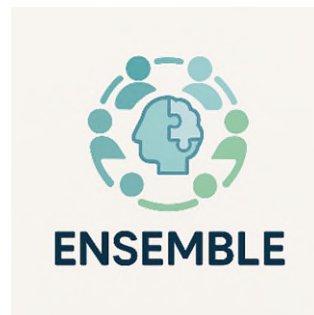


This protocol has regard for the HRA guidance

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 CLUSTER TRIAL



Draft Protocol version 1.1

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NIHR Research for Patient Benefit

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Ensemble Partnership Group (mixed stakeholders including community workers and charities, including Bristol Dementia Action Alliance and Alive Activities, who support people living with dementia and their carers)

Dementia Health Integration Team (Bristol Health Partners) Providers Forum

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1. Background and Rationale

Dementia affects over 676,000 people in England and costs the UK economy £23 billion annually—more than heart disease, stroke, or cancer. Timely diagnosis is essential for accessing treatment, support, and care planning. However, current diagnostic pathways are often slow, with waiting times for memory clinics reaching up to two years. These delays are particularly burdensome for older adults and underserved populations.

Primary care offers a potential route to earlier diagnosis, but GPs face time and resource constraints. 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.

Although the National Institute for Clinical Excellence has not approved recent disease-modifying treatments such as Lecanemab and Donanemab for NHS use, their development highlights the growing interest in earlier diagnosis and the need for scalable diagnostic pathways.

This feasibility study will assess the acceptability and practicality of this approach with a primary focus on the feasibility of recruitment, delivery, and outcome measurement, and a secondary focus on changes in patient and supporter anxiety and quality of life.

While multilingual testing and community-based drop-in sessions are not part of this feasibility phase, they are being explored through ongoing PPI and may be incorporated into the main trial.

2. Patient and Public Involvement (PPI)

Early Engagement and Partnership Development

PPI has been at the centre of the development of the Ensemble study. From June 2023 to September 2024, we engaged with people living with dementia, carers, and community stakeholders through a range of activities:

- Visits to three Bristol-based memory cafés and the Alzheimer’s Society’s Dementia Voice group
- Meetings with the ReMemBr Group’s PPI panel at the Bristol Brain Centre
- Discussions with the Providers Forum of the Dementia Health Integration Team (Bristol Health Partners)
- A stakeholder workshop in October 2024 involving representatives from Alive, the Chinese Community Wellbeing Society, and the Bristol Dementia Action Alliance.

Once we had obtained study funding, we established a Partnership Group, which met on four occasions to co-design the test bundles and training materials. This group includes people with lived experience, carers, community leaders, and health professionals. Our PPI co-

applicants, Winsome Barrett-Muir and Julie Clayton, have played central roles in facilitating inclusive and meaningful engagement throughout. Feedback from people living with dementia, carers, and community stakeholders has directly shaped the Ensemble study processes. The following themes emerged from our engagement activities and have been incorporated into the study design:

- **Pathway design:** There was strong support for a model where patients are first seen by a GP and then referred to a Health Care Assistant (HCA) to carry out cognitive assessments. This was seen as more acceptable and less formal than an assessment with a GP alone.
- **Acceptability of HCA-led assessments:** Some participants had already experienced cognitive assessments conducted at home by a nurse and found this approach acceptable and reassuring.
- **Comfort and accessibility:** Patients may feel more at ease with an HCA, especially in the context of anxiety around memory concerns. This informed the decision to use HCAs as the primary assessors in the intervention.
- **Acknowledgement of GP workload:** Contributors recognised the time pressures on GPs and the difficulty of securing appointments. This reinforced the need for a model that supports GPs without increasing their burden.
- **Training quality:** The importance of comprehensive, empathetic training for HCAs was emphasised. Awareness of cultural sensitivities, stigma and fear has been built into the training package.
- **Co-design and governance:** There was strong support for the co-design process, including the involvement of a stakeholder steering group comprising health professionals, people living with dementia, and carers. This group has been central to shaping the intervention.
- **Trial design:** PPI contributors agreed with that study recruitment could be at the level of Primary Care Networks (PCNs), to reflect real-world implementation.
- **Study team communication:** Initial contact from the study team to potential participants should be via email. Unexpected calls will likely be unanswered. A careful approach is required when investigating reasons for declining the study.
- **Site selection:** There was support for the feasibility study recruiting in a coastal community with a high level of socioeconomic deprivation, to test the study protocol among underserved patient populations.
- **Outcome measures:** Contributors endorsed the inclusion of patient anxiety as a key outcome, recognising the emotional impact of both symptoms and the diagnostic process. The Geriatric Anxiety Inventory (GAI) will be used.

- Non-participation feedback: PPI members advised that it was acceptable to approach patients who decline participation to share their reasons and advised using a short questionnaire or optional phone interview.
- Summary of participant journey and time commitment: PPI members approved a participant timeline, outlining all patient activities with estimated time required, for inclusion in information materials.

These insights have been instrumental in shaping the study's structure, recruitment strategy, training content, and outcome selection. Table 1: influence of PPI on Ensemble study design summarises each recommendation and how it has been incorporated into the study design. This includes adaptations to recruitment materials, test bundle design, training content, and plans for future scalability.

