ISRCTN54091957 https://doi.org/10.1186/ISRCTN54091957

PuntoCare: Digital support platform for mild cognitive impairment (MCI) and dementia (v1.0)

Submission date
10/09/2026

Recruitment status
Recruiting

Registration date
18/09/2026

Overall study status
Ongoing

Last Edited
05/10/2026

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

After diagnosis with mild cognitive impairment (MCI) or dementia, many people in the UK receive little structured support. Only 16% of people with dementia say they get adequate support from memory clinics, GPs, or charities. Over half of families experience a dementia-related crisis within a year, and carers often feel stressed and anxious.

PuntoCare is a smartphone app designed to help people with MCI or early dementia, and their carers, manage life after diagnosis. It provides daily personalised activities, including memory exercises, physical activity, educational information, and a symptom diary to track changes over time.

This study will test whether PuntoCare can work well within NHS memory services. We'll check if people can be recruited and stay in the study, if the app fits into routine care, and if people find it acceptable and easy to use.

Who can participate?

You can participate if you:

• Are aged 50 years or over
• Are able to give informed consent
• Have one of the following: subjective memory concerns, mild cognitive impairment, mild dementia, or no memory concerns (as a healthy comparison volunteer)
• Have sufficient English to complete the study procedures and use the digital app
• Are willing and able to use the PuntoCare app over the 24-week study period
• Have access to a compatible smartphone or tablet, either your own or via a carer

You cannot participate if you have:

• Moderate or severe dementia, or any condition that affects your ability to give informed consent
• Severe sensory, motor, or cognitive impairments that would prevent you from using the digital app, even with support
• Acute or unstable physical or mental health problems that, in the opinion of the clinical team, would make participation inappropriate

What does the study involve?

Participants will use the PuntoCare app for 24 weeks (about 6 months). They'll get training and

support from a research nurse to get started. They'll complete short surveys in the app about their wellbeing and how they're getting on with the app. Some participants may be invited to take part in a short interview at the end. There are no extra hospital visits needed; everything fits around usual care.

What are the possible benefits and risks of participating?
Benefits: Your participation will help us understand whether PuntoCare can be successfully used within NHS memory services and whether it improves wellbeing and support for people with memory difficulties. The findings could benefit many people with mild cognitive impairment or dementia in the future and help improve post-diagnosis support across the NHS.
Taking part may not directly benefit you personally. However, you will have free access to Punto-Care throughout the 24-week study, and you will be able to continue using the app at no cost after the study ends. You will also receive regular support from a research nurse during the study.
Your participation also contributes to valuable research that could shape how the NHS delivers care for people with memory concerns in the future.
Risks: There are no known medical risks associated with taking part in this study. The main activity involves using the PuntoCare app at home over 24 weeks and completing short questionnaires about your wellbeing.
Some people may find reflecting on memory difficulties slightly stressful or upsetting, or may experience technical issues with the app. The app is designed to be supportive and positive, and the research team are trained to respond sensitively if any concerns arise.
You can withdraw from the study at any time, and you are free to take breaks from using the app whenever you need to. If you find anything difficult, you can speak to the research team for support. Your participation will not affect your usual care in any way.

Where is the study run from?
The study is conducted across two NHS sites in England:
• North London NHS Foundation Trust
• Oxleas NHS Foundation Trust
• Gallions Reach Health Centre, as Participant Identification Centre.

When is the study starting and how long is it expected to run for?
The study is expected to start in September 2026, depending on site setup. We will recruit participants over approximately 12 months (from September 2026 to July 2027). Data analysis is anticipated to be completed by December 2027, although this date is indicative and may change de-pending on recruitment progress and data collection completion.

Who is funding the study?
The National Institute for Health and Care Research (NIHR) i4i FAST Programme. Punto Health Ltd is sponsoring the research.

Who is the main contact?
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Contact information

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Additional identifiers

Integrated Research Application System (IRAS)
367218

Central Portfolio Management System (CPMS)
72016

National Institute for Health and Care Research (NIHR)
510915

Study information

Scientific Title
PuntoCare: Digital post-diagnosis support platform for MCI and early dementia

Study objectives
Primary objective:
To assess the feasibility of implementing PuntoCare within NHS memory services. This includes:
1. The ability to recruit the target number of participants across sites
2. Participant retention over the 24-week intervention period
3. Feasibility of integrating the platform within routine clinical pathways

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

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

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/09/2026, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; no telephone number provided; bradfordleeds.rec@hra.nhs.uk), ref: 26/YH/0128

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Dementia and neurodegeneration

Interventions
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 primary and secondary care settings, 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. Where appropriate, carers may also take part alongside participants.
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.

