Protocol for the feasibility and implementation study of a model of best practice in primary care led postdiagnostic dementia care: PriDem

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ABSTRACT

Introduction Care is often inadequate and poorly integrated after a dementia diagnosis. Research and policy highlight the unaffordability and unsustainability of specialist-led support, and instead suggest a task-shared model, led by primary care. This study is part of the PriDem primary care led postdiagnostic dementia care research programme and will assess delivery of an evidence-informed, primary care based, person-centred intervention. The intervention involves Clinical Dementia Leads (CDLs) working in primary care to develop effective dementia care systems that build workforce capacity and support teams to deliver tailored support to people living with dementia and their carers.

Methods and analysis This is a 15-month mixed-methods feasibility and implementation study, situated in four National Health Service (NHS) primary care networks in England. The primary outcome is adoption of personalised care planning by participating general practices, assessed through a patient records audit. Feasibility outcomes include recruitment and retention; appropriateness and acceptability of outcome measures; acceptability, feasibility and fidelity of intervention components. People living with dementia (n=80) and carers (n=66) will be recruited through participating general practices and will complete standardised measures of health and well-being. Participant service use data will be extracted from electronic medical records. A process evaluation will explore implementation barriers and facilitators through methods including semistructured interviews with people living with dementia, carers and professionals; observation of CDL engagement with practice staff; and a practice fidelity log. Process evaluation data will be analysed qualitatively using codebook thematic analysis, and quantitatively using descriptive statistics. Economic analysis will determine intervention cost-effectiveness.

Ethics and dissemination The study has received favourable ethical opinion from Wales REC4. NHS Confidentiality Advisory Group support allows researchers preconsent access to patient data. Results will inform intervention adaptations and a future large-scale evaluation. Dissemination through peer-review journals, engagement with policy-makers and conferences will inform recommendations for dementia services commissioning.

Trial registration number ISRCTN11677384.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study includes both qualitative and quantitative data, providing depth and breadth to the feasibility and implementation analyses.
⇒ The study team gained support from the National Health Service Confidentiality Advisory Group for researchers to gain preconsent access to electronic care records, thus minimising burden on general practice staff during recruitment and an audit of personalised care plans.
⇒ The study is limited in scale, involving seven general practices across two regions: the Southeast and the Northeast of England.

INTRODUCTION

There are around 944 000 people with dementia in the UK, projected to rise to nearly 1.6 million by 2040.[1] The total costs of dementia in the UK amount to £34.7 billion, of which £13.9 billion are met by unpaid carers, generally family members. By 2040, these costs are projected to rise to £94.1 billion per year.[1]

Postdiagnostic care for people living with dementia and their families is inadequate and poorly integrated.[2 3] An Alzheimer's Society survey found that around half of people living with dementia responding felt anxious or depressed and received insufficient support, a finding echoed by half of the surveyed general practitioners (GPs).[4] Policy and research[5–9] highlight the need to improve

postdiagnostic dementia care both in terms of quality of care and equity of access by reducing geographical and other inequalities.

PriDem: primary care led postdiagnostic dementia care (2019–2023) is a research programme funded by the Alzheimer's Society, which aims to develop and evaluate acceptable, feasible and sustainable approaches to primary care led postdiagnostic dementia care, to maintain and improve quality of life for people living with dementia and their families. The programme has five workstreams (see online supplemental appendix 1); this protocol relates to workstream 4. Although PriDem is conducted in England within a specific healthcare setting (the National Health Service, NHS), we anticipate key findings will be of relevance internationally. The programme targets conclusions from the 2016 World Alzheimer Report[10] that existing specialist-led healthcare models of postdiagnostic dementia care are unsustainable and unaffordable. This report highlights the urgent need for more efficient use of existing resources via the introduction of a task-shifted and task-shared model where primary care takes lead responsibility for postdiagnostic care coordination, thus facilitating more appropriate and timely specialist care input as and when required. The need for improved person-centredness, accessibility and co-ordination of dementia care remain key themes in the 2022 World Alzheimer's Report.[7]

The PriDem intervention

A person-centred intervention was codeveloped with key stakeholders, informed by evidence gathered through workstreams 1–3. These workstreams identified key components of postdiagnostic support[11] and a need to focus on three interlinked intervention strands (see box 1).

