, potentially improving wellbeing and reducing caregiver burden. By enabling patients and carers to access support remotely and consistently, PuntoCare may help reduce reliance on intensive clinical input and improve overall efficiency within memory services.

This approach aligns with broader NHS strategic priorities, including the NHS Long Term Plan, which emphasises prevention, personalised care, and the use of digital technologies to deliver care closer to home. Within this context, PuntoCare represents a potential mechanism for addressing gaps in post-diagnostic support, improving access to care, and supporting more sustainable service delivery models.

This study will evaluate the feasibility of implementing this model within NHS settings and explore its potential to contribute to improved patient and service-level outcomes.

## 4 RESEARCH QUESTION/AIM(S)

Can PuntoCare, a digital post-diagnosis support platform, be feasibly implemented within NHS memory services, and what is its potential impact on usability, acceptability, and service utilisation, including preliminary health-economic outcomes?

### 4.1 Objectives

Primary Objective

To assess the feasibility of implementing PuntoCare within NHS memory services. This includes:

- The ability to recruit the target number of participants across sites
- Participant retention over the 24-week intervention period
- Feasibility of integrating the platform within routine clinical pathways

Secondary Objectives

- To evaluate the usability and acceptability of PuntoCare amongst patients, carers, and clinicians
- To assess participant engagement with the platform, including usage patterns and feature utilisation
- To generate preliminary health economics data through a cost-consequence analysis conducted from an NHS perspective
- To explore the impact of PuntoCare on CST-equivalent support, including programme offer, uptake, completion, dropout, and total sessions delivered
- To explore the potential impact of PuntoCare on memory service waiting lists, including changes in waiting list size and average waiting time

Exploratory Objectives

- To estimate key parameters to inform a future definitive effectiveness trial (e.g. quality of life, carer burden, and service costs)

### 4.2 Outcomes

Primary Outcomes (Feasibility Criteria)

- Participant retention at 24 weeks
- Data completeness across study measures
- Feasibility of integration within routine clinical pathways

Secondary Outcomes (Usability, Acceptability, and Engagement)

- Usability and acceptability of the PuntoCare platform among patients, carers, and clinicians
- Participant engagement with the platform, including frequency and patterns of use
- Delivery of CST-equivalent support, including programme uptake, completion, and session delivery
- Potential impact on memory service waiting lists, including changes in waiting list size and waiting times
- Intervention costs and resource use associated with the implementation of PuntoCare

Exploratory Outcomes

- Patient and carer outcomes, including wellbeing, quality of life, and carer burden
- Participant, carer, and clinician experiences of the intervention, including barriers and facilitators to implementation

# 5 STUDY DESIGN, METHODS of DATA COLLECTION and DATA ANALYSIS

## 5.1 Study Design

This is a multi-site feasibility study with an embedded health economics evaluation.

The study is designed to assess the feasibility of implementing PuntoCare within NHS memory services, including participants referred from both primary and secondary care pathways, alongside an exploratory evaluation of usability, acceptability, and service-level impact.

The study design has been informed by Patient and Public Involvement and Engagement (PPIE) activities, incorporating feedback from lived-experience representatives to ensure relevance and acceptability to patients and carers.

Participants will engage with the PuntoCare digital platform over a 24-week intervention period, integrated within routine post-diagnosis care pathways.

Health economic evaluation will be conducted using a cost-consequence framework from an NHS perspective, focusing on delivery of CST-equivalent support and potential impact on memory service waiting lists.

**End of study definition**

The end of the study is defined as the date on which the last participant has completed all protocol-defined study procedures, follow-up assessments and all study-related data collection required to meet the study objectives. This includes the completion of all participant assessments and the collection of all data required to evaluate the study feasibility outcomes.

The anticipated study completion is December 2027; however, 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 be onboarded onto the PuntoCare platform and supported by a research nurse to initiate use of the intervention within routine care pathways. No additional in-person study visits are required beyond those aligned with routine clinical care.

