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RESEARCH ARTICLE

Empowering Better End-of-Life Dementia Care (EMBED-Care): A mixed methods protocol to achieve integrated person-centred care across settings

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Objectives: Globally, the number of people with dementia who have palliative care needs will increase fourfold over the next 40 years. The Empowering Better End-of-Life Dementia Care (EMBED-Care) Programme aims to deliver a step change in care through a large sequential study, spanning multiple work streams.

Methods: We will use mixed methods across settings where people with dementia live and die: their own homes, care homes, and hospitals. Beginning with policy syntheses and reviews of interventions, we will develop a conceptual framework and underpinning theory of change. We will use linked data sets to explore current service use, care transitions, and inequalities and predict future need for end-of-life dementia care. Longitudinal cohort studies of people with dementia (including young onset and prion dementias) and their carers will describe care transitions, quality of life, symptoms, formal and informal care provision, and costs. Data will be synthesised, underpinned by the Knowledge-to-Action Implementation Framework, to design a novel complex intervention to support

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assessment, decision making, and communication between patients, carers, and inter-professional teams. This will be feasibility and pilot tested in UK settings. Patient and public involvement and engagement, innovative work with artists, policymakers, and third sector organisations are embedded to drive impact. We will build research capacity and develop an international network for excellence in dementia palliative care.

Conclusions: EMBED-Care will help us understand current and future need, develop novel cost-effective care innovations, build research capacity, and promote international collaborations in research and practice to ensure people live and die well with dementia.

KEYWORDS

dementia, end-of-life care, family caregivers, health economics, health services research, implementation science, palliative care, policy, quality of life, symptom assessment

1 | INTRODUCTION

1.1 | Dying with dementia

One-third of people aged over 65 will die with dementia,¹ the commonest cause of death in the United Kingdom. By 2040, it is estimated that 220 000 people will die each year with dementia in England and Wales, and many will have palliative care needs.² Although people may die in the early or moderate stages from diseases other than dementia, about one-third of people with dementia live until advanced stages.³ Globally, the number of people dying with dementia who experience serious health-related suffering will increase fourfold over the next 40 years.⁴ Most live and die with dementia and other conditions that are becoming increasingly common with advancing age (eg, diabetes and heart disease).

As dementia and multi-morbidities progress, symptoms such as pain and breathlessness^{3,5} are common and cause significant distress for the person and their carers.⁶ People with dementia and their families may struggle to express their needs and concerns, leaving problems under detected and undertreated over the last months and years of life. Death can be unpredictable, and uncertainty is inherent,⁷ with inequity of access to palliative care.⁵ A shift is required, from delivering care based on an often unreliable prognosis to care that is responsive and based on need, whatever the stage of dementia.

1.2 | The role of palliative care for people with dementia

Dementia is the most feared disease for people aged over 60 years,⁸ but there is less awareness of dementia as a life limiting illness where a “good death” is possible. The concept that a person can “live well” with dementia is promoted widely and is beginning to gain widespread understanding by the public. That people can “die well” with dementia is less accepted.

Key Points

- Dementia palliative care is an under developed priority area.
- We lack cost-effective interventions to empower people with dementia, carers and staff, to identify and meet physical, psychosocial and spiritual needs, across care settings and transitions.
- We will undertake policy and literature reviews, large data and cohort studies, knowledge synthesis, develop and evaluate interventions, underpinned by a new conceptual framework for dementia palliative care.
- Research is guided by patient and public involvement, innovative work with artists, policymakers and third sector organisations amend accordingly.

Most people with dementia die in care homes (58%).⁹ England has one of the highest rates of hospital death in dementia (40%),¹⁰ and few people die at home.^{11,12} Avoiding care transitions is an important goal, but policy has focussed mainly on promoting death in usual place of residence rather than on quality of dying.¹² Carers and people with dementia report comfort and quality of life (QoL) should be the main goals of care.¹³ Recent NICE Dementia Guidance states people with dementia should receive flexible, needs-based palliative care that takes into account the unpredictable progression.¹⁴

Palliative care is patient-centred care in advanced disease (see Box 1).¹⁵ The cornerstone is a focus on detailed detection and assessment of physical, psychosocial, and spiritual needs, with regular review and careful management. This needs-based approach allows the person, their carers, and staff to focus on living well, maximising comfort, QoL, and managing uncertainty. Palliative care models for other life-limiting conditions reduce symptom burden and are cost effective.¹⁶ A palliative care approach for people with dementia is recommended¹⁷ but not

BOX 1 Definitions of palliative and end of life care

Palliative care is the active, total care of the patient whose disease is not responsive to curative treatment. Control of pain, of other symptoms, and of social, psychological, and spiritual problems is paramount. Palliative care is interdisciplinary in its approach and encompasses the patient, the family, and the community in its scope. In a sense, palliative care is to offer the most basic concept of care—that of providing for the needs of the patient wherever he or she is cared for, either at home or in the hospital. Palliative care affirms life and regards dying as a normal process; it neither hastens nor postpones death. It sets out to preserve the best possible quality of life until death.