Box 1 Three primary care led postdiagnostic dementia care intervention strands

1. Developing systems—Clinical Dementia Lead (CDL) activities to include: working closely with local stakeholders (general practitioners and other primary, secondary and third sector staff) to review referral and transition processes; developing a map of local dementia services to facilitate timely and tailored referrals; facilitating work to establish a named point of contact for each person living with dementia.[32]
2. Delivering tailored care and support—CDL activities to include: providing advice and direct management of people with more complex needs; working with general practice teams to strengthen annual dementia reviews (a Quality and Outcomes Framework indicator for dementia care[34]) and deliver personalised dementia care planning.[15] To achieve this, CDLs will work with practices to develop the resources required to perform these tasks.
3. Building capacity and capability—CDL activities to include: Building practice-based dementia teams (groups of staff in each practice committed to progressing dementia care improvements); Providing support and bespoke training to upskill the primary care workforce. Training and joint patient visits will support primary care staff to provide improved care for people living with dementia and their carers.

The three intervention strands are led by Clinical Dementia Leads (CDLs). CDLs are from a nursing/allied health professional background, and will collaborate with local stakeholders, providing expert knowledge and support on dementia care from diagnosis to end of life. The intervention also provides specially designed adaptable PriDem resources to support improved dementia reviews and care planning. As a service-level intervention, CDLs will be situated within general practices, working with practice teams in order to influence change, to improve and develop their dementia care provision, through upskilling the workforce (building capacity and capability), streamlining and navigating services (developing systems) and encouraging holistic and personalised care (delivering tailored care and support). CDLs will also work clinically, providing direct support to patients with particularly complex needs, with the ultimate aim of upskilling and supporting primary care teams in their ability to provide appropriate care, by using cases as teaching opportunities within multidisciplinary meetings and carrying out joint visits where possible. The intervention has been designed to respond to the needs and strengths of individual general practices. Through working closely with practices, CDLs will support sustainable change across the intervention.

The PriDem Logic model (online supplemental appendix figure) shows how the intervention activities respond to the current challenges in postdiagnostic dementia care. Although this is a service-level intervention, the logic model outlines the theorised outputs and outcomes at both service and patient level that will result from employing implementation strategies to deliver these activities. Hypothesised mechanisms underpinning outcomes are specified.

Aims and objectives

Overall AIM

The aim of PriDem workstream 4 is to test the feasibility of the PriDem intervention and the methods used to evaluate it, as well as the implementation of the intervention when delivered in primary care networks (PCNs). PCNs are groups of general practices working alongside other health and social care organisations to provide integrated care services to the local population. The primary and secondary objectives for the feasibility and implementation elements are shown in table 1.

METHODS AND ANALYSIS

Design

This is a 15-month multisite, mixed-methods feasibility and implementation study. The implementation element is a 'Hybrid Effectiveness-Implementation' design whereby the primary aim is to determine the impact of an implementation strategy, and a secondary aim is to assess clinical outcomes associated with implementation, that

Table 1 Primary and secondary feasibility and implementation study objectives

	Feasibility and acceptability	Implementation
Primary objective/s	Assess: Recruitment and retention rates at follow-up (PCN level, practice level and individual level) Acceptability and engagement with the intervention and implementation study procedures Proportion of recruited people living with dementia whose medical notes are reviewed for service use data	Assess whether: The PriDem intervention increases the no of people living with dementia with a personalised care plan at recruited general practices The intervention can be implemented in wider primary care settings
Secondary objective/s	Assess: Feasibility and acceptability of recruiting and training Clinical Dementia Leads and embedding them within existing care pathways/ service delivery models Whether the intervention can be delivered as intended Resource requirements to access, collect and analyse study data Acceptability and appropriateness of the potential primary and secondary outcomes for the implementation study	Examine how the intervention is delivered and adapted within practice Identify context and delivery variations/factors which influence embedding the intervention in usual care Identify factors that increase adoption, coverage and sustainability of the intervention including acceptability, appropriateness, fidelity Collect data on resources needed for implementation Determine cost-effectiveness of the intervention Explore context, mechanisms and impact of the intervention for people living with dementia, carers and professionals and the barriers and levers to implementation at scale

PCN, primary care network; PriDem, primary care led postdiagnostic dementia care.

is, the impact on people living with dementia and their carers (hybrid type 3).[12] A trial protocol adhering to the requirements of the Guideline for Good Clinical Practice was prepared for and approved by the Sponsor, Joint Research Office, University College London (Protocol Version 6.0, 8 August 2022).

