Evaluating a model of best practice in primary care led post-diagnostic dementia care: Feasibility and acceptability findings from the PriDem Study

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ABSTRACT

Objectives: To evaluate the feasibility and acceptability of a primary care-based intervention for improving post-diagnostic dementia care and support (PriDem), and implementation study procedures.

Design: A non-randomised, mixed methods, feasibility study.

Setting: Seven general practices from four Primary Care Networks (PCNs) in the Northeast and Southeast of England.

Participants: We aimed to recruit 80 people with dementia (PWD) and 66 carers

Intervention: Clinical Dementia Leads (CDL) delivered a 12-month intervention in participating PCNs, to develop care systems, build staff capacity and capability, and deliver tailored care and support to PWD and carers.

Outcomes: Recruitment and retention rates were measured. A mixed methods process evaluation evaluated feasibility and acceptability of the intervention and study procedures. Using electronic care records, researchers extracted service use data and undertook a dementia care plan audit, pre-

and post-intervention, assessing feasibility of measuring the primary implementation outcome: adoption of personalised care planning by participating general practices. Participants completed quality of life (QOL), and service use measures at baseline, 4 and 9 months.

Results: 60 PWD (75% of recruitment target) and 51 carers (77% recruitment target) were recruited from seven general practices across four PCNs. Retention rate at nine months was 70.0% of PWD and 76.5% carers. The recruitment approach showed potential for including under-represented groups within dementia. Despite implementation challenges, the intervention was feasible and acceptable, and showed early signs of sustainability. Study procedures were feasible and accessible, although researcher capacity was crucial. Participants needed time and support to engage with the study. Care plan audit procedures were feasible and acceptable.

Conclusions: The PriDem model is an acceptable and feasible intervention. A definitive study is warranted to fully inform dementia care policy and personalised dementia care planning guidance. Successful strategies to support inclusion of PWD and their carers in future research were developed**.**

Trial registration number: ISRCTN11677384

STRENGTHS AND LIMITATIONS OF THE STUDY

- National Health Service (NHS) Confidentiality Advisory Group (CAG) support allowed researchers pre-consent access to electronic care notes for recruitment screening and care plan audit data collection. This reduced burden on general practice staff, thereby supporting their involvement in the study.
- A proactive, staged recruitment approach including accessible study information and follow up phone calls, maximised recruitment opportunities.
- Researchers developed study procedures with involvement of people with lived experience of dementia: the PriDem Dementia Care Community (DCC).
- Qualitative data was gathered on participant experiences of the study procedures.
- This was a non-randomised design with no control, thereby limiting intervention effectiveness conclusions.
- Post-COVID-19 NHS pressures and reduced staff capacity led to challenges recruiting general practices to the study.

BACKGROUND

Dementia is a progressive neurological condition, affecting cognitive functioning, behaviour, emotional wellbeing and activities of daily living (1). Over 900,000 people in England and Wales have a dementia diagnosis. This figure is projected to rise to 1.7 million by 2040 (2) with annual care costs anticipated to rise from £34.7 billion to £94.1 billion in that period (3). With incidence levels rising significantly worldwide, dementia is a global public health issue (4). Post-diagnostic dementia care, historically situated in secondary care and specialist-led, is often described as inadequate, unaffordable, and poorly integrated (5, 6). International policy (7, 8) and research (9-12) highlights an urgent need for post-diagnostic care co-ordination to be led by primary care. This has potential to utilise existing resources more efficiently and improve timely and tailored access to specialist and

community services, thus improving quality of life for people with dementia (PWD) and their carers (13).

Elements of existing primary care led models show potential to improve outcomes for PWD and their families, including embedding dementia-focused health professionals into primary care and building workforce capacity and collaboration (10). Informed by evidence reviews and qualitative research, the PriDem research programme developed a primary care led complex intervention to improve post diagnostic dementia care and support (14). This involves Clinical Dementia Leads (CDLs) situated within primary care, supporting improvements to dementia care systems, delivery of holistic tailored care, and workforce capacity building.

In line with MRC guidance (15,16), we tested the PriDem intervention in practice to assess the feasibility and acceptability of the intervention and evaluation methods, and to support decisions about a future large-scale implementation study. As PWD are often excluded from research about their needs, especially when they have no informal carer to support their inclusion (17), we examined methods of recruiting and retaining PWD, including those who lack capacity to consent.