End-of-life care may be used synonymously with palliative care or hospice care, with end of life understood as an extended period of 1 to 2 years during which the patient/family and health professionals become aware of the life-limiting nature of their illness. End-of-life care may also be understood more specifically as comprehensive care for dying patients in the last few hours or days of life.⁵²

widely used in practice. Most care for people with dementia is delivered via “generalist” staff who frequently deal with palliative care in their role (ie, general practitioner [GP], community and mental health nurses, and ambulance and care home staff) without specialist training or support. A palliative care approach is often started in a crisis or when dying is imminent⁵ but should be integrated earlier into routine practice by generalist staff and be “everybody’s business.”¹⁸

Significant deficits in knowledge and service provision remain; palliative care is a neglected area of dementia research.¹⁹ Prior studies have focussed on the advanced stages of dementia in care home residents.^{3,5,13} There are no UK studies of palliative care need in those with early-stage or moderate dementia who may be dying from other life limiting diseases or co-morbidities, which have different profiles of symptoms and carer experiences, compared with those dying from advanced dementia, or in people with young onset and rapidly progressive dementias (an archetype of which is prion disease). The latter conditions pose special challenges, with rapid deterioration, a lack of time to prepare for death and are highly distressing for carers who may also be managing employment and younger families. Services are patchy, inequitable, and not always age appropriate.^{20,21}

Given the increasing numbers of people who will die with dementia, the distress this can cause carers, the pressures on staff to manage dying in the context of an unpredictable trajectory and funding pressures on the health system, we need to develop new knowledge and innovative cost-effective care. New interventions will need to empower people with dementia of all ages, carers, and staff, to identify and act upon changing physical, psychosocial, and spiritual needs, addressing unmet needs across care settings and facilitating the transfer of information across transitions.

The Empowering Better End-of-Life Dementia Care (EMBED-Care) Programme aims to generate new knowledge to promote these necessary sustained improvements in care. EMBED-Care began in January 2019 and runs until December 2023. It is funded by the UK Economic and Social Research Council (ESRC) and the National Institute for Health Research (NIHR) under their dementia research initiative 2018.

1.3 | Previous work informing EMBED-Care

In previous studies, we found high levels of persistent pain and distressing symptoms in care home residents with severe dementia⁵ and increasing distress in carers.^{6,22} Our routine data analyses show place of death is moving from hospital to the community¹⁰ but increasing numbers of people with dementia attend emergency departments in the last year of life.²³ We have developed decision aids, using a co-design approach, based on heuristics^{24,25} (rules of thumb) to manage difficult decisions towards the end of life.²⁵ We developed, validated, and refined the Palliative Care Outcome Scale (POS, <http://pos-pal.org/>), a tool to improve comprehensive assessment, identification of unmet needs, screening, communication, care, and outcomes in life-limiting disease in routine care.²⁶ Systematic reviews²⁷ and empirical, quantitative, and qualitative work^{28,29} have informed development of the Integrated-POS for Dementia (IPOS-Dem).^{30,31} This multifaceted tool takes a person-centred approach,²⁷ which asks about the person’s most important concerns, and then assesses symptoms and unmet needs, enabling carers and nonclinical staff to identify needs and plan and improve care.³¹ Using realist methods, we developed an understanding of integration,³² facilitators and barriers to good dementia palliative care,³³ and guidance for evaluation of regional health care strategies and policies.³⁴ The EMBED-Care Programme will add to our existing knowledge and build on this work, developing a complex intervention based on our research to identify unmet needs using IPOS-Dem and providing practitioners with resources to inform clinical decision making, communication, and management of these needs (ie, heuristics or clinical “rules of thumb”).

2 | AIMS AND OBJECTIVES

Our overall aim is to promote a “step change” in care for people with dementia and their carers to enable delivery of timely person-centred care, to identify unmet needs and improve outcomes, including comfort and QoL, towards end of life. Each of six-interdependent work streams (WSs) will deliver new knowledge and sequentially build a complex intervention to improve palliative dementia care. Our objectives are to:

1. Synthesise health and social care policy, guidance, and evidence for the effectiveness of interventions to improve QoL, to understand context, inequalities, workforce, and levers for change. We will use this data to develop our programme theory to underpin our research (WS 1);

2. Develop new knowledge on current service use, care transitions, and inequalities in care using linked datasets (WS 2).
3. Describe unmet needs, comfort, care transitions, QoL, formal and informal care, and societal costs in longitudinal cohort studies (WS 3);
4. Synthesise evidence and knowledge generated from WSs 1 to 3, to provide a foundation and inform recommendations and components for our new intervention (WS 4);
5. Design the novel EMBED-Care intervention package (WS 5);
6. Test in community settings the feasibility and acceptability of the EMBED-Care intervention, and pilot methods for a full cluster randomised controlled trial (RCT) (WS 6);
7. Create a network for excellence in dementia palliative care (NEDPC) with UK and international partners, to leverage a sustained step change in care. We will involve people affected by dementia, carers, staff, researchers, third sector, and policymakers to stimulate a public discourse on dying with dementia and provide a platform for workforce development, research, education, implementation, policy, and public engagement.