Patient and public involvement

A stakeholder group of people living with dementia, current and former carers, and professionals—the PriDem 'Dementia Care Community' (DCC) advised on research design, including accessibility of materials and participant burden.[13] They were consulted on an NHS Confidentiality Advisory Group (CAG) application: their insights helped minimise potential harms of researchers accessing medical records of non-consented patients, resulting in a positive application outcome, for example through codesigning a poster notifying the relevant practice population of the research and methods for opting out. Researchers piloted validated outcome measures with people living with dementia and carers from the DCC. The advice of DCC members led to the streamlining of data to be gathered and a new plan to include paper or online survey options for carers to self-complete questionnaires about their own health and well-being. It also led to insights on how best to support the completion of these questionnaires to avoid distress and reduce burden. These insights were included in a 'Researcher Guide' detailing recruitment, data collection and safeguarding procedures.

Study procedures

Figure 1 shows a timeline for workstream 4. Two CDLs will deliver the intervention in two study sites; one in the Southeast and one in the Northeast of England. Both CDLs have nursing backgrounds and will receive manualised bespoke training and ongoing intervention supervision developed and delivered by the research team. They will also receive clinical supervision with a dementia specialist nurse.

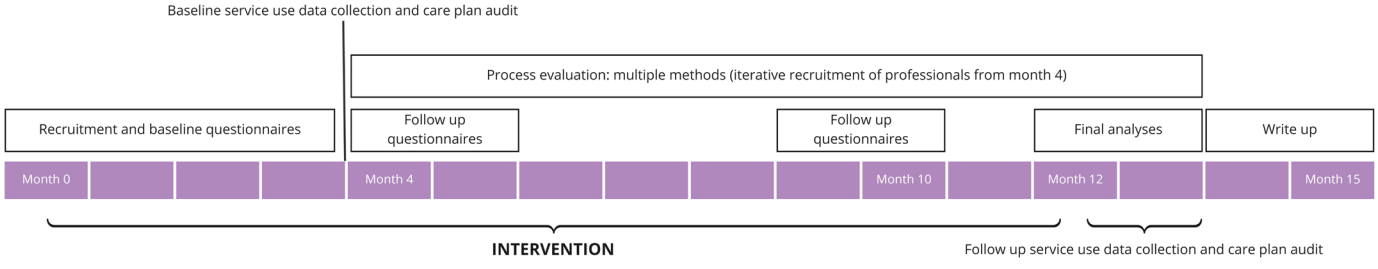

Figure 1 Workstream 4 timeline.

Table 2 Recruitment targets and inclusion/exclusion criteria

Site/participant group	Recruitment target	Inclusion criteria	Exclusion criteria
Primary care networks (PCNs)	Four PCNs across the Southeast and Northeast of England, each containing up to five general practices		
People living with dementia	80	Over 18 years old, registered with a participating general practice, diagnosis of dementia recorded in the patient's medical record, community dwelling, capacity to consent to the study or the patient can be recruited via a personal consultee	Judged as inappropriate for the study by a member of the primary care team (eg, due to concurrent life events such as bereavement or receiving end of life care), patients with an advance statement indicating that they do not wish to take part in research studies, living in a care home
Care partners	66	Over 18 years old, carer of a person living with dementia who has agreed to take part in the study* and is willing and able to provide informed consent	Judged as inappropriate for the study by a member of the primary care team (for same reasons as the person living with dementia), non-fluent English speaking
Professionals (health and social care professionals and commissioners)	Up to 32	Over 18 years old, identified as working for or with people living with dementia, willing and able to provide informed consent	Professionals who do not provide or commission postdiagnostic dementia support

*Carers will not be recruited without a person living with dementia.

The study will run from March 2022 (month 0) to June 2023 (month 15), with the intervention lasting 12 months. Recruitment of people living with dementia and carers and administration of baseline clinical outcome questionnaires will take place from months 0–3, with follow ups taking place 4 months and 9 months postbaseline. Recruitment of professionals for qualitative interviews and observations will be iterative from month 4. A mix of face-to-face and remote recruitment and data collection methods will be used, dependent on participant preference and practicality. Researchers will collect participant service use data for the duration of the intervention as well as the previous 12 months. Researchers will additionally access electronic medical records to conduct an audit of personalised care plans. This will involve a random sample of patients on the dementia registers of participating practices at baseline and follow-up postintervention.