AIMS

We aimed to evaluate the feasibility and acceptability of the PriDem intervention and study processes, with outcomes measured through i) recruited samples of PWD, carers and professionals, and ii) a general audit sample of PWD on general practice dementia registers, pre- and post-intervention, accessed through electronic care records.

Primary Feasibility and Acceptability objectives:

1. Evaluate recruitment and retention rates at Primary Care Network (PCN), general practice and individual levels.
2. Assess acceptability and engagement with the intervention and implementation study procedures.
3. Assess feasibility of service use data collection through electronic records, by measuring the proportion of notes available for review.

Secondary Feasibility and Acceptability Objectives:

1. Measure the number of patient records reviewed in a dementia care plan audit (audit sample).
2. Assess feasibility and acceptability of recruiting and training CDLs and embedding them within existing care pathways/service delivery models.
3. Determine intervention fidelity.
4. Identify resource requirements to access, collect and analyse study data.
5. Evaluate acceptability and appropriateness of the primary implementation outcome: an increase in the number of PWD with a personalised care plan at recruited general practices.

METHODS

Study design and procedures

A non-randomised, mixed methods, feasibility and implementation study was conducted. Detailed methods are described in the study protocol (18) (See Supplementary File for original protocol). Study reporting has been informed by guidelines for reporting non-randomised pilot and feasibility studies (19) and CONSORT extension guidelines (20).

Ethics

Approval was obtained from Wales REC4 on 20/08/2021, IRAS ID 294881. NHS Confidentiality Advisory Group (CAG) support was obtained on 23/12/2021, allowing researchers pre-consent access to electronic care notes of patients for specific study purposes: CAG reference 21/CAG/0182.

Patient and Public Involvement

A stakeholder group of PWD, current and former carers, and professionals – the PriDem 'Dementia Care Community' (DCC) – advised on research design, including accessibility of materials. They worked with us to pilot outcome measures.

Sites and Participants

We aimed to conduct the study within four Primary Care Networks (PCNs); two in Northeast (NE) and two in the Southeast (SE) England (see sample size below)

PWD were eligible if they were: over 18 years old, registered with a participating general practice, diagnosed with dementia, community dwelling, able to consent, or able to be recruited via personal consultee. Carers were eligible if they were over 18 years old, caring for a person with dementia who had agreed to take part, English speaking, and willing and able to provide informed consent. Both PWD and carers were ineligible if judged inappropriate for the study by their general practitioner (GP) (e.g., due to current life events such as a bereavement) or had an advance statement indicating they did not wish to participate in research.

The study took place during increasing demands on general practice staff due to Covid-19. To reduce burden on participating practices, researchers undertook eligibility screening and mail out activities with NHS CAG support. The mail out included an accessible written Patient Information Sheet (see https://tinyurl.com/585rrwh) with audio and visual versions available on request. Non-responders were contacted by telephone to provide an opportunity to find out about the study and opt in or out. Researchers informed general practice teams of those who were uncontactable after three attempts.

Participating sites and participants had exposure to the intervention over a twelve-month period.

PriDem Intervention

The intervention aimed to promote sustainable change in post-diagnostic care for PWD and carers, led by primary care. A manualised intervention was developed (14, 21), focusing on three interlinked intervention strands:

1. **Developing systems** - Mapping local dementia services, reviewing referral and transition processes.
2. **Delivering tailored care and support** - Working with general practice teams to develop tailored approaches and resources to optimise annual dementia reviews (an NHS Quality

and Outcomes Framework (QOF) indicator for dementia care (22)) and personalised dementia care planning (23). Providing advice and management for PWD with complex needs.

3. **Building capacity and capability** – Upskilling the workforce.

Two CDLs from a nursing background, one in the SE and one in the NE, led the intervention. They undertook a bespoke PriDem training programme and were supported by ongoing clinical supervision with a specialist dementia nurse, and intervention supervision with researchers and the clinical supervisor.

Data Collection

For the recruited PWD/carer sample, a range of data was collected, shown in Table One, with follow-up times for questionnaires at baseline, four months and nine months. Service use data was also collected for this sample, covering the 12-month period prior to the intervention and the 12-month period from the start of the intervention.

For the care plan audit sample, demographic data and outcomes related to dementia care plans were collected for 2018-2019 and 2022-2023 QOF years, with separate audit samples for each period.