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

Intervention Type
Other

Primary outcome(s)
1. Participant retention measured using recruitment and retention records at 24 weeks

2. Data completeness measured using Case Report Form (CRF) and questionnaire completion rates at baseline and week 24

3. Feasibility of integration within routine clinical pathways measured using qualitative interviews with healthcare staff and site teams involved in the study (assessing implementation feasibility, barriers, and facilitators) at week 24 (end of study)

Key secondary outcome(s)
1. Usability and acceptability of the PuntoCare platform among patients, carers and clinicians measured using Customer Satisfaction (CSAT) questionnaires at day 7, day 30 and day 74, the Net Promoter Score (NPS) at day 30 and day 74, User Perception surveys at day 21 and day 63, and optional semi-structured qualitative interviews with a subset of patients and carers to gather detailed feedback on usability and acceptability at week 24 (end of study)
2. Participant engagement with the PuntoCare platform, including frequency and patterns of use measured using in-app telemetry data (logins, module access, session duration, feature utilisation) collected continuously throughout the 24-week study period
3. Uptake, completion and delivery of CST-equivalent support measured using NHS trust service utilisation records and PuntoCare app data (number of patients offered, started, completed, and dropped out) at baseline and week 24
4. Memory service waiting list size and waiting times measured using NHS trust administrative data on waiting list size and average waiting times at baseline and week 24
5. Intervention costs and resource use associated with implementation of PuntoCare measured using Cost-Consequence Analysis (CCA) from an NHS perspective, including intervention delivery costs (licensing, training, ongoing support), healthcare resource use (memory clinic contacts, CST activity), waiting list metrics (size and average waiting time), and CST-equivalent delivery metrics (uptake, completion, dropout), at baseline and week 24

EXPLORATORY OUTCOMES:
1. Patient wellbeing measured using the WHO-5 Well-Being Index at baseline and every 2 weeks
2. Patient self-efficacy measured using the New General Self-Efficacy Scale (NGSE) at baseline and every 2 weeks
3. Carer burden measured using the Zarit Caregiver Burden Scale (short form) at day 0 and day 70
4. Patient quality of life measured using the EQ-5D-5L at baseline and week 24
5. Participant, carer and clinician experiences of the intervention, including barriers and facilitators to implementation measured using semi-structured qualitative interviews at end of study (week 24)
6. Product-market fit measured using the Sean Ellis Product Market Fit questionnaire at day 74

Completion date
17/12/2027

Eligibility

Key inclusion criteria
Patients:
1. Adults aged >=50 years
2. Capacity to provide informed consent
3. 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
4. Sufficient proficiency in English to complete the study procedures and use the digital platform
5. Willingness and ability to engage with the PuntoCare digital platform over the study period
6. Access to a compatible smartphone capable of running the PuntoCare application, either personally or via a carer.

Carers (participation is voluntary and not required for patient enrolment):
1. Age >=18 years
2. Named carer of an eligible enrolled patient

3. Capacity to provide informed consent
4. Sufficient proficiency in English
5. Able and willing to participate in study procedures

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
50 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Patients:
1. Moderate or severe dementia, or any condition associated with lack of capacity to provide informed consent
2. Severe sensory, motor, or cognitive impairments that would prevent completion of the study procedures, including use of the digital assessment tools, even with support
3. Acute or unstable physical or mental health conditions that, in the opinion of the clinical team, would make participation inappropriate

Carers:
1. Lack capacity to provide informed consent

Date of first enrolment
28/09/2026

Date of final enrolment
31/07/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

OXLEAS NHS Foundation Trust - Greenwich Memory Service
Memorial Hospital, Shooters Hill, Woolwich
London
England
SE18 3RG

Study participating centre
North London NHS Foundation Trust - Enfield Memory Service (EMS)
Chase Farm Hospital, The Ridgeway, Enfield
London
England
EN2 8JL

Study participating centre
Gallions Reach Health Centre (Participant Identification Centre (PIC) only)
Bentham Road
London
England
SE28 8BE

Sponsor information

Organisation
Punto Health Ltd

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository
- Repository name/location: Google Cloud Platform (managed by Punto Health Ltd)
- Type of data: Pseudonymised app engagement data, survey responses
- When available: Following completion of data analysis (estimated late 2027/early 2028)
- Duration: 10 years post-study completion
- Access criteria: Restricted to authorised Punto Health
- Access mechanism: Controlled via multi-factor authentication; audit trail maintained
- Consent obtained: Yes. All data protection measures, retention period, and potential future use are detailed in the Participant Information Sheet. Participants provide explicit informed consent to these arrangements by signing the Consent Form, which includes statements confirming understanding of data processing, pseudonymisation, and potential sharing for future research and publication in anonymised form.
- Data anonymisation: Pseudonymised with unique codes; direct identifiers removed- Ethical /legal restrictions: NHS REC approved; GDPR-compliant; Data Protection compliant
- Comments: Data will be aggregated and fully anonymised before any sharing or publication. Anonymised data may be used to support future research building on this study, shared with other researchers as part of future studies, and presented in scientific publications and presentations. No individual participant results will be identified

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3.0	14/08/2026	05/10/2026	No	No