Recruitment

Recruitment targets and inclusion/exclusion criteria are shown in table 2.

Recruitment strategy

With greater demands on general practice staff due to COVID-19 and its consequences on health service capacity, the recruitment strategy was designed to minimise burden on practice staff. The NHS CAG recommended that support under Regulation 5 of the Health Service (control of patient information) Regulations 2002 ('section 251 support') be given for the processing of patient information. Following this recommendation, Health Research Authority approval enables researchers to undertake recruitment activities traditionally undertaken by practice staff. Posters displayed in the general practices notify relevant patients that researchers will be given access to their medical notes for recruitment purposes and provide information on how to opt out of this process. Activities undertaken by researchers include screening electronic medical notes for eligible patients and completing mail-outs on behalf of each general practice, including an accessible written patient information sheet (found at https://tinyurl.com/585rrwh), and the option to request audio/video versions of this. Non-response does not always indicate intention not to take part, as people living with dementia may not open their post, may throw it away, or forget to post back a response slip. Therefore, three attempts will be made to follow-up non-responders via phone call (on different days and times) to provide an opportunity to hear more about the study and opt in or out. Researchers will inform general practice teams of any non-responders who are uncontactable, so they may flag the notes for any potential unmet needs and, where appropriate, alert those patients to the PriDem study. In cases where patients are uncontactable, they will be excluded with no contact details retained.

Researchers will obtain written or verbal (audio recorded) consent. Where potential participants lack decision-making capacity to consent to take part in the

study, as assessed by the researcher using a protocol adapted from the British Psychological Society,[14] a family member or friend will be invited to act as personal consultee. Participants who self-consent will identify a person who may be approached to act as a consultee in circumstances where the participant is determined to lack specific decision-making capacity later in the study. Please see online supplemental file for consent forms and Nominated Consultee Declaration form.

A subset of people living with dementia and carers recruited to the study will be approached to take part in a qualitative interview. These participants will be sampled purposively, based on level of engagement with initiatives driven by the intervention (determined through CDL and participant feedback) and demographic characteristics (eg, dementia severity, living situation, relationship to care partner). CDLs will where possible be blind to which patients are participating in the study. We will take an opportunistic approach to recruiting professionals. CDLs and researchers will identify professionals to approach who have interacted with the intervention, for example, GPs, receptionists, dementia advisors, care co-ordinators, social prescribers and commissioners.

Study measures

Feasibility outcomes

Data will be collected on rates of recruitment at baseline and retention at final follow-up: at PCN, practice and individual level. The proportion of recruited people living with dementia whose medical notes are reviewed for service use data will also be reported.

Implementation and effectiveness outcomes

A multimethods approach will be taken to evaluating a range of implementation and effectiveness outcomes (see logic model, online supplemental appendix figure).

Primary outcome

The primary implementation outcome is adoption of personalised care planning by general practices (see implementation outcomes in logic model, online supplemental appendix figure). In order to assess this, researchers will carry out an audit of electronic care records, recording the presence/absence and quality of personalised care plans.

An annual review of dementia care plans is a key quality indicator for dementia care, but there is little formal guidance on what constitutes a personalised care plan. The research team worked with patient and public involvement representatives and a wider advisory group to define personalised care planning for the purposes of this audit. A case report form (CRF) was developed to record features of the plan, based on NHS England criteria,[15] shown in box 2, as well as the domains covered within the plan (eg, activities of daily living, advance care planning, medication review).

Extensive work with stakeholders and PPI highlighted the breadth of views on what is important to personalised care planning, with numerous components central to providing high quality care. For the purpose of this audit, it was agreed that the minimum requirement for a care plan to be assessed as 'personalised' was the presence of the person living with dementia and/or carer for its formulation. However, in addition to the binary outcome (presence/absence of a personalised care plan), we will report on the proportions of care plans that incorporate each feature of personalisation captured on the CRFs and on the care domains covered.

Box 2 Features of care plan recorded on care plan audit case report form

- ⇒ Are outcomes, identified needs or goals recorded?
- ⇒ Is there evidence outcomes were agreed with the person living with dementia and/or carer?
- ⇒ Is there a plan for how these outcomes will be achieved (actions)?
- ⇒ Is there a clear date for when the care plan will be reviewed?
- ⇒ Did the person living with dementia and/or carer attend the meeting?
- ⇒ Was the person living with dementia and/or carer invited to consider their priorities?
- ⇒ Was the person living with dementia and/or carer sent information on care planning in advance?
- ⇒ Has the person living with dementia/carer been provided with a copy of the care plan?