Participants will use the PuntoCare mobile application over a 24-week period. The application comprises three main components:

1. **Daily Care Plans:** Participants will be guided through structured daily care plans, which include:
   - Adaptive cognitive stimulation exercises (evidence-based CST activities)
   - Video-based physical exercise protocols (tailored to mobility level)
   - Guided relaxation sessions
   - Healthy habits suggestions
   - Rewards system and progress tracking to support engagement
2. **Resource Library** of clinically validated educational modules and articles related to cognitive impairment and dementia management and care strategies, adapted to each participant's diagnosis and stage
3. **Symptom Diary:** allowing users, primarily carers, to log cognitive and behavioural symptoms over time.

Participants will receive structured support throughout the study, including:

- Onboarding workshops (digital literacy guidance, peer support, and device setup)
- Weekly contact during the first month (intensive support phase)
- Periodic check-ins at weeks 6, 12, and 24
- Ongoing technical support via email (pilots@puntohealth.com)
- In-app support form available throughout the study

Data Collection Schedule

Data will be collected automatically via the app at multiple timepoints, as outlined below. The measures collected are described in the following section.

- Baseline: WHO-5 Well-being Index , New General Self-Efficacy Scale (NGSE), demographic data
- Day 7 and 30: Customer Satisfaction survey (CSAT)
- Every 2 weeks: WHO-5 and NGSE
- Day 21 and 63: User Perception survey
- Day 30: Net Promoter Score (NPS)
- Day 74: Sean Ellis product market fit, NPS, and CSAT

Carers will also receive the Zarit carer burden survey at day 0 and day 70.

Data Collection Measures

The following data will be collected as part of the study:

**Feasibility data:**

- Recruitment and retention data (e.g. number of participants enrolled and completing the study)

- Participant adherence to the intervention (e.g. completion of study procedures and app use over time)
- Participation of carers, where applicable
- Study delivery metrics (e.g. completion rates, follow-up completion, and data completeness)

**Clinical and wellbeing data:**

- WHO-5 Well-Being Index: primary patient wellbeing outcome
- Zarit Caregiver Burden Scale (short form): carer burden
- New General Self-Efficacy Scale (NGSE): patient self-efficacy

**Health economics data:**

- Service utilisation data
- Data to support cost-consequence analysis from an NHS perspective

**Usability, acceptability, and satisfaction data:**

- Customer Satisfaction (CSAT) questionnaires: onboarding and overall satisfaction
- Net Promoter Score (NPS): likelihood to recommend the platform
- Perception questionnaires: perceived usefulness, ease of use, and impact

**Engagement metrics:**

- Sean Ellis Product Market fit questionnaire: how disappointed participants would be if they could no longer use PuntoCare
- In-app telemetry data, including logins, module access, session duration, and feature utilisation

### 5.3 Data analysis

Data analysis will be primarily descriptive, consistent with the feasibility design of the study. No formal hypothesis testing is planned.

Feasibility outcomes, including recruitment, participant retention, integration within clinical pathways, and data completeness, will be summarised using descriptive statistics.

Patient and carer-reported outcomes, including wellbeing (WHO-5), carer burden (Zarit), self-efficacy (NGSE) will be summarised descriptively. Where appropriate, changes between baseline and follow-up time points will be described.

Usability, acceptability, and satisfaction will be assessed using questionnaire-based measures, including Customer Satisfaction (CSAT), Net Promoter Score (NPS), and perception questionnaires. Results will be summarised descriptively.

Engagement with the platform will be described using in-app telemetry data, including frequency of use, session duration, module access, and feature utilisation.

Health economic analysis will be conducted using a cost-consequence analysis (CCA) framework from an NHS perspective. Costs and outcomes will be presented in a disaggregated format, focusing on intervention delivery, service activity, and relevant service-level metrics where available.

Qualitative data from PPIE interviews will be analysed using thematic analysis to identify key themes related to usability, acceptability, and implementation.

## 6 STUDY SETTING

This is a multi-site study conducted across NHS memory services in England. The participating sites are:

- NHS Oxleas NHS FT (Site Investigator: Dr. Monica Crugel)
- North London NHS FT (Site Investigator: Dr. Reshad Malik)

## 7 SAMPLE AND RECRUITMENT

### 7.1 Eligibility Criteria

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

#### 7.1.1 Inclusion criteria

**Patients:**

- Adults aged ≥50 years
- Capacity to provide informed consent
- Individuals in one of the following groups, as determined through routine clinical assessment and application of the following criteria:
    - 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

- Sufficient proficiency in English to complete the study procedures and use the digital platform
- Willingness and ability to engage with the PuntoCare digital platform over the study period
- Access to a compatible smartphone capable of running the PuntoCare application, either personally or via a carer.