Table One: Data Collection Sources

Outcome	**Measures**	**Point of collection (m: months)**						
		2018-2019 QOF year	**12m pre-intervention phase**	**Baseline**	**4 m**	**9 m**	**12 m intervention phase**	**2022-2023 QOF year**
People with dementia								
Cognitive screening	Montreal Cognitive Assessment (MoCA Blind) (24).			X				
Quality of Life and Wellbeing	Completed by people with dementia: Dementia Quality of Life measure (DEMQOL) (25), EQ-5D-5L (26).			X	X	X		
	Completed by carers: Proxy DEMQOL and EQ-5D-5L. Neuropsychiatric Inventory (27).			X	X	X		
Service use	Participant service use data (contacts with health, social and voluntary sector) extracted from electronic medical records.		X				X	
	Completed by carers: Client Services Receipt Inventory (CSRI (28), adapted from iMTA Valuation of Informal Care Questionnaire (iVICQ) (29).			X	X	X		

PRIMARY OUTCOME: Adoption of personalised care planning by participating general practice	Care plan audit of electronic care records, measuring presence/absence of personalised care plans. Pre-intervention QOF year 2018-2019 compared with intervention year 2022-2023. Random sample of 215 registered patients with dementia diagnosis living at home at beginning of each audit period **(not restricted to recruited participants).** Stratified sampling based on estimated number of eligible patients on each practice register. **Individual patients not followed up.**	x						x
Description of sample	***Participant demographics:*** a) Age; b) Gender; c) Ethnicity; d) Site (NE or SE); e) Relationship of PWD to carer; f) Type of dementia; g) Time since dementia diagnosis; h) Social deprivation score (using postcode-based Index of Multiple Deprivation (IMD) quintile).			x				
Carers								
Quality of Life and Wellbeing	Hospital anxiety and depression scale (HADS) (30), Carer-DEMQOL (31) , EQ-5D-5L (26).			x	x	x		

Researchers kept a written log of their reflections following participant visits.

The primary outcome was the proportion of personalised care plans in each of the 2018-2019 and 2022-2023 QOF years. Secondary outcomes included quality of life and wellbeing outcomes (e.g., DEMQoL, EQ-5D-5L, NPI), and service use, as detailed in Table One.

Sample Size

For the care plan audit, it was anticipated that approximately 40% of people diagnosed with dementia had a personalised care plan, based on a pilot audit carried out by clinical research team members. A sample of 215 PWD is sufficient to detect an increase of at least 0.1 in the proportion of PWD with a personalised care plan, from a null hypothesis of 0.4, using a one-sided, one-sample Z-test with a power of 90% and a 5% significance level.

For the recruited sample, we anticipated that up to four PCNs would participate in the study and expected to recruit up to 80 PWD and 66 carers during the first four months of the study.

As this was a feasibility study, a formal hypothesis-based sample size calculation was not performed.

Data analysis

Participants' baseline characteristics were summarised using appropriate statistics, with categorical variables reported as counts and percentages and continuous variables using means, standard deviations and ranges.

The primary outcome was analysed by reporting the proportion of people living with dementia who have a personalised care plan in place, together with an associated 95% confidence interval, for each of the 2018-2019 audit and 2022-2023 audit periods (i.e., pre- and post- intervention). The minimum requirement for a care plan to be judged as personalised was the presence of the PWD and/or carer when agreeing the plan (see (18) for more detailed information). A one sample Z-test was used to test the null hypothesis that the proportion of PWD who have a personalised care plan is 0.4, against a one-sided alternative that this proportion is >0.4, for each of the 2018-2019 and 2022-2023 audit years.

For the recruited sample, secondary outcomes are reported at baseline and at each follow-up time using appropriate summary statistics. All analyses were complete case with no adjustment for missing data. Numbers of withdrawals from the study are reported with reasons.

Process evaluation

A mixed methods process evaluation aimed to describe factors influencing implementation of the intervention in practice. Qualitative data comprised semi-structured interviews with PWD, carers, practitioners and commissioners, observation fieldnotes of relevant intervention activities, and researcher fieldnotes on CDL intervention supervision sessions. Codebook thematic analysis (32) was used to develop themes relevant to implementation barriers and facilitators, with Normalisation Process Theory (NPT) (33) used as an analytic lens. Detailed qualitative process evaluation findings will be reported separately.
A checklist of 15 key intervention activities (Practice Engagement Log), was completed at one timepoint, at the intervention end, in discussion with CDLs to assess fidelity of engagement by general practices with the intervention using descriptive statistics.