Table 5: influence of PPI on Ensemble study design

Recommendation	Influence on study design
Overall design	
Role of partner: it's important to have a partner/spouse/carer present to be the 'memory' for the person living with dementia	Inclusion of a study partner to provide additional information via an informant and activities of daily living questionnaire. Patient participants will choose who accompanies them for the assessment.
Recruitment: getting an invitation letter helps patients to take the invitation seriously	Information materials will be sent by post or email once research team have confirmed eligibility
Communication between GP, HCAs and patients/carers	
Importance of continuity of staff and a compassionate and empathetic manner	To be incorporated into training materials for GPs and HCAs
Staff must understand that patients experience a lot of fear and stigma around getting a diagnosis and anxiety around the testing process	Design training materials for GPs and HCAs to reflect this. Plan to incorporate dignity-preserving practices, such as offering private assessments or allowing patients to choose who is present.
It can take a long time before someone is willing to go to the GP	To be incorporated into training materials for GPs and HCAs

For some, they may feel relief at getting a diagnosis when had suspected something was wrong	To be incorporated into training materials for GPs and HCAs
Importance of providing post-diagnostic support	Signposting to Alzheimer's Society resources. The Partnership Group agreed that future phases of Ensemble should consider how to integrate or signpost post-diagnostic pathways.
Staff must understand that patients can go away feeling that they are not being believed (especially due to insensitivity of tests used for patients with high cognitive reserve)	To be incorporated into training materials for GPs and HCAs
Language and cultural barriers may prevent patients and carers from coming forwards	Design of a test bundle for people whose first language is not English. Creation of Easy Read versions of recruitment materials to allow for different levels of literacy and with images representing diversity of people eg from different ethnicities and disabilities.
Low literacy levels may be a barrier to participation	Future iterations of the test bundles should consider non-written formats (e.g. audio, pictorial, or verbal administration) and ensure that materials are accessible to those with limited literacy
Careful consideration of who conducts test bundles in order to facilitate participation of people from underrepresented groups e.g. minoritised ethnic communities	Future extended work could include more co-design workshops, community advisory panels, or pilot testing in diverse settings to strengthen inclusivity and trust.
There may be religious and cultural taboos around discussing memory loss or mental health; seeking a diagnosis may be seen as shameful or as a failure of familial duty	Future bundle development could benefit from engagement with faith leaders and cultural mediators to co-design approaches that are respectful and effective within specific cultural frameworks
Ethical issues, such as assessing patients who may not fully understand the process, or who are brought in by family members	To be addressed in training materials and study protocol

under pressure, highlight the importance of informed consent and safeguarding	
Support a 'drop-in' informal opportunity for patients and carers to chat to someone before having tests – e.g. in the GP practice or community – for people to ask questions and feel more confident to ask GP for a test	Study advertising materials will be shared with local community groups and organisations to help raise awareness about the study and encourage conversations with community group leaders as part of the ongoing engagement work around the study, targeted locally to the PCNs in Weston-Super-Mare and Avonmouth.
Design of cognitive assessments	
The importance of having a range of tests for a more holistic assessment of the patient	Co-design of four different test bundles to distinguish between different categories of patients, discussed and agreed by Partnership Group.
Tailor assessments to distinguish between a patient who is highly educated and has 'cognitive reserve' and one who is less educated and performs less well on the same tests	Design of a test bundle for patients with high baseline functioning.
Need to allow adequate time for assessments especially as patients will feel nervous and will need to have time to calm down before doing tests	Allow around an hour per assessment appointment
Scheduling of study appointments	The optimum time for patients to have study appointments at the surgery was identified as 11.30-14.30.
Information materials	PPI members co-designed two information resources: A Poster style A4 sheet with a summary on the back and a full length Easy Read style information sheet.

3. Study Aims, Design and Methods

3.1.1 Principal Study Aims

With the ultimate aim of hastening 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, the study has four main objectives:

1. Develop, deliver and evaluate a training package that GPs and HCAs can undertake to enable them to assess and/or diagnose people with cognitive symptoms.
2. Co-design, implement and evaluate four cognitive test bundles tailored to different patient presentations.
3. Evaluate the feasibility and acceptability of delivering dementia assessments in primary care (rather than usual referral to secondary care based specialist memory clinic), including recruitment, data collection, and diagnostic decision-making.
4. Conduct a process evaluation (including fidelity to the study protocol) to inform the design of a future cluster randomised trial.

To meet these objectives three Work Packages have been developed:

- Work Package 1 (WP1), development of bundles of tests for the assessment of cognitive symptoms in primary care, to be delivered by an HCA.
- Work Package 2 (WP2), development of a training package to support the delivery of the test bundles in primary care by an HCA.
- Work Package 3 (WP3) aims to test outcomes for patients, supporters, GPs and HCAs, evaluate the feasibility and acceptability of delivering dementia assessments in primary care, and review study processes to inform the design of a future cluster randomised trial.

The Ensemble Feasibility Cluster Trial, aims to assess feasibility by examining whether practices can:

1. Recruit an average of five eligible patients per month
2. Collect at least 80% of outcome measures at baseline and follow-up.

This will enable us to evaluate whether a full-scale trial is achievable. The process evaluation will assess if the training package improves the confidence of primary care staff in conducting dementia assessments, and whether the process is acceptable to patients, their supporters, and NHS stakeholders, and members of the wider dementia community.

3.1.2 Secondary Aims and Objectives

1. **Diagnostic accuracy:** Clinical experts will review selected cases to assess diagnostic quality to assess whether the study protocol supports appropriate and robust dementia diagnosis in primary care. Long term outcomes such as onward referrals and confirmed diagnoses will be monitored over a seven year period using practice records.
2. **Inclusion of underserved populations:** We will assess how well the study protocol works in practices serving socioeconomically deprived and ethnically diverse communities. Socioeconomic and ethnicity data will be collected using screening logs.
3. **Understanding reasons for non-participation:** To understand why some patients choose not to take part in the study, we will capture reasons for declining on screening logs. In addition, a small number of patients who decline and their supporters (a supporter is a partner, carer, friend, or family member who knows the participant well) will be invited to participate in brief interviews.