3 | METHODS

We first describe the key perspectives and theoretical models that underpin the programme followed by aspects of the work that run through the programme, including patient and public involvement and engagement activities. We then give an overview of the individual WSs and how these will work together to build knowledge and develop interventions to improve care. The overall structure of the programme is illustrated in Figure 1.

3.1 | Conceptual framework and implementation

A conceptual framework of integrated palliative dementia care will underpin the programme. A theory of change (ToC) model³⁵ will be

used to understand how the EMBED-Care intervention can facilitate integrated palliative dementia care using a theory-driven approach. This will describe organisational context, the challenges facing integrated palliative dementia care, implementation requirements, and linkages between processes and intended outcomes. The framework will provide theoretical cohesion, inform the choice of research methods, for example the selection of tools and outcomes, and be refined across the programme as we build knowledge.

Implementation is considered from the beginning of the programme. The Knowledge-to-Action (KTA) Implementation Framework³⁶ is designed to guide the translation of research evidence into practice and informs all WSs. This iterative model includes all processes for intervention development from initial research to implementation. It ensures user perspectives and contextual understanding are included from the earliest stage. It comprises a central core of knowledge creation: knowledge inquiry (WSs 1-3), synthesis (WS 4), and products (WSs 5 and 6), surrounded by an action cycle where we will, in feasibility and pilot trials, consider adaptations required to local context, tailor and implement the intervention, and evaluate processes and outcomes.

3.2 | Involvement of people with dementia and their carers

Our programme is built on research priorities identified by people affected by dementia, the Alzheimer's Society and James Lind Alliance.³⁷ Active and collaborative involvement is integrated throughout. Experts by experience, one of whom is a co-applicant, helped write the proposal. We held a workshop funded by the NIHR Research Design Service "Enabling Involvement Fund," which led to changes including developing thinking around comfort as a key outcome and widening to include QoL, endorsing the use of the term "carer" for family and friend carers and strengthening our social media strategy.

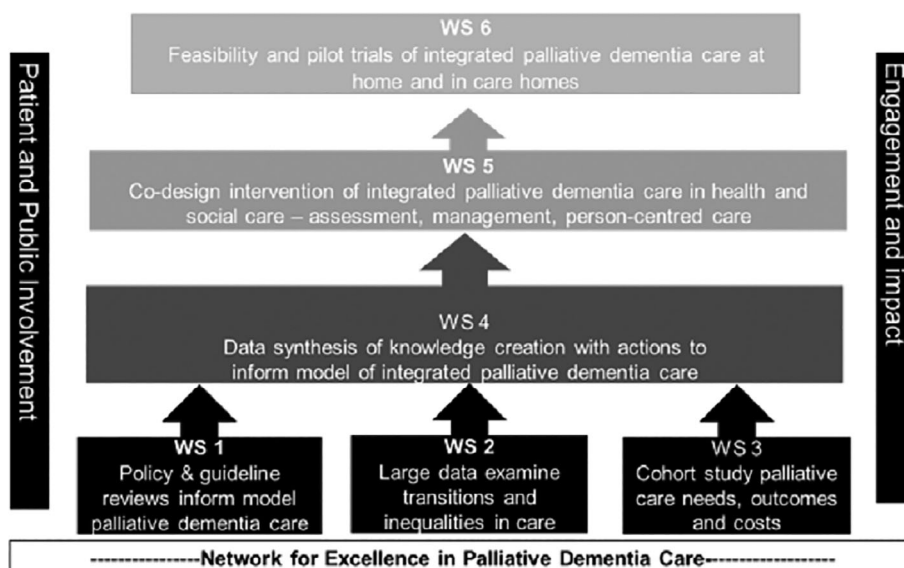


FIGURE 1 Overview of the EMBED-Care Programme. EMBED-Care, Empowering Better End-of-Life Dementia Care; WS, work stream

Our study reference panel will comprise eight experts by experience: carers and people with dementia, including young onset and prion diseases. It will meet every 4 to 6 months with programme and WS leads and their teams to inform important aspects of the work. The panel will contribute to study materials such as information sheets to improve accessibility, develop qualitative topic guides, and support data analysis. They will inform broader public and policy engagement, for example, designing of our YouGov social attitudes survey and contributing personal narratives. We will work with people living with dementia holding four workshops across the United Kingdom with the Dementia Engagement and Empowerment Project (DEEP) at key stages of the programme.

3.3 | Engagement

We will deliver a novel programme of public and policy engagement targeting different sections of society to maximise knowledge exchange. We will work with Science Gallery London (<https://london.sciencegallery.com/engage>), a space hosting participatory exhibitions, linking art, science and health, the university, and the local community, particularly young people. Our objective is to start conversations among groups who may not have been previously engaged with this issue but are likely to experience dementia in the future as relatives or carers. Key beneficiaries are people with dementia and their families and friends, with whom we hope to build awareness and understanding; service commissioners, voluntary sector organisations, and policymakers who we need to equip with information to drive change; and health and social care practitioners to ensure the intervention is embedded in day-to-day practice.

Our impact plan is based around three phases.