RESULTS

Primary feasibility outcomes

1. **Rates of recruitment and retention at follow-up**

NHS sites

The target four PCNs were recruited. Within these PCNs, seven GP practices were recruited: three in the SE (from one PCN) and four in the NE (spanning three PCNs). An additional practice agreed to take part but withdrew after a Site Initiation Visit, citing lack of capacity to engage with the intervention.

Participants: PWD and carers

Recruitment duration was 19 weeks in the SE and 14 weeks in the NE. We recruited 60 PWD (28 in the SE; 32 in the NE – 75% of recruitment target) and 51 carers (23 in the SE; 28 in the NE – 77% recruitment target). Of patients screened, 50.4% (291) were eligible. Of those eligible, 20.6% (60) were recruited to the study (Figure One).

Figure One: CONSORT Diagram – Recruitment and retention rates for the seven general practices

The sample included those who are typically under-represented in dementia research (12). Almost half (44.8%) of PWD were recruited via consultee declaration (Table Two), demonstrating potential to involve people with more advanced dementia in research, reflected in MoCA scores, which indicated moderate to severe cognitive impairment. Over a quarter (25.9%) of participants with dementia lived alone and 15.5% did not have a carer participating alongside. 15.5% of PWD and 22.4% of carers were from non-white ethnic backgrounds.

Table Two: Participant characteristics

Characteristic		**PWD**	**Carers**
Age (years) Mean (Std. dev.) (min., max.), n. .		81.4 (7.3) (61, 97), n = 58	66.3 (32,95); n = 48
Gender **N (%)**	Male	33 (56.9)	12 (24.5)
	Female	25 (43.1)	37 24.5)
Region N (%)	Northeast	30 (51.7)	26 (53.1)
	Southeast	28 (48.3)	23 (46.9)
Diagnosis N (%)	Alzheimer's	45 (77.6)	
	Lewy Body	1 (1.7)	
	Vascular	1 (1.7)	
	Mixed	4 (6.9)	
	Other	2 (3.5)	
	Not known	5 (8.6)	
MOCA score Mean (Std. dev.) (Min., Max.), n.		10.6 (4.3) (2, 19), n = 49	
Time since dementia diagnosis (years) Mean (Std. dev.) (Min., Max.), n.		2.8 (2.6) (0.3, 9.5), n = 47	
Deprivation score (IMD quintile) N (%)	5	22 (40.0) (37.9)	
	4	12 (21.8) (20.7)	
	3	11 (20.0) (19.0)	
	2	3 (5.5) (5.2)	
	1	7 (12.7) (12.0)	
	Missing	3 (5.2)	
Approach to consent N (%)	Self-consent	32 (5.2)	
	Consultee	26 (44.8)	
Participating with/without carer N (%) Data available: 58 P	With carer	49 (84.5)	
	Without carer	9 (15.5)	

Ethnicity N (%)	White	49 (84.5)	38 (77.6)
	Asian/Asian British	4 (6.9)	5 (10.2)
	Black, African, Caribbean or Black British	1 (1.7)	1 (2.0)
	Mixed or multiple ethnic groups	1 (1.7)	1 (2.0)
	Other ethnic group	3 (5.2)	4 (8.2)
Marital status N (%)	Married	32 (55.2)	38 (77.6)
	Widowed	16 (27.6)	0
	Divorced	6 (10.3)	4 (8.2)
	Single (never married)	4 (6.9)	2 (4.1)
	Co-habiting	0	3 (6.0)
	Separated	0	2 (4.1)
Living status N (%)	Lives with spouse or partner only	28 (48.3)	39 (79.6)
	Lives with other family (not spouse or partner)	9 (15.5)	8 (16.3)
	Lives with spouse/partner and other family	1 (1.7)	2 (4.1)
	Lives with other (not family)	1 (1.7)	0
	Lives with other family (not spouse or partner) and other (not family)	1 (1.7)	0
	Lives alone	15 (25.9)	0
	Unknown	3 (5.2)	0
Relationship to carer N (%)	Spouse	23 (39.7)	
	Son/Daughter	18 (31.1)	
	Son/Daughter in law	2 (3.4)	
	Brother/ Sister	3 (5.2)	
	Friend	2 (3.4)	
	Neighbour	1 (1.7)	
	Participated without carer	9 (15.5)	