3.2 Work Package 1 – development of the test bundles

We have developed four test modules (bundles) tailored to different patient presentations, to be administered by HCAs in primary care. These were co-designed with our stakeholder Partnership Group, who helped ensure the test bundles are practical, acceptable, and feasible to deliver in busy general practice settings. Each bundle includes: One cognitive test; one informant questionnaire, and one functional assessment. The test bundles are designed to take no more than 30 minutes to administer and are matched to the following patient presentations:

1. General memory problems
2. Post-acute illness or frailty
3. Language and cultural barriers
4. High baseline cognitive functioning

To simplify delivery, the same informant questionnaire (IQCODE-Short Form) and functional assessment (Lawton IADL) are used across all test bundles. In this study, we will use the term 'supporter' to describe the informant. The supporter may be a partner, carer, friend or family member that the patient has known for several years.

3.2.1 Individual tests and assessments

1. General Practice Assessment of Cognition – GPCOG

GPCOG consists of cognitive test items and historical questions asked of an informant. There are nine cognitive test items covering clock drawing (time orientation clock drawing, with numbers and spacing, placing hands correctly), awareness of current news event, and recall of a name and address (including first name, last name, number, street and suburb). The informant interview covers six domains (memory, word finding difficulty, trouble managing finances, difficulty managing medication, needing assistance with transportation).

The cognitive items will typically take four minutes, and the informant questionnaire will typically take two minutes.

Brodaty, H., et al., The GPCOG: a new screening test for dementia designed for general practice. *Journal of the American Geriatrics Society*, 2002. 50(3):530-4.

2. The Montreal Cognitive Assessment (MoCA)

A 10-minute assessment of mild cognitive impairment, with 30 items covering the domains of orientation, short term memory, focus and spatial awareness, language, concentration and a clock drawing test.

(mocacognition.com)

3. The Rowland Universal Dementia Assessment Scale (RUDAS)

RUDAS is a six-item test across the following cognitive domains: short term memory (recalling grocery items), visuospatial orientation (identifying left/right parts of the body), praxis (copying exercises with hands), drawing (copying a cube), judgement (crossing the road) and language (naming a number of animals). It is designed to minimise the effects of cultural learning and language in the assessment of cognition.

Storey, J., Rowland, J. T. J., Conforti, D. A., & Dickson, H. G. (2004). Rowland Universal Dementia Assessment Scale (RUDAS) [Database record]. APA PsycTests <https://doi.org/10.1037/t28535-000>

4. The informant questionnaire – the Informant Questionnaire on Cognitive Decline (IQCODE) – short version (16 items)

IQCODE contains everyday situations where a person is asked to use their memory or intelligence. For each item the informant is asked to report whether the person has improved, not changed or got worse in these situations. Examples of the situations are recalling things about their family and friends and remembering where things are kept. IQCODE measures change in the person, so their results do not correlate with intelligence or education.

To standardise and streamline the test bundles, IQCODE is chosen as the informant questionnaire across all test bundles.

Jorm, A. F. (1994). *"A short form of the Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE): Development and cross-validation"*. Psychological Medicine. 24 (1): 145-153. [doi:10.1017/S003329170002691X](https://doi.org/10.1017/S003329170002691X). [PMID 8208879](https://pubmed.ncbi.nlm.nih.gov/8208879/). [S2CID 43263986](https://pubmed.ncbi.nlm.nih.gov/43263986/).

5. Functionality Assessment Questionnaire – Instrumental Activities of Daily Living (IADL)

This test assesses the level of disease and to determine the ability of the patient to care for themselves, by measuring the functional impact of emotional, cognitive and physical impairments. Domains include using the telephone, shopping, food preparation, housekeeping, laundry, transportation, and responsibility for own medicine.

Lawton, M.P., and Brody, E.M. "Assessment of older people: Self-maintaining and instrumental activities of daily living." *Gerontologist* 9:179-186, (1969)

3.2.2 Summary of Test Bundles

Table 6: Overview of the four cognitive test bundles used in the Ensemble study, each tailored to a specific patient presentation. Each bundle includes a cognitive test, an informant (supporter) questionnaire (IQCODE), and a functional assessment (Lawton IADL).

Bundle	Patient Presentation	Cognitive Test(s)	Informant	Functional
1	General Memory Problems	GPCOG ± MoCA MoCA score of <18	IQCODE	Lawton IADL
2	Post-Acute Illness/Frailty	GPCOG	IQCODE	Lawton IADL

Bundle	Patient Presentation	Cognitive Test(s)	Informant	Functional
3	Language and Cultural Barriers	RUDAS	IQCODE	Lawton IADL
4	High Baseline Functioning	MoCA (score of ≥ 18 but < 25)	IQCODE	Lawton IADL

3.2.3 Patient Presentation Criteria

1. **General Memory Problems:** Patients aged 75+ with no prior dementia diagnosis or significant language/cultural barriers.
2. **Post-Acute Illness/Frailty:** Patients aged 75+ recovering from illness or with multiple comorbidities. Shorter assessments are prioritised.
3. **Language and Cultural Barriers:** Patients aged 75+ with limited English proficiency or from underserved communities.
4. **High Baseline Functioning:** Patients aged 75+ with high cognitive reserve (e.g. professionals), presenting with subtle or atypical symptoms.