1. Early programme: a co-creation model to shape our research and engagement strategy. Activities include a co-creation workshop with young people, which will inform an art installation by commissioned artists from the Science Gallery London network. We will hold public workshops to identify questions for a nationally representative YouGov survey to understand knowledge, attitudes, priorities, and concerns around dying with dementia. A policy lab, which is an interactive event bringing together researchers and policymakers using co-design techniques, will define the information policymakers require and how we can best work with them.
2. Mid programme: a collaborative model to promote discussion of emerging research findings through public workshops, social media, and policy labs. We will work with Hospice UK to produce educational materials from emerging findings, disseminated directly via project Extension for Community Healthcare Outcomes (ECHO) super hub, a knowledge-sharing network of generalists and specialists (ie, care homes, acute and community health trusts, and social care) who form communities of practice with trained facilitators for learning via videoconferencing and virtual meetings.
3. Late programme: a dissemination model to share research findings and refine messages. This includes the production of shareable

digital content, high-profile public debates, knowledge exchange events with commissioners and policymakers, and parliamentary engagement.

Monitoring and evaluation of impact will be led by a specialist evaluation consultant from SGL's network. Working with the research team, they will employ mixed methods, pre- and post-participation questionnaires deployed at each activity, semi-structured interviews, and focus groups.

The Network for Excellence in Palliative Dementia Care will bring together the third sector, academics, policymakers, advisors, and international partner organisations from across the specialities of dementia and palliative care, including the Worldwide Hospice Palliative Care Alliance, Marie Curie, Hospice UK, Dementia UK, Alzheimer's Society, CJD Support Network, and YoungDementia UK. The NEPDC facilitates input from this broad range of stakeholders into design and delivery of this and future research and supports dissemination and implementation of research outputs. The Network for Excellence in Palliative Dementia Care will be facilitated through our website, regular newsletters, and knowledge exchange events and will facilitate dissemination of our findings and learning to stakeholders including people with dementia, carers, and staff.

3.4 | Capacity building

We have included four PhD studentships, linked to local ESRC graduate schools, in the programme to build capacity at doctoral level: (a) understanding care transitions in the last years of life for people with dementia (linked to WS 2), (b) identifying palliative care need in young onset dementia (linked to WS 3), (c) appraising implementation and sustainment of innovations in care homes to manage palliative care needs for people (linked to WSs 4-6); and (d) empowering informal carers of people with dementia living at home: development and use of decision support tools (linked to WSs 4-6). Mid-career researchers will develop skills by leading WS and broadening their networks, supported and mentored by senior academics. They will have dedicated time to attend management training and undertake placements in policy units and with partner charities. Additional support for PhD students and mid-career researchers is provided by the INTERDEM academy (http://interdem.org/?page_id=4636). This will deliver a cohort of young researchers with specialism in palliative dementia care, linked to international networks through INTERDEM skilled in delivering impactful research and its subsequent implementation.

3.5 | Research methods

Methods will change and develop during the programme as knowledge is built at each stage. Below, we give an overview of each WS and how they will work together. Indicative details of methods, populations, and deliverables for each WS are given in Table 1.

TABLE 1 Overview of work streams and methods

	Main Objective	Main Methods	Data Sources/Participants	Key Deliverables
Work stream 1	Synthesise health and social care policy and guidance to understand context, inequalities, workforce, and levers for change.	<p>Informed by KTA framework and theory of change (ToC) specific to complex interventions, we will map intervention causal pathways to achieve change and impact.</p> <ol style="list-style-type: none"> 1. Overview of systematic reviews on service delivery models in palliative care and dementia. 2. Policy review of UK and international health and social care: qualitative documentary analysis and summative content analysis. 	<ol style="list-style-type: none"> 1. Relevant reviews, combined MeSH and text terms, search from 2000 to end date in databases for social care (IBSS, Social Policy, and Practice), health (MEDLINE, EMBASE, and CINAHL), and systematic reviews (Cochrane, DoPHER, and DARE). 2. Review of UK and international policy and strategies with widened focus to dementia and palliative care. 3. Focus groups of health and social care practitioners, policymakers, and carers will review findings to ensure knowledge generated is relevant and useful. 	<ol style="list-style-type: none"> 1. Conceptual framework of integrated palliative dementia care; 2. Practical model of integrated palliative dementia care across services; and 3. Description of key intervention components, implementation, workforce needs, sustainability and scalability, and context to inform policy briefings and support intervention uptake.
Work stream 2	Develop new knowledge on current service use, care transitions, and inequalities in care using linked data sets.	Retrospective observational study: to describe patterns of health service use (including NHS costs). Statistical modelling to understand inequalities and co-morbidity and predict trends and future projections of health service use.	South London and Maudsley National Health Service (NHS) Foundation Trust Biomedical Research Centre (SLaM BRC) Case Register and Clinical Record Interactive Search (CRIS). Population with clinical diagnosis of dementia (ICD-10) and open-text data search.	<ol style="list-style-type: none"> 4. Data on service use, inequalities, and transition of people who died with dementia, and how they transition through the health care system to inform programme theory and subsequent works streams. 5. Methodological innovation, for example, linking community palliative care records to other large data sets.
Work stream 3	Describe unmet needs comfort, care transitions, QoL, formal and informal care, and societal costs	<p>Longitudinal cohort: people with dementia and their carers. Measures informed by WSS 1 and 2 and PPI panel to include demographics, frailty, co-morbidity, and unmet needs (IPOS-Dem) at baseline and 3-monthly for 9 months.</p> <p>Qualitative study: explore care transitions, empowerment in managing care, using individual interviews with carers at baseline, 3 months and 6 months. We will use thematic analysis, triangulated with our quantitative data.</p>	<p>Longitudinal cohort: 294 people living at home or in care homes, rural, city/ suburban areas. Inclusion criteria guided by WS 2. Recruited via networks, ie, NIHR Enabling Research in Care Homes, NIHR Join Dementia Research, and NHS trusts. Embedded studies of people with prion dementias from National Prion Clinic UCLH and MRC Prion Unit and young-onset dementia (National Hospital for Neurology and Neurosurgery Queen Square).</p> <p>Qualitative study: 25 dyads (10 young onset) comprising person with dementia and carer. Separate interview with main practitioner</p>	<ol style="list-style-type: none"> 6. New knowledge on unmet palliative care needs and their impact defines main topics for decision support tools developed in WSS 4 and 5. 7. Case studies for detailed understanding of how “good” care works will inform WS 4 8. New knowledge on service use, inequalities, and transitions through the system will refine conceptual framework and inform policy. 9. New data on young onset/ prion dementias for future research, intervention studies, and policy. 10. Data on cohort characteristics and need inform participant