Withdrawals

Withdrawals by study stage are shown in Figure One. Overall retention rate at 9 month follow up was 70.0% of PWD and 76.5% carers. The most common reasons for withdrawal were the person with dementia had moved into a care home or died. One dyad lost to baseline (Figure One) were found to be ineligible only following 9m follow up. The patient had been on the general practice dementia register but was later found to have no formal diagnosis. One person with dementia withdrew as they were upset with a lack of support from their general practice and cynical that anything would change. This echoed some of comments from people opting out during the recruitment phase.

2. Acceptability and engagement with the intervention and implementation study procedures

Intervention

Engagement with the intervention was measured using the Practice Engagement Log (Table One). Engagement varied between practices, from one practice engaging with only six of the 15 intervention activities, to three practices engaging with 14 activities (median = 13). The qualitative process evaluation (to be reported elsewhere) provided a nuanced understanding of engagement.

For example, although both CDLs reported via the log that all practices had engaged with dementia training, there were important differences identified through the qualitative data analysis. In one region, training was delivered to a wide range of staff (e.g., receptionists, GPs, social prescribers), and in the other region the focus was on social prescribers.

Assessment of Study procedures

i) Recruiting and retaining PWD and carers

Participants predominantly opted for in-person rather than remote meetings with researchers. Some found these tiring: *'I know all these questions have got to be done but it was far too long even I was weary.'* [Interview with carer]. However, most reported that in-person visits brought much-needed conversation and company in the post-Covid 19 restrictions era. Ten of 49 carers completed some questionnaires as an online survey, after meeting a researcher in person, and found this an acceptable option.

Researchers routinely phoned participants the day before a scheduled visit to check the visit was still convenient and as a memory prompt. We aimed for consistency, with a named researcher carrying out all baseline and follow up visits with an individual person with dementia and their carer. This helped build relationships and trust.

ii) Recruiting and retaining practice teams

Practice teams valued researcher efforts to reduce burden: *'We didn't have to hold your hands; you knew what you were doing, and we just let you get on with it.'* [Interview with care co-ordinator, General practice 02]. Researcher-staff relationships developed over time, facilitating study engagement: *'…the way you have collaborated with us I think, has been really receptive…I think we've bounced things backwards and forwards really nicely, you guys have adapted to…the…individualised needs of the different practices.'* [Interview with GP, General practice 03].

Some practice staff remained disengaged despite their practice's participation. Research was seen as an additional burden in the context of an overwhelmed workforce with limited resources and little financial incentive. The National Institute for Health Research Clinical Research Network provided research support costs for sites; however, these rates were questioned as not factoring in meetings with the research team prior to agreeing to take part. One CDL commented that a GP was initially reluctant to engage: *'they won't do anything new unless it's for money*' but that this stance changed completely once the intervention's potential was demonstrated through tangible changes to care planning systems.

iii) Participant experiences of outcome measures

We created written cue cards, to support participants (both PWD and carers) in responding to multiple choice questionnaire items, which they found helpful. These were used as a visual prompt to aid recall, to help stay on track and to allow participants to respond privately by pointing, when worried a relative could hear their responses.

DEMQOL (19) and EQ-5D-5L (20) responses were sometimes skewed towards a 'no problem' presentation, compared to lower carer proxy ratings, a pattern previously reported in the literature (34, 35). It was usually discussed with the carer and a decision made about whether to complete the same measures at follow up. Carers found it increasingly problematic to complete proxy QoL measures the more advanced the dementia, expressing that they could not guess the person with

dementia's emotions. Despite researchers being sensitive to participant needs, carer distress was common. However, carers typically wished to continue with questionnaires, finding it helpful to talk about their caring experiences: '*I could imagine some [researchers] might …. hold themselves outside it, ''I can't get involved''…. But…it's such a sad and difficult thing… so if somebody doesn't say to you, "It is tough," or, "Oh yes, I can see that's tricky," whatever it might be, so I do find that helpful, just that acknowledgement.'* [Interview with carer].

3. **Proportion of PWD whose notes were reviewed for service use data**

Baseline service use data collection was feasible. This was collected for 55 PWD (91.6% of participants) and 12 month follow up data collected for 53 PWD (88.3%).