3.3 Work Package 2 – development of the training packages

This work package focuses on developing and delivering a training package to support the implementation of the cognitive test bundles (developed in WP1) by HCAs and GPs in primary care. There are separate packages for GPs and HCAs. We plan to train one GP and one HCA from each recruiting practice.

The training has been co-designed with input from our stakeholder Partnership Group, including experts in healthcare education, clinicians, and people with lived experience of dementia. The training is delivered remotely e.g. via a Sway document with embedded videos, to ensure accessibility and scalability.

3.3.1 Training for GPs

The GP training features interviews with up to three experienced GPs who share their approaches to:

- Tailoring cognitive assessments to individual patient presentations
- Deciding when to refer patients to specialist services versus managing within primary care
- Collaborating with HCAs and other practice staff to coordinate assessments and follow-up

The training emphasises the importance of clinical judgement, appropriate use of test bundles, and maintaining a patient-centred approach.

3.3.2 Training for HCAs

The HCA training provides step-by-step guidance on:

- Administering the cognitive test bundles developed in WP1
- Preparing the environment and supporting patient comfort (e.g. ensuring glasses/hearing aids are available)
- Setting expectations with patients (e.g. clarifying that diagnosis will follow a GP consultation)
- Managing the involvement of supporters, including when and how to complete informant and functional questionnaires
- Respecting patient preferences regarding supporter presence during testing
- Scheduling and conducting 30-minute appointments in a quiet, private space
- Following up with patients and coordinating with the practice team

The training also includes a strong focus on interpersonal skills, including how to support patients who may be anxious, confused, or distressed. Dignity-preserving practices are embedded throughout.

The training also addresses time management and workflow integration to minimise disruption to routine HCA duties.

3.3.3 Consent and Ethics Training

A separate module within the HCA training will cover the process of obtaining informed consent, including:

- Explaining the study clearly and compassionately
- Ensuring patients understand their rights and the voluntary nature of participation
- Supporting patients with communication or cognitive difficulties during the consent process

3.3.4 Stakeholder Feedback and Iteration

Stakeholder sessions during WP2 have been used to:

- Gather feedback on the training content and delivery
- Address concerns raised by clinicians or PPI contributors
- Refine the training to ensure it is practical, acceptable, and adaptable to different primary care settings

These sessions included members of the Partnership Group and representatives from participating practices.

3.3.5 Flexibility and Scalability

The training package is designed to be:

- **Scalable:** Suitable for wider rollout in a future definitive trial
- **Flexible:** Adaptable to local contexts, resources, and staffing models
- **Accessible:** Delivered online via platforms compatible with NHS systems (e.g. e-LfH, YouTube, MS Teams)

3.4 Work Package 3 - Process Evaluation

A mixed methods process evaluation will evaluate intervention acceptability to patients and their supporters, and health care practitioners, fidelity of study delivery, and reach of the study. It will also contribute to an assessment of Primary Care's capacity to deliver the intervention. The findings will be used to refine and optimise the intervention and study processes for a future trial.

The evaluation study will involve the following research methods: semi-structured interviews, mixed methods observations and quantitative data collection.

3.4.1 Participant recruitment for process evaluation

At recruiting sites, patients and their supporters, HCPs involved in delivering the intervention, GP practice managers and any other HCPs who may be impacted by the intervention, will be provided with a participant information sheet and invited to participate in a semi-structured interview.

Participant consent

Patient consent to participate in a semi-structured interview and to be observed (trial participants only) will be an optional add-on to the main study and will be sought at the same time as consent is sought to join the intervention study.

We will use a single comprehensive consent form when a person consents to both the main (intervention) study and the process evaluation interviews. We will use a separate consent form only covering process evaluation interviews when someone declines the intervention study but is happy to be interviewed.

Consent from GPs, HCAs, and HCPs at recruiting sites will be sought at site set up.

3.4.2 Semi Structured Interviews

Semi-structured interviews will be conducted with:

- Trial participants and their supporters after receiving the intervention to explore their experience and acceptability of the intervention and study procedures.
- Individuals who decline to participate in the trial, to explore factors considered in the decision.
- GPs and HCAs at two time points: 1. after training - to understand experience of training and acceptability of the intervention, 2. after delivery of the intervention to assess acceptability and fidelity of intervention delivery and reasons for any non-compliance.
- Practice managers and participating sites
- Staff at recruiting sites to assess acceptability of the intervention.
- Members of the wider dementia community to assess acceptability of the intervention and plans for a future trial.
- The qualitative researchers have worked in partnership with PPI members to co-design the conduct and content of interviews with patients who accept and decline participation in the study. These interviews are referred to as 'Research conversations' in the patient facing material, a term collectively arrived at to put potential interviewees at ease and to convey a welcoming friendly encounter.

3.4.3 Mixed-methods observations

- Observations of at least two patients receiving the intervention per site. A quantitative checklist will be used to assess fidelity of delivery as will qualitative observation field notes (optional).

3.4.4 Quantitative data

- Screening logs (eligibility, invitation, consent rates)
- Demographics (including ethnicity and postcode for IMD)
- Training confidence surveys (pre- and post-training)
- Site-level data (e.g. bundle used, time taken, referrals made, fidelity to bundle, scheduling of the extended GP appointment)
- Follow-up data (referral to memory clinic, referral for other diagnostic tests, number of new diagnoses of dementia and other cognitive disorders e.g., mild cognitive impairment (MCI)).