(Continues)

TABLE 1 (Continued)

	Main Objective	Main Methods	Data Sources/Participants	Key Deliverables
			providing care. Maximum variation sampling to understand “standard” and “good” care.	selection criteria for trials in WS 6.
Work stream 4	Synthesise evidence and knowledge from WSs 1 to 3, to provide a foundation and inform recommendations and components for our new intervention.	<p>Data synthesis using a matrix approach that draws on framework analysis and systematically evaluates evidence for strategies to address unmet needs.</p> <p>Focus groups will appraise the matrix to help understand and organise the data and introduce conflicting evidence and ideas that provide a rich “real world” discussion.</p>	<p>WS 1 policy reviews, WS 2 linked data sets analysis, and WS 3 cohort studies</p> <p>Focus groups: (7-10 participants per group) for different target populations; people with dementia via DEEP workshop 4, carers, and a wide range of health and social care practitioners.</p>	<p>11. Comprehensive synthesis matrix of best available evidence (WSs 1-3) for meeting unmet palliative care needs, reviewed by key stakeholders for applicability across care contexts, to provide the evidence base and recommendations for WS 5 co-design.</p> <p>12. Qualitative data on stakeholder development of key intervention components.</p>
Work stream 5	Design the novel EMBED-Care intervention package	Co-design groups.	Three groups, up to 10 participants: (a) Practitioners from across settings and disciplines; (b) current and former carers, including those caring for people with young onset and prion dementias; (c) people with mild dementia, purposively recruited to maximise sample diversity, via sources described in WS 3.	<p>13. Co-designed, user-tested EMBED-Care intervention for WS 6, including implementation strategy and processes for care homes and community settings and training package</p> <p>14. Methodological development in co-design of complex palliative dementia care intervention</p>
Work stream 6	Test in community settings the feasibility and acceptability of the EMBED-Care intervention. Pilot methods for a full cluster randomised controlled trial	<p>Mixed-methods feasibility study and pilot cluster-randomised controlled trial</p> <p>Feasibility study data analysis: completeness of outcome data, including completion of the IPOS-Dem and frequency of use. Directed content analysis is used for qualitative data, underpinned by our theoretical model.</p> <p>Pilot data analysis: levels of missing data will be assessed and evaluated. Recruitment and attrition rates will be estimated using proportions with associated 95% CI. We will estimate the difference (and CI) in our main clinical outcomes between trial arms, using appropriate regression models adjusted for baseline values. This will inform sample size calculations for a full cluster RCT.</p>	<p>Feasibility study: four clusters (two care homes, two communities of practice (CoP-multidisciplinary teams providing care to people with complex care needs at home or in care homes), chosen to demonstrate feasibility of intervention delivery in both settings. We aim to recruit 40 participants, with a minimum of 8-10 per cluster.</p> <p>Pilot study: 10 settings (six care homes, four CoP) randomised by trial statistician to five interventions and five controls. Numbers chosen pragmatically to be sufficient to pilot recruitment, acceptance of randomisation and attrition. We aim to recruit 100 participants, minimum of eight per cluster.</p>	<p>15. Feasibility and pilot-tested intervention</p> <p>16. Methods (including health economics) and sample size to inform full cluster RCT (if warranted)</p> <p>17. Detailed understanding of implementation and context requirements for EMBED-Care intervention</p>

(Continues)

TABLE 1 (Continued)

Main Objective	Main Methods	Data Sources/Participants	Key Deliverables
	Study flow reported per CONSORT for randomised feasibility and pilot studies.		
	Economic evaluation: health and social services perspective, describing costs of delivering the intervention including support, equipment, supervision and monitoring, staff recruitment, training and project management. Resource utilisation will be multiplied by unit costs to estimate individual patient costs at baseline and over 6 months.		