Secondary Feasibility results

1. **Number of patient records reviewed in the dementia care plan audit**

For the baseline care plan audit, there was a lower than estimated number of eligible patients on the dementia registers for four of the seven practices. We over-recruited in two practices until all potentially eligible participants had been included. The stratified sampling strategy for the follow-up audit was successful. At baseline, 179 patient records were audited (83.7% target) and at follow-up, 215 (100% target).

2. **Feasibility and acceptability of engaging and training clinical dementia specialists and embedding within existing care pathways and models of service delivery**

i) Engaging and training the CDLs

It was challenging to recruit to short-term (12 months) CDL posts, in the context of NHS staff shortages. Highlighting secondment and job share opportunities helped attract candidates, as did advertising locally through NHS networks in project localities.

The PriDem intervention manual and training were well received by CDLs and supervisors. Support provided beyond initial training through intervention supervision and clinical supervision were thought to be essential by CDLs and supervisors: ' *…primary care can be very challenging….it's valuing them as individuals and making sure their well-being is maintained within what is sometimes a really complex situation.' [Interview with Clinical Supervisor]*

ii) Embedding CDLs in general practice

CDLs experienced difficulties becoming embedded in practices, especially as post-Covid-19, structures for team face-to-face meetings had yet to be reintroduced: '*The challenges have been…having to persuade people… not having an office base… or a visible presence. Working from home has been a major challenge.'* [Interview with CDL]. To combat these challenges, they used their clinical backgrounds as a 'hook' to engage practice staff. For instance, one CDL used evidence based PriDem annual dementia review and care plan templates with a patient, sharing their learning with a GP, which led to a discussion about annual dementia review systems in the practice. One CDL reflected that mapping local dementia services involved making links with a range of service providers. This led to building relationships with commissioners, becoming embedded in dementia pathway planning groups, working across silos and bringing practitioners together.

iii) Intervention sustainability

Towards the intervention end, CDLs worked with practice teams towards sustainability. Two practices in the SE had set up 'One Stop Shop Dementia Review Clinics' for instance, whereby several PWD and carers attended a practice on the same day for a review with their GP, other practice team members (e.g., practice nurse, social prescriber, dementia advisor) and staff from Age UK. This innovation sustained beyond the intervention lifetime.

3. Intervention fidelity

The intervention was delivered over the planned 12 months. Although qualitative data suggest the intervention was delivered broadly as intended across research sites, intervention flexibility meant some elements were stretched, risking fidelity to intervention aims. For example, in some cases patient-facing aspects of CDL roles were extended beyond intervention aims, or delivery of staff training minimised.

1. **Resource requirements to access, collect and analyse data**

From initial meetings with PCNs to recruiting seven general practices took five months.

Although outcome measures were trialled with our DCC members, completion time was underestimated. Carers needed longer than anticipated to expand on multiple choice responses and verbalise emotional responses. Often, consent was obtained, and measures completed over two or three visits, with visits taking over two hours. Participants valued having time to build relationships with researchers and enjoyed sharing refreshments with them; an important element of trust building and retention. Therefore, data collection was resource intensive.

Although researchers received informal training and support, including shadowing of more experienced researchers, and informal debriefing following participant visits, study set up delays led to a condensed timeline. With recruitment a priority, there was less inbuilt researcher training and formal debriefing (given the emotional impact often experienced by researchers) than would have ideally been incorporated. There were also limited resources for peer visiting, although when this occurred, researchers found it supportive and efficient.

2. **Acceptability and appropriateness of the primary implementation outcome**

Qualitative interviews revealed that personalised care was of great importance to participants. There were challenges however in operationalising the concept of 'personalised care planning.' Informed by literature, existing care plan templates, national policy (23) and key components of post-diagnostic care (14), we worked with the DCC to develop an acceptable data extraction form (see (18) for detailed methods). General practices were able to provide dementia registers for the baseline and follow up QOF years.

SAFETY

This was a low-risk intervention. There were 21 serious adverse events (SAEs), comprising hospital admissions (n=17) and deaths (n=4). No SAEs were related to the intervention. One non-serious AE was judged possibly related to the intervention: a person with dementia experienced increased anxiety and depression, potentially precipitated by change in medication following an annual dementia review.