3.4.5 Data Analysis for process evaluation

Semi-structured interview data and any observational field notes will be analysed thematically using the constant comparison approach adopted from Grounded Theory [1]. Anonymised transcripts will be uploaded to NVIVO software to facilitate coding and the grouping of codes into themes. All transcripts will be coded by a Senior Researcher Associate and a sample will be double coded by a Research Fellow to ensure rigour, to resolve any discrepancies and to refine the coding system. Data collection and analysis will be iterative and the sample size will be guided by an assessment of data sufficiency and information power [2]. Descriptive statistics will be used to analyse screening log data.

3.4.6 Data management for process evaluation

Semi-structured interview data will be collected as encoded digital audio-files or video files and transferred to a secure UoB server with access restricted to the Ensemble study team. Audio files (digital and video) will be transcribed into word files by secure University of Bristol approved transcription services. Transcriptions will be anonymised on receipt.

The transcripts and audio-files will be labelled with a unique code – never the participant's name. Coding keys matching the name of the participants with their study participation number will be stored in a password protected spreadsheet on the secure University of Bristol server. The participant's name, any names mentioned during the interview or observed meeting, and any other form of identifiable information, will never be stated on or

within any written data or research reports, publications, or presentations. Any personal identifiable information (name, address) will be deleted at the end of the study.

If a video is captured during the interview this will be deleted and only the audio will be saved. Digital interview recordings and electronic transcripts will be saved in a secure computer and to a password protected University of Bristol network space, in accordance with the University of Bristol's data security policies. Interview recordings will be stored for 10 years, after which they will be deleted, and all copies destroyed. Transcripts will be stored indefinitely, with the participant's permission.

Participants can make a request for their data to be withdrawn within two weeks of the interview being conducted. Thereafter, it will not be possible as it will have been anonymised and analysis will have begun.

3.4.7 Access to data for process evaluation

Audio-files of the recorded interviews will not be suitable for sharing as they carry a high risk of allowing the participants to be identified. Whilst qualitative transcripts will be anonymised, there is a risk of identification and so access will be controlled. Permission will be sought from participants to make any transcripts of data "Controlled Access". This means the transcripts will be stored in a secure online database indefinitely for potential analysis by other researchers. These individuals will need to apply to do this, and an independent University of Bristol committee will assess the request. Data will only be released if approval is given by the committee. Any data released will be anonymised, so that individuals will not be identifiable.

1. Glaser, B.G., Strauss, A.L., *The discovery of grounded theory: Strategies for qualitative research* 1967, Chicago, IL: Aldine.
2. LaDonna, K.A., A.R. Artino, Jr., and D.F. Balmer, *Beyond the Guise of Saturation: Rigor and Qualitative Interview Data*. J Grad Med Educ, 2021. **13**(5): p. 607-611.

3.4.8 Mapping primary care processes to existing referral pathways

We recognise the need for primary care dementia processes to incorporate and in bed with an existing memory services which we recognise vary around the country as part of the process evaluation. Our team will conduct interviews and conversations with colleagues working in areas outside of recruiting practices do you understand how referral pathways to

secondary care and memory services work at present and how a primary care based service might influence this.

3.5 Trial Processes

3.5.1 Recruitment and Setting

We aim to recruit between **40 and 80 patients** aged 75 and over from two primary care networks (PCNs) in the Bristol, North Somerset and South Gloucestershire Integrated Care Board (ICB) area, selected to test feasibility in underserved and diverse populations:

- **Pioneer Medical Group** (North Bristol): ~22,000 patients, 20% aged 70+, high deprivation (IMD decile 2)
- **Pier Health Group** (Weston-super-Mare): ~95,000 patients, 34% aged 70+, high deprivation (IMD decile 3), with significant Eastern European and refugee populations.

Sample size

Based on expert statistical advice, a total sample size of 40-80 participants will allow estimation of key feasibility parameters with a suitable level of precision. As a feasibility study a sample size calculation based on power to detect a specific effect size at a defined alpha level is not appropriate.

Recruitment model

We intend to compare two recruitment models, a single practice model and PCN model. Pioneer Medical Group will recruit from a single practice within the PCN, and Pier Health Group may recruit from any of the eight practices within their PCN and will arrange recruitment sites and processes according to their own organisational imperative. We will use learning of how each model worked to inform design of a possible full scale trial.

Additional sites

Workload and staffing factors are liable to pressurise and restrict the capacity of primary care sites in England to carry out research. There are also seasonal factors to consider. If recruitment cannot proceed as planned in the two sites we have worked with in the development of the study, then additional sites will be sought where the study's budget allows.

We will seek, where possible, to retain the aims of testing the feasibility of the Ensemble protocol according to the single practices and PCN models as outlined above, and to test the study among underserved and high socioeconomic patient populations.

The initial patient journey

Patients could be introduced to the Ensemble study through a variety of carefully considered routes, all designed to be sensitive to the needs of older adults experiencing memory concerns. Recruitment begins within participating general practices, where posters are displayed in waiting rooms. These posters are deliberately designed using soft colours and gentle language to ensure they are accessible and non-intimidating for people who may be experiencing cognitive difficulties. The posters include contact details for the study coordinator, allowing patients or their supporters to reach out directly if they are interested in learning more. Or patients may mention the poster in a consultation with a GP, who can print out the poster from EMIS and refer the patient to a brief description of the study on the reverse of the A4 poster.

