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Impact on patient anxiety and quality of life of a training package for evaluation of dementia symptoms in primary care using test bundles - the Ensemble feasibility study

Submission date
09/12/2025

Recruitment status
Recruiting

Registration date
28/01/2026

Overall study status
Ongoing

Last Edited
06/02/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Having symptoms of dementia, and waiting for a diagnosis, can be a very anxious time. The pressure on secondary care-based memory services is increasing. Timely diagnosis is essential for people affected by dementia to access to treatment, support, and care planning. Current diagnostic pathways are often slow and burdensome, with waiting times for memory clinics reaching up to two years.
Primary care offers a potential route to earlier diagnosis, but time and resources are constrained. This study explores whether a structured, scalable approach—using trained Health Care Assistants (HCAs) to administer cognitive test bundles—can support GPs in making timely and accurate diagnoses for patients aged 75 and over.

Who can participate?
People may participate if they are 75 or older, have had cognitive symptoms for more than 6 months but no prior diagnosis of dementia, and have a supporter/partner/carer who is prepared to complete information and supporter questionnaires.
People may not participate if they have another neurological condition that typically requires specialist assessment, a sensory impairment, a learning disability, or do not have a supporter /partner/carer/

What does the study involve?
The study involves delivery of training packages to enable General Practitioners (GPs) to identify appropriate patients and select tailored cognitive test bundles, which are then administered by Healthcare Assistants (HCAs) in NHS primary care settings. A bespoke training package will be also delivered to HCAs to support their care of patients with cognitive symptoms and the administration of the assessments. The bundles include a cognitive test, an informant questionnaire, and a functionality assessment. The results will help inform GP led diagnosis in primary care.

What are the possible benefits and risks of participating?
The structured and tailored assessments that participants would be given may support more timely and robust clinical decision making. Referral to unsettling and unfamiliar secondary care environments may be avoided, and diagnoses may be delivered in the more familiar and local primary care environment.
There are no known or anticipated risks from participation.

Where is the study run from?
The study is run from the Centre for Academic Primary Care, Bristol Medical School, University of Bristol (UK).

When is the study starting and how long is it expected to run for?
Recruitment will commence December 2025 and may continue until September 2026.

Who is funding the study?
National Institute for Health Research, Research for Patient Benefit (rfpb@nihr.ac.uk)

Who is the main contact?
Chief Investigator: Dr Sam Creavin MRCGP PhD, NIHR Clinical Lecturer General Practice, sam.creavin@bristol.ac.uk
Study coordinator: Leigh Johnson, leigh.johnson@bristol.ac.uk

Contact information

Type(s)
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Additional identifiers

Integrated Research Application System (IRAS)
342515

Central Portfolio Management System (CPMS)
61841

Study information

Scientific Title
Impact on patient anxiety and quality of life of a training package for evaluation of dementia symptoms in primary care using test bundles - the Ensemble feasibility study

Acronym
Ensemble

Study objectives
To hasten the diagnosis and treatment of some patients with cognitive symptoms, to reduce the anxious time for patients waiting for a diagnosis, and to reduce the burden on specialist services

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/11/2025, Harrow REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8154; harrow.rec@hra.nhs.uk), ref: 25/LO/0760

Study design
Cluster feasibility trial (not randomized)

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied

Dementia

Interventions
This study explores whether a structured, scalable approach, using trained Health Care Assistants (HCAs) to administer cognitive test bundles tailored to patient presentation, can support GPs in making timely and accurate diagnoses for patients aged 75 years and over.

Potential participants may learn about the study via posters in the GP practice, via contact from the practice inviting them to review study information and speak to their GP if interested, or via a GP proactively mentioning the study and discussing the possibility of participation during a consultation.

If the GP considers a patient to be potentially eligible, they will provide a brief information leaflet and ask for verbal consent to share the patient's contact details with the study team. The study coordinator contacts patients by phone or email to explain the study in more detail and to determine eligibility. Patients are then sent a participant information sheet by email or post. They are given as much time as they need to consider participation, with no imposed deadline.