RESULTS: PRIMARY OUTCOME

A one-sample Z-test of the null hypothesis that the true proportion of people with a personalised care plan is 0.4 was carried out for each audit year. While 37.4% ([95% CI 30.3% to 44.5%], p=0.759)

of patients had a personalised care plan in place during the pre-intervention audit year (2018-2019), this increased substantially to 64.7% ([95% CI 58.3% to 71.0%] p<0.0001) in the intervention year (2022-2023). Those without any form of care plan (whether personalised or non-personalised) reduced from 45.8% (95% CI 38.5% to 53.1%) pre-intervention to 22.3% (95% CI 16.8% to 27.9%) of PWD.

RESULTS: SECONDARY OUTCOMES

The results of patient and carer questionnaires remained relatively consistent from baseline to 9 months (Table Three), and there were no marked changes in service use.

Table Three: Patient and carer questionnaire results

Measure	Baseline	4 months	9 months
PWD ratings of own health and wellbeing (n = number of PWD who completed questionnaires)			
DEMQOL score - Mean (Std. dev.) (Min., Max.)	n = 48 87.9 (16.1) (39, 110)	n = 42 87.9 (14.8) (55, 110)	N = 38 88.0 (14.6) (56, 109)
DEMQOL overall quality of life (QOL) - n (%)	n = 48 Very good: 14 (29.2 Good: 19 (39.6) Fair: 11 (22.9) Poor: 4 (8.3)	n = 41 Very good: 8 (19.5) Good: 18 (43.9) Fair: 12 (29.3) Poor: 3 (7.3)	n = 38 Very good: 9 (23.7) Good: 18 (47.4) Fair: 9 (23.7) Poor: 2 (5.2)
EQ-5D-5L EUROQOL index score (England) - Mean (Std. dev.) (Min., Max.)	n = 48 0.79 (0.19) (0.30, 1)	n = 42 0.77 (0.19) (0.30, 1)	n = 38 0.80 (0.22) (0.08, 1)
Carer ratings of PWD health and wellbeing (n = number of carers who completed questionnaires)			
DEMQOL Proxy - Mean (Std. dev.) (Min., Max.)	n = 49 96.09 (12.7) (67.8, 122)	n = 42 96.23 (13.4) (62, 121)	n = 32 92.19 (14.9) (57.1, 120)
DEMQOL-Proxy overall quality of life of PWD – n (%)	n = 49 Very good: 7 (14.3) Good: 23 (46.9) Fair: 14 (28.6) Poor: 5 (10.2)	n = 43 Very good: 6 (14.0) Good: 17 (39.5) Fair: 13 (30.2) Poor: 7 (16.3)	n = 32 Very good: 4 (12.5) Good: 10 (31.3) Fair: 14 (43.7) Poor: 4 (12.5)
EQ5D-5L Proxy EUROQOL index score (England) - Mean (Std. dev.) (Min., Max.)	n = 49 0.63 (0.23) (0.03, 1)	n = 42 0.64 (0.29) (-0.16, 1)	n = 31 0.66 (0.22) (0.10, 1)
Neuropsychiatric inventory Scores (Total, Carer Distress) - Mean (Std. dev.) (Min., Max.)	n = 49 Total: 17.61 (16.7) (0, 93) Distress: 8.71 (7.1) (0, 38)	n = 43 Total: 17.12 (14.1) (0, 52) Distress: 8.42 (7.4) (0, 28)	n = 33 Total: 14.0 (12.1) (0, 46) Distress: 8.45 (6.0) (0, 21)
Carer ratings of own health and wellbeing (n = number of carers who completed questionnaires)			

HADS Anxiety and depression scale Mean (Std. dev.) (Min., Max.)	Anxiety (n = 49): 7.02 (3.8) (1, 16) Depression (n = 49): 4.84 (3.4) (0, 14)	Anxiety (n = 43): 7.30 (3,8) (1, 15) Depression (n = 40): 4.80 (3.5) (0, 16)	Anxiety (n = 35): 6.83 (3.9) (0, 15) Depression (n = 31): 4.26 (3.1) (0, 14)
Carer DEMQOL - Mean (Std. dev.) (Min., Max.)	n = 49 87.7 (18.7) (46.8, 124)	n = 42 90.7 (17.2) (57, 136)	n = 29 91.9 (17.3) (51.7, 123.3)
Carer EQ5D-5L EUROQOL index score (England) - Mean (Std. dev.) (Min., Max.)	n = 49 0.85 (0.15) (0.42, 1)	n = 43 0.84 (0.13) (0.39, 1)	n = 35 0.86 (0.13) (0.41, 1)

DISCUSSION

The PriDem intervention was found to be feasible and acceptable. Taking a proactive and staged recruitment approach led to meeting 75% of our recruitment target of PWD. This approach supported inclusion of PWD in research but also showed potential for inclusion of under-represented groups within dementia research, such as people from minority ethnic communities, people living alone with dementia and those with advanced dementia. Retention rates were comparable to those reported in dementia trials (37).