Abbreviations: DEEP, Dementia Engagement and Empowerment Project; EMBED-Dem, Empowering Better End-of-Life Dementia Care; IPOS-Dem, Integrated Palliative Care Outcome Scale for Dementia; KTA, Knowledge to Action; NIHR, National Institute for Health Research; PPI, patient and public involvement; QoL, quality of life; RCT, randomised controlled trial; WS, work stream.

3.5.1 | WS 1: Developing a conceptual framework of integrated palliative dementia care

The underpinning conceptual framework will be refined as we build knowledge through the programme. Our aim is to define a practical service delivery model of integrated palliative dementia care for people with dementia and their carers to increase comfort and QoL across health and social care services. To do this, we need to understand what the key components of this should be and consider sustainability, costs, and workforce implications.

We will complete two reviews: (a) an overview of systematic reviews on service delivery models in palliative and dementia care to conceptualise palliative dementia care and inform our initial ToC and (b) a review of health and social care policy using qualitative documentary analysis to understand: national and international context, integration of palliative and dementia care, inequalities, workforce needs, and policy levers for change.^{34,38} Focus groups involving health and social care practitioners, policymakers, and carers and a DEEP workshop with people with dementia will review the findings to ensure that the knowledge generated is relevant and useful.^{35,36}

3.5.2 | WS 2: New knowledge on service use, inequalities, and future population need

Our aim is to study health service use and transitions between care settings among people with dementia as they near the end of life using large linked health care data sets from mental health and general hospital trusts. This will be a retrospective observational study centred on the South London and Maudsley National Health Service (NHS) Foundation Trust Biomedical Research Centre (SLaM BRC) Case Register and its Clinical Record Interactive Search (CRIS). SLaM

provides mental health and dementia services to over 1.2 million residents in four south London boroughs (Croydon, Lambeth, Lewisham, and Southwark). The register is a research repository of anonymised, structured, and open-text data from electronic records within SLaM (over 400 000 patients), enriched with a range of external data linkages and natural language-processing algorithms to extract structured data from free text.³⁹ CRIS has been previously used to investigate end-of-life issues in dementia,²³ and this WS builds on WS 1 reviews and will inform the case for new models of dementia palliative care. We will specifically investigate key factors, including inequalities and multi-morbidity, associated with health service use in the last 2 years of life for people with a previous diagnosis of dementia of any severity and use this information to project future need. Analysis will be informed by our prior work and the programme conceptual framework. We will hold a second DEEP workshop to consider the implications of findings for people with dementia.

3.5.3 | WS 3: Cohort studies on unmet palliative care needs

The aim of this WS is to understand unmet palliative care needs in people at all stages of dementia, including those in the early and moderate stages who may be dying from other illnesses. We will include sub-cohorts with young onset and rapidly progressive (prion) dementias. This will be a prospective longitudinal mixed method cohort study involving people with dementia (all subtypes) over 9 months. Inclusion criteria will be informed by WS 2 and our prior studies. Study measures will be informed by WSs 1 and 2 and our patient and public involvement (PPI) Study Reference Panel. We will define unmet needs using tools such as IPOS-Dem.³⁰ Outcomes will include validated scales for comfort and symptom management and care transitions. We will

measure carer unmet needs and outcomes such as anxiety, depression, and anticipatory grief, to explore how these are associated with unmet palliative care need. If participants die, we will interview carers post-bereavement to understand final care transitions and care quality.

Health economics

Our aims in the economic evaluation are to assess participants' QoL and estimate costs of care from health and social care (NHS) cost perspectives. This will include social services and community support, day care services, outreach, symptom control, and respite services. Unit costs will be obtained from Personal Social Services Research Unit and National End of Life Care Intelligence Network.

Unpaid carers often provide essential support and care to patients with dementia. Their contribution to care needs to be recognised and valued. A failure to do so risks undervaluing the total cost of care. Thus, in addition to health and social care costs, our analysis will take into account the contribution of unpaid carers as if they were paid at the same rate as a paid carer. Total cost estimates will also be expressed as increments per 1 point change in our primary outcome, IPOS-Dem. Quality-adjusted life years (QALYs) will be calculated using the EQ-5D-5L values from each follow-up point from baseline to 9 months. In the population nearing the end of life, it is unclear how well the EQ-5D-5L will function, and so a dementia-specific QoL measure, DEMQOL, will also be utilised.

Sample size

We estimate that care transition occurs in 50% of people with dementia in the last year of life.^{5,23} A total of 294 will be recruited. Allowing for 25% attrition, we expect 110 to have a transition. Primary analysis is based on logistic regression models. Using the rule of 10 events (in this case, transitions) per variable, this allows estimation of 11 regression coefficients for a logistic regression model with adequate precision.⁴⁰ Prion dementias sample size estimated 50 participants over an 18-month recruitment period based on approximately 120 new cases per year.