Two approaches to consent will be tested – one is consent received by an Ensemble-trained Healthcare Assistant (HCA) at their GP practice, and one is consent received remotely by the Study Coordinator at the University of Bristol. If the patient agrees to participate, the study team will ask the GP practice to schedule an in-person Ensemble appointment.

The participant is sent baseline General Anxiety Inventory (GAI), EQ5D and ICECAP-O questionnaires prior to attending their Ensemble appointment, where the HCA administers the cognitive test chosen by their GP as part of their tailored assessment bundle. During this appointment, the participant will be given the opportunity to undertake an optional 20-minute Cognospeak assessment. An appointment is then made for the participant to see the Ensemble-trained GP for a diagnostic consultation.

The final involvement for the participant is completing follow-up GAI, EQ5D and ICECAP-O questionnaires 6 weeks after the Ensemble appointment. The total duration of the study activities, including the optional 20-minute Cognospeak assessment, is estimated to be 100 minutes.

Supporter participation:
Supporters (e.g. partners, carers or family members of the patient participants) are asked to complete questionnaires for Ensemble. It is not a requirement of the study that Supporters are present during the study activities of the patient participant, but Supporters will be asked to complete GAI, EQ5D, IQCODE, Lawton IADL and ASCOT questionnaires before the HCA-led Ensemble appointment, and the GAI and EQ5D 6 weeks later. We estimate that these questionnaires will take 20 minutes to complete.

Intervention Type
Other

Primary outcome(s)
1. Recruitment rate of eligible patients in each practice measured using recruitment records at the end of the study
2. % of outcome measures (General Anxiety Inventory, EQ5D-5L, ICECAP-O items) collected at baseline and follow up in each practice measured using data records at the end of the study

Key secondary outcome(s))
1. Acceptability of the intervention to patients, supporters, and healthcare professionals is measured using semi-structured interviews and observations at end of study
2. GP confidence in assessing dementia is measured using pre- and post-training surveys at baseline and immediately post-training
3. HCA confidence in assessing dementia is measured using pre- and post-training surveys at baseline and immediately post-training
4. Fidelity to the study protocol is measured using observations of assessment delivery and documentation of deviations with rationale at end of study
5. Diagnostic robustness is measured using expert clinical review of selected cases to assess appropriateness and quality of diagnoses at end of study
6. Long-term outcomes including onward referrals and confirmed diagnoses are measured using GP records at baseline and annually for seven years
7. Recruitment reach and representation for underserved NHS populations is measured using screening logs at end of study
8. Reasons for non-participation are measured using screening logs and optional brief interviews with a small number of patients and supporters who decline participation at end of study

Completion date
30/09/2026

Eligibility

Key inclusion criteria
1. Be aged 75 years or older
2. Present with cognitive symptoms for at least 6 months
3. Not have a prior diagnosis of dementia
4. Have a supporter they have known for several years who is prepared to complete informant and functionality questionnaires

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
75 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Sensory impairment (registered blind or unable to use a phone due to deafness)
2. Learning disability
3. No availability of a supporter (e.g. family member or friend) who knows them well and is willing to complete informant and functional questionnaires. Supporters may provide input remotely if needed
4. Presence of other neurological conditions (e.g. Parkinson's disease) that would typically require specialist assessment

Date of first enrolment
10/11/2025

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Pier Health Pcn
168 Locking Road
Weston-super-mare
England
BS23 3HQ

Study participating centre
Pioneer Medical Group
Ardenton Walk
Bristol
England
BS10 6SP

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Not defined

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

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 and/or analysed during the study will be stored in a non-publicly available storage (encrypted University of Bristol servers): https://www.bristol.ac.uk/acrc/research-data-storage-facility/

IPD sharing plan summary
Stored in non-publicly available repository