Study procedures were feasible and largely acceptable, although there is a need for consideration of participant emotional burden, fatigue and acceptability regarding outcome measures. Researcher capacity for recruitment, retention, obtaining individual-level data and qualitative analysis should not be underestimated. Participants need time and support to engage and build relationships with researchers.

In a future study, to mitigate eligible participants opting out, funding for replacement care should be incorporated to support carer participation. Although we worked alongside our patient and public involvement group (DCC) to develop study information resources, we would revisit these to explore ways of further enhancing accessibility, for instance, developing further strategies to alleviate concerns of PWD about participating (e.g., being anxious about talking with strangers). It is also important for researchers to be sensitive to PWD and carers with histories of receiving poor/no dementia care, who may be cynical about joining or continuing to participate in a dementia care study, and to develop strategies to support their engagement.

Working with our DCC was a key strength, essential to ensuring accessible study procedures which took account of peoples' everyday lives. However, this still led to an underestimation of time needed to conduct a real participant home visit. Recruiting general practices was challenging. The study took place when general practices were engaged in managing the COVID-19 vaccination programme and NHS Recovery Plan (38). Having NHS CAG support in place allowed researchers to carry out pre-consent recruitment and care plan audit activities, thereby reducing burden on practice staff and supporting study engagement. A generous study lead-in time is needed in future research to build relationships with potential sites, ensure they understand the intervention, problem solve how best to support their involvement and recruit clinicians to deliver the intervention.

CONCLUSIONS

Despite implementation challenges, our findings indicate that a feasible and acceptable intervention showed early signs of sustainability, such as improving consistency and quality of annual dementia reviews. The positive recruitment, retention and primary outcome results suggest a definitive study is warranted. Funding for a larger scale implementation study should include adequate time for relationship-building with sites and participants and should consider researcher capacity, training and support. Such a study could inform future NICE guidelines (39), commissioning decisions and NHS England recommendations for personalised dementia care planning (17), thereby improving quality of life for those affected by dementia.

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COLLABORATORS

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AUTHOR CONTRIBUTIONS

All authors meet ICMJE criteria for authorship. SG wrote the first draft and was lead author on subsequent drafts. GR, ES and KF refined the first draft. All other authors commented on later drafts. AO'K, JW, KW, LR and GR were involved in the conception of the original PriDem study protocol. SG, ES, KF, FDA, LB, MP AH and MP collected data. AO'K, MW and RH analysed statistical data. Qualitative data analysis was led by ES in collaboration with KF, and oversight from SG. GR, as chief investigator, approved the final draft.

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DISCLAIMER

The views expressed are those of the authors and not necessarily those of the funders, NHS or Department of Health and Social Care.

PATIENT CONSENT FOR PUBLICATION

Not applicable

ETHICS APPROVAL

Ethical approval for the study was obtained from Wales REC 4 of the National Research Ethics Service (21/WA/0267). NHS Confidentiality Advisory Group (21/CAG/0182) recommended that support under Regulation 5 of the Health Service (control of patient information) Regulations 2002 ('section 251 support') was given for the processing of patient information, enabling researchers to access specific patient data without prior informed consent. Recruited participants gave informed consent to participate in the study before taking part.

DATA AVAILABILITY STATEMENT

The deidentified data that support the findings of this study were collected through and are held by University College London. Restrictions on the availability of these data apply, which were used under license for the current study, and are not publicly available. Quantitative data is available from the authors upon reasonable request with permission of Professor Greta Rait (g.rait@ucl.ac.uk). Qualitative data, which has been pseudonymised rather than anonymised, will not be available. Requests to use data will be submitted on a standard form and reviewed by a committee prior to data-sharing agreements being developed.

COMPETING INTERESTS

None declared

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