Analysis

We will describe participant characteristics and quantitative outcome measures using mean/median (SD, IQ range) and counts (percentage) as appropriate. We will investigate bias from missing data and use multiple imputation for missing values of explanatory variables if considered appropriate. Logistic regression accounting for whether patients are recruited from care homes or the community will be used to estimate the associations between pre-specified explanatory variables such as unmet needs and outcomes, ie, first care transition during the study. To explore trends in IPOS-Dem, comfort, symptom management, and care transitions over time, we will use regression models that can incorporate repeated measurements.

We will explore further unmet needs and care transitions using individual interviews comprising dyads of a person with dementia (when possible) and a carer (ie, family). We will interview separately

the main practitioner involved in providing care identified by the family to understand their perspective. Interview data will undergo thematic analysis, triangulated with our quantitative data. A third DEEP workshop will consider implications of findings for people with dementia, key messages for policymakers and commissioners, and how they should inform care.

3.5.4 | WS 4: Knowledge synthesis for intervention development

This critical step of the EMBED-Care programme will synthesise knowledge into a product (the intervention) to enable translation of research evidence into practice as part of the KTA Framework.⁴¹ This innovative approach moves beyond traditional evidence-based guidelines, by incorporating information about existing practice and policy and the resources needed in different contexts. Our complex intervention will require synthesis of diverse types of knowledge, in differing formats, with varying degrees of value, to be robust, reliable, and practical for implementation in real world settings.⁴² We will synthesise data from WSs 1 to 3, our work on IPOS-Dem³⁰ and the heuristic decision aid.²⁵ We will systematically evaluate evidence for strategies to address unmet needs, incorporating them into a knowledge synthesis matrix (for an example of this, see Table 2). This pivotal step of the KTA links knowledge creation with action to support effective uptake by potential end users.

The matrix will be based on framework analysis,⁴³ a method for synthesising applied qualitative data, adapted to include the results of quantitative effectiveness studies and meta analyses. Existing evidence-based approaches consider RCT and meta-analysis evidence as the gold standard; however, these can fail to account for the impact of context, policy, resources, and mechanisms underlying interventions that enable or inhibit translation into practice.⁴⁴ Using this approach, multiple strategies can be assessed against unmet needs; eg, there may be strong evidence that repositioning improves pressure sores but not pain. The matrix provides a comprehensive synthesis of best available evidence, providing recommendations for intervention development. Focus groups with key professionals will consider and provide feedback on the emerging results before translating the matrix into a practical, multi-component intervention. A DEEP workshop will be held to ensure our findings are relevant to people with dementia.

3.5.5 | WS 5: Co-design of intervention to support better palliative dementia care

Our aim is to co-design with people with dementia, carers, and staff, an innovative complex intervention to enable and empower assessment and management of needs, develop person-centred care, and integrate palliative dementia care into health and social care practice. The EMBED-Care intervention will likely comprise as follows:

TABLE 2 Example of synthesis matrix for intervention development

Strategies for Addressing Unmet Needs	Unmet Needs This Strategy may Address	Source of Evidence (WSs 1, 2, and 3 or previous research)	Mechanism for Addressing Unmet Need	Consistency with UK Policy and Practice (from WS 1)	Resources Needed for Implementing in UK Settings and Neglected Populations and to Meet Projected Needs Identified in WS 2	Recommendation Based on Current Evidence?
Strategy 1	(new row for each unmet need)					
Example 1: repositioning	Pain	WS 1 policy review WS 3 cohort	Reduces discomfort, pressure sores, improves body alignment	Carer and staff interviews	Used in UK hospital and care home settings; implications on staff time	Yes/no (identified in WS 1)

Abbreviation: WS, work stream.

1. A resource to holistically assess and identify concerns and symptoms, prioritise needs and goals by the person with dementia and their carer or staff, and trigger alerts of changing or unmet needs (IPOS-Dem).
2. A heuristic decision resource detailing evidence-based actions to enable staff and/ or carers to put in place the right care, at the right time, in the right place.
3. An intervention manual and training and support package for staff.

We will consider the use of telehealth as a key mode of delivery. We will use the WS 4 knowledge synthesis to develop prototype decision aids. We will work with co-design⁴⁵ groups involving practitioners, current and former carers, and people with mild dementia. This allows collaboration on intervention design and delivery between researchers and end users to promote successful implementation and translation into practice⁴⁶ and links knowledge creation with action in our KTA framework.³⁶ Co-design groups will iteratively refine the heuristic resource. A training and support package will be designed and reviewed in a final workshop. The intervention will be field tested in practice (home and care home settings) for 4 weeks, and after this, we will hold a focus group to explore use barriers and facilitators, content and design, and modifications to implementation or delivery.