The audit will include a random sample of 215 patients on the dementia registers of the general practices involved in the study, therefore, not limited to recruited participants. As such, this will demonstrate the impact of the intervention on the wider practice population of people living with dementia. Using a stratified sampling strategy, proportions of cases sampled on each dementia register will be based on the total numbers of eligible patients on each of these registers. The baseline audit will cover the period April 2018–March 2019, considered a more typical year for annual dementia reviews than later preintervention years given disruptions faced in Quality and Outcomes Framework (QOF) reporting resulting from the COVID-19 pandemic. Patients will be included in the audit if they are community-dwelling and had received their diagnosis of dementia prior to the start of the 2018/2019 QOF year. The number of patients with a personalised care plan during the baseline period will be compared with the number at follow-up. The follow-up audit will cover the period April 2022–March 2023, reflecting the intervention QOF year. Through collecting additional data on the characteristics of available care plans, differences in quality between the baseline and follow-up years will also be examined.

Secondary outcomes

Secondary quality of life and well-being outcomes (see logic model online supplemental appendix figure) include the Dementia Quality of Life measure, DEMQOL[16] and the health-related quality of life measure EQ-5D-5L[17] completed with the person living with dementia. The carer will complete the proxy versions

of DEMQOL and EQ-5D-5L, and the Neuro-Psychiatric Inventory.[18] In addition, carers will complete the following measures of their own health and well-being: the Hospital Anxiety and Depression Scale,[19] dementia carers quality of life measure C-DEMQOL[20] and quality of life EQ-5D-5L. For these measures, carers will have the option of researcher-administered, self-complete paper or online survey versions in line with DCC feedback. All secondary outcome measures will be assessed at baseline, 4 and 9 months.

Service use over 12 months at baseline and 12-month follow-up will be collected from electronic medical records. At baseline, 4 and 9 months, carers will complete the Client Services Receipt Inventory (CSRI),[21] a bespoke questionnaire asking about social care use, including out-of-pocket costs and impact on unpaid and paid carer time for specific activities of daily living, adapted from iMTA Valuation of Informal Care Questionnaire (iVICQ).[22]

Sample size

Based on a pilot audit by clinical members of the research team, it is anticipated that a maximum of 40% of people diagnosed with dementia currently have a personalised care plan. During the implementation phase, we aim to increase this figure to at least 50% of people diagnosed with dementia. As such, a sample size of 215 is sufficient to detect an increase in the proportion of people with a personalised care plan of at least 0.1, using a one-sided Z-test at the 5% significance level with 90% power. This outcome will be summarised as the proportion of people who have a personalised care plan with an associated 95% CI.

Statistical analysis

Analyses will follow a predefined statistical analysis plan that will be approved by the principal investigator and programme management board prior to implementation and locking of the database.

Participants' baseline characteristics will be presented descriptively in tables using appropriate summary statistics, with categorical variables reported as counts and percentages and continuous variables using means, medians, SD and ranges.

The primary outcome will be analysed by reporting the proportion of people living with dementia who have a personalised care plan in place, together with an associated 95% CI, for each of the baseline audit and 2022–2023 audit periods. A Z-test will be carried out to test the null hypothesis that the proportion of people with a personalised care plan in place in the 2022–2023 year is 0.4, against a one-sided alternative that this proportion is >0.4, using a 5% significance level.

For recruited participants, secondary outcomes will be reported at baseline and at each follow-up time using appropriate summary statistics. In addition, 95% CIs will be reported for each secondary outcome at each follow-up time. All analyses will be complete case with no adjustment for missing data. Numbers of withdrawals from the study will be reported with reasons (if provided).

Health economics analysis

The economic analysis for the implementation study will calculate the mean incremental cost per quality-adjusted life-year (QALY) gained from a healthcare perspective. A secondary analysis will also report the incremental cost per QALY from a wider cost perspective to capture the impact on carers and any patient/carer out-of-pocket costs for health and social care. QALYs will be calculated from participant responses to the EQ-5D-5L at baseline and 9 months as the area under the curve adjusting for baseline[23] with site as a fixed effect and a random effect for practice clustering. The difference in total cost at 12 months will be adjusted using baseline values.[24] 95% CIs will be calculated using bootstrapping.