GPs may actively identify potential participants, during routine consultations. We intend that each recruiting site has one Ensemble trained GP, but that all GPs within a recruiting practice will be briefed on the study, and may refer patients, if they consider that a patient may match eligibility criteria. Verbal consent would be asked to pass their contact details to the study team using a referral form available via EMIS. This form also includes the GP's recommendation for which of the four test bundles would be most appropriate for the patient, based on their clinical judgement.

To further support recruitment, practice staff may conduct a search of the electronic medical records to identify patients who meet the inclusion criteria. Importantly, all searches and initial contacts are carried out by practice staff, ensuring that patient confidentiality is maintained and that no identifiable information is shared with the research team without explicit consent. These patients may then be contacted by SMS, email or letter, with a brief message about the study and an invitation to contact the study team directly to discuss further. The study team will liaise with the practice to arrange a GP appointment, where the referral form will be completed, with an appropriate test bundle indicated by the referring GP. All participant recruitment must begin with a GP referral to the study team, as indication of an appropriate test bundle is necessary for the next steps to be arranged.

The study coordinator, based at the University of Bristol, will hold honorary NHS status so may receive referral notification via NHS email. The study coordinator contacts patients by phone or email to explain the study in more detail. 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. If they decide to take part, an Ensemble appointment is arranged at their GP practice.

Throughout the recruitment process, every effort is made to ensure that patients feel informed, supported, and respected. The study team has drawn on extensive input from its stakeholder group, including people with lived experience of dementia, to ensure that recruitment materials and procedures are as accessible and compassionate as possible.

3.5.2 Eligibility, Capacity and Consent

Eligible patients will:

1. Be aged 75 or older
2. Present with cognitive symptoms for at least six 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

Exclusion criteria are:

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
5. Lack of capacity to consent

The Partnership Group identified these patients as needing specialist care. In these cases, the GP would then refer them, and they would not be diagnosed in primary care.

Consent will be obtained for:

- Participation in the intervention
- Completion of outcome measures
- Optional qualitative interviews and observations (see Process Evaluation)

- Supporters (e.g. carers or family members) will also be invited to participate in outcome measurement and interviews.

Supporter consent

We will also obtain informed consent from Supporters (e.g. carers or family members). Supporters will be provided with the Patient Supporter PIL to inform their understanding of the study and the reason that the person they are accompanying has been invited to take part. Because the supporter will also be completing outcome measures regarding their own well-being and anxiety they will also be invited to participate in the study as well. The supporter will also complete an evaluation about the patients thinking and reasoning as part of the holistic test bundle. We will obtain informed consent from supporters for the completion of these evaluations regarding the patients every-day thinking, reason and functioning and for the supporters completion of the outcome measures relating to their own mental health and well-being. Where supporters and undertake interviews with the research team as part of the process evaluation they will also complete informed consent.

Capacity Assessment

The research team will assess capacity 3 to 4 days prior to the appointment if they are taking consent. If the research team are not taking consent and this is being done by the HCA at the research appointment, then the HCA will assess capacity before taking consent, with support from a GP where there is uncertainty. Capacity to consent will be evaluated using a structured checklist, in line with NIHR guidance on research involving adults lacking capacity. We will use the NIHR-endorsed “Checklist for preparing to assess mental capacity” (PRN01699, 2025) to support this process.

Consent Process

We intend to test two approaches to inform a possible future full trial. One is consent by the HCA at their usual practice, and one is that consent is obtained remotely by the Study Coordinator at the University of Bristol.

All consent records are stored securely using the REDCap system hosted by the University of Bristol. The study coordinator will oversee participant contact and act as the primary liaison between the research team and the participating practices.

For patients who are considered potentially eligible for the Ensemble study, a one page summary of available brain health resources, such as those provided by Age UK and the Alzheimer's Society, will be made available to the patients. This has been developed in

response to a need for information support highlighted by the Ensemble’s PPI representatives, and forms no part of the study intervention as such.

3.5.3 Outcome Measures

We will assess changes in patient and supporter outcomes at baseline and follow-up (6 weeks post-assessment):

Table 7: Summary of outcome measures used to assess anxiety, quality of life, cognitive function, and informant (supporter)-reported change for patients and their supporters.

Domain	Patients	Supporters
Anxiety	Geriatric Anxiety Inventory (GAI)	GAI
Quality of Life	EQ-5D-5L, ICECAP-O	EQ-5D-5L, ASCOT
Cognitive Function	Cognospeak (digital tool)	—
Informant Report	—	IQCODE, Lawton IADL

Geriatric Anxiety Inventory

The Geriatric Anxiety Inventory (GAI) is a brief, 20 item self-report questionnaire to measure anxiety symptoms in older people. The items are statements such as “I worry a lot of the time”, or “I can often feel nervous”, and the respondent can indicate a binary response that they agree or disagree.

Pachana, N. A., Byrne, G. J., Siddle, H., Koloski, N., Harley, E., & Arnold, E. (2007). Development and validation of the Geriatric Anxiety Inventory. *International Psychogeriatrics*, 19, 103–114

EQ5D

The EQ5D is an instrument for the self-reporting of health across five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has the option to describe no problems, some problems, or extreme problems. Additionally, overall health on the day can be reported using a visual analogue scale (EQ-VAS) between 0 and 100 where 100 is perfect health. EQ5D has been widely used in general and patient populations.

Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727–36. [10.1007/s11136-011-9903-x](https://doi.org/10.1007/s11136-011-9903-x)

ICECAP-O

ICECAP-O measure attributes of well-being, found to be important for older people in the UK, for the purposes of economic evaluation. The attributes are: Attachment (live and friendship); Security (thinking about the future without concern); Role (doing things that make you feel valued); Enjoyment (enjoyment and pleasure) and Control (independence).