3.5.6 | WS 6 Feasibility study

We will conduct a feasibility study of intervention implementation and recruitment and then pilot the intervention in a cluster RCT. Clusters will be individual care homes or communities of practice. We will refine the intervention, inform the design of future studies, and establish whether a future definitive trial is warranted. To ensure methodological rigour, we are supported by an MRC-registered clinical trials unit (PRIMENT-CTU), who will be involved at all stages: planning, approvals, randomisation, data collection, storage, and analysis. We will need to be flexible with feasibility and pilot trial design to allow for likely changes in health and social care systems during the programme. Detailed methods will be informed by WSs 1 to 5. For example, potential outcome measures will likely include care transitions, comfort and service use, but selection will be informed by programme theory (WS 1). Participant recruitment criteria, including carers, will be

guided by WSs 2 and 3 and PPI consultation. Both feasibility and pilot studies will use mixed methods, informed by the MRC framework for complex intervention development⁴⁷ and MORECare^{48,49} guidance for palliative and social care, which defines best practice to develop and evaluate models of service delivery and complex interventions in palliative and end-of-life care.

The feasibility study will run the intervention for 3 months, supported by a champion in each care setting. We will test the feasibility of data collection at baseline and 3 months. We will evaluate acceptability of the intervention and conduct a process evaluation to understand risks of harm, implementation requirements, and context-specific adaptations.⁵⁰ We will use data from a range of organisational levels and informants. For example, clinical commissioning group service data to examine unplanned care transitions to hospital and a utility questionnaire for staff to explore practical use of the tools. Semi-structured interviews/focus groups in each cluster, detailed case studies, observations of multidisciplinary meetings, and case note review will inform adaptations. Final consultation with potential end users will employ consensus methods to make recommendations on intervention components and implementation requirements.⁵¹

The pilot cluster RC will run for 6 months in six clusters (three intervention and three control). Outcome measures will be identified from the feasibility study. Data will be collected on people with dementia and their carers at baseline and monthly. Levels of missing data will be assessed and evaluated. Recruitment and attrition rates will be estimated using proportions with associated 95% CI. We will estimate the difference (with 95% CI) in our main clinical outcomes between trial arms, using appropriate regression models adjusted for baseline values. This will inform sample size calculations for a full cluster RCT. We will assess intervention fidelity and hold focus groups and semi-structured interviews with people with dementia, carers, and health and social care staff. We will test recruitment processes, whether outcome data can be collected by researchers blind to allocation, implementation, and identify stop-go criteria for a full trial.

3.6 | Key outputs from EMBED-Care

We will ensure that EMBED-Care produces outputs that benefit people with dementia, their family carers, practitioners, and wider society.

Data sets and methodological developments will build research capacity. The main outputs include the following:

- Conceptual framework for integrated palliative dementia care: including key components and mechanisms of change, to underpin all aspects of the programme. Theoretical work will expand notions of "comfort," "person-centredness," and good death with dementia to inform both theory and practice of care in society (All WSs).
- EMBED-Care intervention: which may be delivered via telehealth technologies, with associated training materials and implementation guidance (WSs 5-6).
- Methodological development: innovation in data linkage (WS 2), economic methods in palliative care (WS 3), synthesis of qualitative and quantitative data and underlying theory (WS 4), and development of intervention implementation theory and framework (WS 6).
- Data sets: new quantitative and qualitative data on palliative care needs and outcomes in people with moderate dementia and their carers, and the first data on young onset and prion dementias, will be anonymised and made freely available. This will provide significant scientific benefit to sociological, economic, gerontological, and health researchers and a basis to develop and evaluate future interventions, instrument design, and services (WS 3).
- Future projections of need for palliative dementia care: to inform service planning and commissioning (WS 2).
- Policy briefings/labs: to inform and brief policymakers and commissioners together with practitioners and service users to enable evidence-based policymaking.
- Knowledge exchange events: provide pathways to policy and academic impact (all WSs).
- Art installation: co-created in workshops with an artist to increase outreach to groups who may not have engaged with the issue of dying with dementia.
- YouGov poll: snapshot measure of societal attitudes towards dying with dementia.
- Newsletters and blogs: co-developed with patient groups at key milestones to contribute their perspective to policy briefings and dissemination.
- Network for Excellence in Palliative Dementia Care: to boost the impact of the research by uniting contributing practitioners, people with dementia, carers, researchers, other stakeholders and existing communities of practice, and international partners.

4 | DISCUSSION

The multidisciplinary team working on our programme will sequentially build new epidemiological and social science knowledge on dying with dementia and a new model of integrated palliative dementia care. This will address unmet needs regardless of the severity of dementia across a range of care settings. We will apply a person-centred approach maximising comfort and QoL. Our multi-component intervention will be carefully developed with attention to contextual factors such as adaptability to local models of service provision,

workforce capability, and economic factors. Our innovative combination of underpinning theory, implementation science, and co-design methods will ensure adoption in practice and improved palliative care for people with dementia and their carers.

This step change in care provision requires public support and engagement, and therefore, changing societal attitudes towards dying with dementia is key to our work, as demonstrated by our pathways to impact that use a range of methods, from academic dissemination to policy work and novel projects with young people who will be affected by dementia in their future. Active and meaningful engagement of people with dementia and their carers will shape all aspects of our work. We will deliver new knowledge and interventions so that people dying with dementia and their carers receive good quality palliative care in the right place at the right time, delivered by a work force with the skills necessary to achieve this.

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DATA AVAILABILITY STATEMENT

N/A - this is a protocol paper and therefore exempt.

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