Social care utilisation and out-of-pocket costs will be collected using a CSRI,[21] modified for the study population. Carers will be asked about the amount of time spent by paid and unpaid carers on caring activities informed by the iVICQ.[22]

Healthcare resource use (eg, contacts, hospitalisations, medications) will be extracted from patient medical records. Resource use will be costed using nationally published sources (PSSRU[25] and NHS Reference Costs[26]). Carer time will be costed using the replacement cost method assuming the cost per hour of time for social care. The cost of the intervention including staff employment, training, administration, supervision and delivery will be included in the costs of implementation. Aggregate and service-specific costs will be compared between localities.

Uncertainty will be explored using bootstrapping to generate cost-effectiveness planes and cost-effectiveness acceptability curves. We will explore the impact of making different assumptions about the time horizon of the analysis given 9-month outcome data and 12-month resource use data.

Analyses will follow the statistical analysis plan above and a health economics analysis plan that will be approved by the principal investigator and programme management board prior to locking of the database.

Process evaluation

A process evaluation will describe factors influencing implementation of the intervention in practice. This will include the following sources of data: semistructured interviews, observation fieldnotes of relevant CDL training activities and practice meetings, researcher fieldnotes on CDL intervention supervision sessions, practice fidelity log, practice and participant demographics (see online supplemental appendix 2).

Audio-recorded semistructured interviews will be conducted with up to 20 people living with dementia and up to 20 carers to explore participants' experiences of the dementia-related care they receive from primary care, their perspective on the acceptability of the intervention

and of their involvement in the research. The acceptability of the intervention will be further investigated through semistructured interviews with CDLs, the clinical supervisor and up to 32 health and social care professionals including members of the practice team, community mental health teams, commissioners and other community healthcare professionals (eg, dementia advisors and social prescribers). These semistructured interviews will focus on exploring participants' experiences of the intervention, including barriers and facilitators to engagement, as well as outcomes. Topic guides based on the objectives outlined above have been developed and pilot tested.

Researchers will carry out observations of CDLs during multidisciplinary meetings, formal and informal training sessions, and other non-clinical meetings relevant to the intervention delivery. The fieldnotes from the observations will give detailed insight into how the intervention is enacted in practice, how practices engage with the intervention and what support and training are requested from and provided by the CDL. In addition, researcher fieldnotes will be made after each intervention supervision session with the CDLs, clinical supervisor and two members of the research team. Fieldnotes will document the CDLs' experience of delivering the intervention, and capture implementation issues and any local adaptations to the intervention.

To assess intervention fidelity across the participating general practices, a practice fidelity log including the key intervention components will be completed at the end of the study by the research team. This will consist of a checklist of key planned intervention activities, completed in discussion with CDLs.

Quantitative data on general practice demographics (ie, Index of Multiple Deprivation, practice list size, ethnicities, age bands, gender, range of staff roles employed) and patient demographics (ie, Index of Multiple Deprivation, age, gender, ethnicity, living status, presence of a main carer, relationship of person with dementia to main carer) will be documented at two time points and compared with census data to assess the representativeness of the participating general practices and participants in the study.

Implementation outcomes have been checked against the StaRI standards for the reporting of implementation studies.[27]

Process evaluation analysis plan

Codebook thematic analysis[28] will be used to analyse semistructured interviews, observations and intervention supervision fieldnotes. Themes (patterns of meaning) relevant to building an understanding of implementation barriers and facilitators will be generated across the dataset. Audiorecordings of semistructured interviews will be transcribed and imported alongside other sources into qualitative data analysis software NVivo.[29] Early data will be analysed by at least two team members, with codes and themes independently generated using an inductive approach before the development of an initial codebook. This codebook will be further refined through the analysis of subsequently collected data, and in team discussion including DCC contributors. Normalisation process theory, a framework enabling identification of implementation barriers and facilitators within newly evolving integrated care systems,[30] will be used as a lens for refining themes. The thematic analysis findings will inform refinement of the logic model contexts, mechanisms and outcomes.