Grewal I, Lewis J, Flynn T, Brown J, Bond J, Coast J. Developing attributes for a generic quality of life measure for older people: preferences or capabilities? *Social Science and Medicine* 2006; 62:1891-1901.

ASCOT

The Adult Social Care Outcomes Toolkit (ASCOT) measures social care related quality of life. One of the measures of the ASCOT suite is the ASCOT (SCT4) for carers – a four level self-completion questionnaire of seven items, where the respondents indicate to what extent they have for instance, the ability ‘to spend time doing the things I enjoy’, or how much control they have over their daily lives.

Rand S, Malley J, Netten A (2012) Measuring the Social Care Outcomes of Informal Carers, PSSRU Discussion Paper 2833, Personal Social Services Research Unit, University of Kent, Canterbury.

Supplementary Assessment Method - Cognospeak

Cognospeak is a digital tool designed to assess cognitive function through speech-based tasks. It will be used in this study to explore its feasibility and acceptability as a supplementary assessment method, to and may undertaken on the day of the HCA appointment where the test bundle is administered.

3.5.4 Questionnaire Data Collection

All study documents, including consent forms and questionnaires, will be managed electronically via the secure electronic system (REDCap), hosted by the University of Bristol.

Cognitive test and questionnaire scores from the in practice assessment will be entered by the HCA onto REDCap. The cognitive tests will be completed in pen and paper format. The HCA will enter the overall score only onto REDCap and not responses to individual questions. Informant and Functionality questionnaires for the supporter may be completed at the practice at the time of the assessment, if they are present, or later at home electronically or on paper according to their preference.

Follow up questionnaires will be sent 6 weeks later by email or post. Long term follow-up of NHS records via GP practice systems will be conducted if the patient consents. This is to check for subsequent diagnoses. This will help assess if the diagnosis decisions made according to the study protocol are robust. This will be an EMIS search written by the Chief Investigator and run by a practice nurse.

Only patient contact details will be shared with the study team at referral; supporter details will be collected later with consent. Identifiable data will be minimised and securely stored at the University of Bristol.

Questionnaire Data Analysis

The anxiety, quality of life, informant and functionality measures will be scored according to the guidance provided for each measure. Summary statistics will be used to compare outcomes before and after participation in the study protocol. Care will be taken with the use of sociodemographic variables such as ethnicity and socioeconomic deprivation due to the low numbers in the study and the likelihood of disclosing low counts.

Table 8: Measures – before and after assessments

Patients		Supporter/Partner	
Before	After	Before	After
GAI	GAI	GAI	GAI
EQ5D	EQ5D	EQ5D	EQ5D
ICECAP-O	ICECAP-O	IQCODE, Lawton IADL	IQCODE
		ASCOT	

3.5.5 GP follow up assessment

After the assessment, the patient will have a follow-up consultation with an Ensemble-trained GP at their practice. The GP will review the cognitive test results, consider the patient's history and symptoms, and use their clinical judgement to decide whether a diagnosis of dementia is appropriate. No rigid score thresholds will be prescribed, but GPs will receive guidance on interpreting the test results.

Referral criteria

Our proposal is aimed to diagnose established dementia when in the moderate (e.g. Montreal Cognitive Assessment (MOCA) score 18-22) or late (e.g. MOCA < 18) stage, but it is not designed to diagnose prodromal or mild Alzheimer's which remains within secondary care specialist services. Participating GPs would be encouraged to refer people scoring more than 26 on MOCA in whom there was significant concern about possible prodromal or mild dementia. The proportion of people meeting these criteria is an outcome of the feasibility study, it is not an exclusion criteria.

Referral monitoring

Monitoring of the proportion of patients who are referred to specialist services will be carried out within the practice (as a designated research activity), by practice staff running an EMIS query provided by the Ensemble Study Team, as described in Quantitative data.

3.5.6 Participant Activities and Time Estimates

The table below contains estimates of the time each patient participant will likely spend on each of the activities they will be asked to do. These estimates do not include optional Process Review activities.

Table 9: Estimated time and setting for each core activity (excluding optional Process Evaluation activities) undertaken by patients participating in the Ensemble study, from initial contact through to follow-up.

Activity	Estimated Time	Location
Seeing the study poster via GP or waiting room	1 minute	GP surgery
Receiving an email or a text from the study team to arrange a call	1 minute	At home
Phone call from the study team to discuss the study	5 minutes	At home
Receiving information sheet at home and considering participation	10 minutes	At home
Contacting the study team to agree to participate, and possibly consent	2 minutes	At home
Practice calls patient to book initial appointment	1 minute	At home

GAI, EQ5D, ICECAP-O self completed (sent via REDCap)	10 minutes	At home
Consent and HCA administered cognitive test, check completion of GAI, EQ5D and ICECAP-O, and optional 20 minute Cognospeak assessment	50 minutes	GP surgery
GP follow up appointment	10 minutes	GP surgery
Patient issued with follow up questionnaires GAI, EQ5D, ICECAP-O.	10 minutes	GP surgery/ at home
	100 minutes	

The biggest time commitment for the patient participants is the appointment with the HCA in which the test bundle is delivered. The 60 minute estimate accounts for the HCA consenting the patient participant, administering the test bundle and outcome measures (estimated 30 minutes in total), the optional Cognospeak element (estimated 20 minutes), with a further 10 minutes for possible consent of a supporter, and leeway to round up to an hour.