**Carers:**

- Age ≥ 16 years
- Named carer of an eligible enrolled patient
- Capacity to provide informed consent

- Sufficient proficiency in English
- Able and willing to participate in study procedures

### 7.1.2 Exclusion criteria

**Participants:**

- Moderate or severe dementia, or any condition associated with lack of capacity to provide informed consent
- 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

**Carers:**

- Lack capacity to provide informed consent

## 7.2 Sampling

### 7.2.1 Size of sample

Approximately 90 participants will be recruited, with the option for each participant to involve a named carer, forming patient-carer dyads where applicable.

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).

### 7.2.2 Sampling technique

Participants will be recruited using a consecutive sampling approach through routine clinical pathways within NHS memory services, including individuals referred from primary and secondary care.

Eligible participants will be identified by clinical teams during standard care and invited to take part in the study. Where appropriate, participants may invite a named carer to take part in aspects of the study; carer participation is optional and not required for inclusion.

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.

#### 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 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.

#### 7.3.3 Withdrawn
Participants and carers may withdraw from the study at any time, without giving a reason, and without affecting their clinical care. Where a patient participant withdraws, the carer participant will not automatically be withdrawn. Carers will be offered the opportunity to continue participating in the study independently, or may choose to withdraw at the same time as the patient, according to their preference.

## 8 ETHICAL AND REGULATORY CONSIDERATIONS

### 8.1 Assessment and management of risk

Participation in this study is considered low risk. The study involves the use of a digital platform (PuntoCare), alongside completion of questionnaires and optional qualitative interviews.

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

There are no anticipated physical risks associated with participation. However, some participants and carers may experience mild psychological discomfort, such as fatigue, frustration, or emotional distress when reflecting on memory difficulties, caregiving responsibilities, or completing questionnaires related to wellbeing and burden.

To minimise potential distress:

- Participants will receive structured onboarding and ongoing support from a research nurse
- Participants and carers may pause or stop using the platform or completing questionnaires at any time without providing a reason
- Participation is entirely voluntary, and withdrawal from the study will not affect clinical care

There is no direct clinical feedback provided as part of the study. The platform is intended as a support tool and not a diagnostic or clinical decision-making system. Any clinically relevant concerns identified during the study will be communicated to the appropriate healthcare professional in accordance with standard clinical procedures.

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 post-diagnosis support and questionnaire-based research.

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

**Regulatory Review & Compliance**

Prior to study initiation, the study protocol and associated documents will be submitted for review and approval by a UK Research Ethics Committee (REC) and the Health Research Authority (HRA).

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 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.

PPIE input has been obtained from diverse groups to ensure representation, including people with mild cognitive impairment, mild dementia, and/or their carers.

**PPIE Activities Throughout the Study:**

Protocol Development Phase:

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

One workshop focused specifically on the PuntoCare study:

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

Participants included individuals with mild dementia, individuals experiencing memory difficulties, and carers.

During this session, participants were introduced to the PuntoCare study and platform, and reviewed key aspects of the Participant Information Sheet (PIS) and study materials. Feedback highlighted the importance of ensuring that participant-facing materials are clear, accessible, and appropriately structured, particularly for individuals with cognitive impairment. Participants emphasised the need to clearly explain the purpose of the study, what participation involves, potential benefits, and how personal data would be managed.

Participants also highlighted the importance of using accessible materials (e.g. easy-read documents and visual aids) to support understanding.

Feedback on the PuntoCare platform itself identified areas for improvement in usability and content clarity, including the need to better explain the purpose and expected benefit of specific activities, ensure appropriate and understandable language, and provide clearer guidance on how and when to use the platform.

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

During Study Implementation:

- Including lived experience representative(s) on the steering committee. Providing the opportunity for regular feedback and input on decisions
- Co-design workshops with lived experience representatives to inform ongoing study delivery and participant materials, as and when required
- Formal PPIE workshops from study participants to gather qualitative feedback on PuntoCare

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 wherever possible. Research data used for analysis will be pseudonymised to protect participant identity.

All study data, including questionnaire responses, app usage data, and qualitative interview data where applicable, 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.

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 PuntoCare 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.