Descriptive statistics will be used to assess intervention reach and fidelity. The statistical analysis of the practice fidelity log data will enable us to identify differences in implementation at the practice level. Practice and participant demographic data will be compared descriptively to Office for National Statistics area level census data[31] to determine whether any populations are under-represented in those recruited to the study. The percentage recruited from typically underserved older populations (eg, minority ethnic groups, low socioeconomic status, oldest age groups) will be compared with local area data.

Data management

The study is compliant with General Data Protection Regulation (2016/679) requirements of the UK Data Protection Act (2018) with regard to the collection, storage, processing and disclosure of personal information, and will uphold the Act's core principles. The Study Manager is responsible for monitoring site data quality on an on-going basis, with support from University College London Clinical Trials Unit: Priment.

Ethics and dissemination

Approval was obtained from Wales REC4 on 20 August 2021, IRAS ID 294881. NHS CAG support was obtained on 23 December 2021, allowing researchers preconsent access to electronic care notes of patients for the specific purposes of the study: CAG reference 21/CAG/0182. The Study Manager is responsible for submitting protocol amendments to the REC and updating relevant parties, such as the ISRCTN, of such amendments.

Safety considerations

This is a low-risk intervention, and we envision few side effects. It is possible that adverse events (AEs) may occur due to the intervention such as falls (eg, during exercises or social visits encouraged through the intervention), or if greater knowledge of local services results in increased referrals and waiting times.

Recording and reporting AEs will be monitored by the UCL Priment Clinical Trials Unit (CTU). Both researchers and CDLs will be responsible for identifying AEs and will be supported in judging their seriousness and relatedness by clinical members of the research team. Only serious AEs (SAEs) judged to be possibly, probably or definitely related to the intervention will be reported to the chief investigator, who will inform the CTU within 24 hours.

SAEs judged to be unlikely to be related/unrelated to the intervention will be recorded but not reported. These include illness/severe illness requiring hospitalisation, death, loss of capacity/decline in cognition, worsening physical functioning, occurrence or worsening of comorbidities associated with dementia (eg, stroke, diabetes, cardiovascular disease). Unrelated, non-SAEs will be recorded in source data (eg, on CRFs) if not already recorded in medical notes. Any non-SAEs that are possibly related to the intervention will be recorded on a study-specific AE log. GPs will be informed of any AEs where it is not clear they are already informed.

Dissemination

A 'dissemination and impact plan' has been developed by the research team in collaboration with the funders (Alzheimer's Society) and the International Longevity Centre. This includes a series of peer-reviewed journal articles covering feasibility, process evaluation and overall implementation findings and engagement with policy and practice communities.

DISCUSSION

It has long been suggested that dementia care and support are best situated within primary care. This feasibility and implementation study will contribute to the literature on how this can best be achieved, testing an evidence-based approach in real-life practice.

The feasibility findings will inform future dementia studies regarding resource requirements and acceptability of recruitment and data collection processes (for participants and researchers). In addition, key learning on intervention acceptability and the feasibility of recruiting CDLs and embedding these professionals within existing primary care services will be invaluable for future roll-out of this intervention.

We will report on intervention effectiveness based on an increase in personalised care plans by general practices and improved quality of life for people living with dementia and their carers. Process evaluation findings will allow us to refine the logic model based on a more in-depth understanding of required strategies and resources (considering cost implications) for large-scale implementation in varied care settings. This will include mechanisms for adoption, reach, adaptability and sustainability. This knowledge will inform future evaluative research and commissioning decisions. It will also inform future National Institute for Health and Care Excellence (NICE) guidelines[32] and NHS England recommendations for personalised dementia care planning.[15 33]

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Contributors All authors meet ICMJE criteria for authorship. SG and ES wrote the first draft and were lead authors on all subsequent drafts. FD'A refined the introduction and process evaluation sections and wrote the first draft of the abstract. JW, CB, AW, GB, KW, NL, AO'K, RH, RT, KHD, SB, JM, LA, LR and GR commented on drafts. JW, CB, AW, GB, KW, AO'K, RH, RT, KHD, SB, JM, LA, LR and GR were involved in the conception of the original PriDem study protocol. SG, ES, JW, CB, AW, GB, FD'A, KW, NL, AO'K, RH, RT, KHD, SB, JM, LA, LR and GR all contributed to writing subsequent protocol amendments for REC submission. AO'K is Statistics Lead and RH is Health Economics Lead for Workstream 4. GR, as chief investigator, approved the final draft.

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