Supporter activities

The time commitment needed from a supporter will vary according to the extent of their presence during the study activities. If the supporter is present for all study activities, then their time commitment will also be an estimated 100 minutes. Supporter presence at the 60 minute HCA appointment is not compulsory, and the supporter may complete their GAI, EQ5D, IQCODE, Lawton IADL and ASCOT questionnaires remotely at their convenience. In this scenario their overall time commitment for the study would be approximately halved. A minimum estimate of supporter time commitment would be 20 minutes for completion of necessary questionnaires remotely.

3.5.7 Risk and Adverse Event Reporting

The assessments used in the study protocol are non-invasive and widely used in NHS primary care and memory services to support dementia diagnosis. We consider this study to be low risk.

Participant wellbeing will be managed by the direct care team within each GP practice, in accordance with usual NHS procedures. This includes safeguarding protocols, escalation

pathways for clinical concerns, and access to post-diagnostic support services. If researchers become aware of any issues during their interactions with participants or supporters, these will be raised with the clinical team and the Chief Investigator. A Distress Protocol is in place for researchers who may be affected by issues that may arise during interactions with participants.

HCAs will be trained to recognise signs of distress and will be supported to pause or discontinue assessments if needed. The training package includes guidance on trauma-informed and dignity-preserving practices. Participants will also be signposted to relevant support services, such as the Alzheimer's Society, where appropriate.

Given the low-risk nature of the study, a formal data monitoring committee will not be convened. However, the study team will regularly review recruitment, data completeness, and any adverse events or protocol deviations, completing an Adverse Event Reporting Log when necessary, and will report these to the sponsor according to an agreed model.

3.5.8 Quality Event Reporting

3.5.8.1 Breach Reporting

The Ensemble Feasibility Trial will comply with all aspects of with 'The Conditions and Principles which apply to all Clinical Trials', outlined in the Medicines for Human Use (Clinical Trials) Amendment Regulations 2024. Should there be a breach of any of these conditions or principles, where the necessary procedures to secure the quality of every aspect of the trial have not been adhered to, or if there has been deviation from the study protocol, then the study team will report the breach upon becoming aware of it to the Research Governance at the University of Bristol who as Sponsor Representatives, will determine if any further reporting is required.

The breach will be reported using the University of Bristol Research Governance Teams Quality Events Form.

3.5.8.2 Other Quality Events – notes to file

If the Quality Event reported to the Research Governance Team is not considered to be a Breach, it will either be considered to require a Note to File or require no action. Any notes to file recording by the Ensemble Study Team will be shared with the Research Governance Team according to an agreed model.

3.5.9 Indemnity Cover

Provision has been made by the University of Bristol for indemnity to cover the liability of the investigator and sponsor which may arise in relation to the trial.

3.5.10 Data Management

Any access to practice systems or medical records will be via usual practice staff according to usual care. There will be no access to medical records for the research team. Contact details will be sent to the research team once permission has been gained from the patient.

Management of study data will be the secure REDCap system, held on a secure University of Bristol server, according to the policies of Data Protection and Governance. Individuals in the study data will be identifiable by unique study only. Identifiable information will not be included. Participants will be able to access any information held on them via Freedom of Information requests, and according to procedures implemented by the Universities Data Protection Officer. No identifiable data will be accessed without consent.

Study information sheets explain that contact information is the only identifiable information required and that study data will contain only unique study ID and identifiable data, and will be destroyed 7 years after the end of the study. Personal data (contact details and all questionnaire data) will stored on the REDCap system on secure University of Bristol servers. Any hard copy consent forms, questionnaires, interview transcripts will be scanned and stored digitally on secure University of Bristol servers. Physical copies will be securely destroyed.

Data processing and sharing

Data will be shared among three academic institutions, each with defined responsibilities for specific components of the research. All data sharing will be conducted under formal data sharing agreements that ensure compliance with UK GDPR and the Data Protection Act 2018.

1. University of Keele
 - o Responsible for collecting, processing, and analysing data related to the development and evaluation of the training package. This includes feedback and engagement data from healthcare professionals (GPs and HCAs) involved in training.
2. University of Sheffield
 - o Responsible for collecting, processing, and analysing Cognospeak data, a novel digital tool assessing speech and cognition in patients. This involves pseudonymised patient data captured through digital interactions.

3. University of Bristol (Lead Institution)

- o Responsible for the collection, processing, and analysis of all other study data, including:
 - Participant questionnaires (e.g. EQ-5D, GAI)
 - Electronic health record extracts
 - Qualitative interview data
 - Overall trial coordination and oversight

Data Sharing Practices:

- All data will be pseudonymised prior to transfer between institutions.
- Data will be shared via secure, encrypted channels or within approved, access-controlled platforms (e.g., institutional secure cloud storage or data safe havens).
- Access will be strictly limited to named research team members from each collaborating institution, in accordance with their role.

3.5.11 End of study

The definition of the end of the study will be when the final required completion of the 6 week post assessment follow up questionnaires. We will then notify the relevant Research Ethics Committee (REC) and the study funder, the NIHR RfPB.

3.5.12 Dissemination

After a thorough review by independent experts, a report of the Ensemble study Process Evaluation findings and academic papers will be published in peer-reviewed journals. Findings may also be presented at academic conferences/workshops or used for training purposes.

Figure 1 Patient Pathway Flow Diagram The figure below details the patient journey through the study, detailing the activities they will be asked to undertake

