# EMBED-Care (Empowering Better End-of-Life Dementia Care) Framework study

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered		
27/07/2023		☐ Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
15/08/2023		☐ Results		
Last Edited		Individual participant data		
18/12/2023	Mental and Behavioural Disorders	<ul><li>Record updated in last year</li></ul>		

## Plain English summary of protocol

Background and study aims

People living with dementia may have high unmet needs and can benefit from a holistic palliative care approach. These needs often end up under-detected or under-treated which is worsened by inequity of access to good palliative care. The EMBED-Care Framework has been created for people living with dementia which uses principles of palliative care to improve quality of life by focusing on managing symptoms using a questionnaire to monitor common problems.

The study aims to explore whether it is possible and acceptable for people with dementia (including those with memory problems), their carers (family and friends), and health and social care professionals (including care home staff) to use the EMBED-Care intervention and its training and support, together called the EMBED-Care Framework. Based on the findings, the researchers will refine the EMBED-Care Framework to improve its acceptability and support its use in routine care.

#### Who can participate?

Any person over the age of 18 years who is involved in the care of someone living with dementia can participate in this study. This may include the person living with dementia either with a formal diagnosis or suspected dementia living either in a care home or under the care of a PCN team. Other members who may be involved in care include carers who identify as a family or friend of the person living with dementia, and health and social care professionals who provide direct care.

#### What does the study involve?

The study involves health and social care practitioners using a new intervention, the EMBED-Care Framework, when working with people with dementia or their family carers. The EMBED-Care Framework is designed to support holistic assessment and management of symptoms and concerns that may affect people with dementia and their families. The researchers will ask people with dementia, family carers and health and social practitioners about their experiences using the intervention. They will also explore how the EMBED-Care Framework works to benefit people with dementia and their family carers.

What are the possible benefits and risks of participating?

The use of the EMBED-Care framework is a new intervention, it is therefore uncertain as to whether the use of the EMBED-Care Framework will benefit people living with dementia, family carers or practitioners. However, participating in the study will help to inform the future of palliative dementia care. The benefits of participating in this study may include clinical benefits and staff benefits such as improvement in quality of life. Risks of participating in this study include distress in discussing palliative/end-of-life care and/or distressing symptoms. There is also a risk of burden to the participant (person living with dementia, carers or health and social care professionals) through the additional time needed to participate in the study.

Where is the study run from? University College London (UK)

When is the study starting and how long is it expected to run for? January 2019 to December 2024

Who is funding the study? Economic and Social Research Council (UK)

Who is the main contact?

Dr Charlotte Kenten, c.kenten@ucl.ac.uk

## Study website

https://www.ucl.ac.uk/embed-care

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Charlotte Kenten

#### Contact details

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## Additional identifiers

## EudraCT/CTIS number

Nil known

#### IRAS number

305596

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

CPMS 54947, IRAS 305596

# Study information

#### Scientific Title

EMBED-Care (Empowering Better End-of-Life Dementia Care) Framework study

## Acronym

**EMBED-Care Framework** 

## Study objectives

The EMBED-Care Framework is feasible for health and social care practitioners to implement and use in routine practice to improve palliative care delivery for people with dementia and family carers.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

Approved 08/02/2023, London - Queen Square Research Ethics Committee (Meeting held by video-conference via Zoom, London, -, United Kingdom; +44 (0)207 104 8225, +44 (0)207 104 8227, +44 (0)207 104 8284; queensquare.rec@hra.nhs.uk), ref: 23/LO/0055

## Study design

Randomized; Interventional; Design type: Process of Care, Complex Intervention, Management of Care

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Care home

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

## Health condition(s) or problem(s) studied

Dementia

#### **Interventions**

#### STUDY DESIGN:

Our study design follows the Medical Research Council Framework for Developing and Evaluating Complex Interventions. We will also adapt this for methods of evaluation in palliative and end of life care. The study comprises a mixed-methods (combination of qualitative and quantitative data) feasibility study to explore whether the EMBED-Care Framework is possible and acceptable to use. Depending on the results of the feasibility study, we will progress to a pilot cluster randomised controlled study.

## PATIENT AND PUBLIC INVOLVEMENT (PPI):

We have an active PPI group involving people living with dementia and carers and former carers of family members who had dementia. They informed the original grant application and have since provided constructive feedback on the WS6 participant information sheets, consent forms and invitation letters to be used with people living with dementia and their carers to ensure that the content and format are appropriate.

#### **FEASIBILITY STUDY:**

## Setting:

The feasibility study is a single-arm mixed-methods study conducted in care homes and Primary Care Teams (PCNs). The feasibility study will be conducted in four settings (clusters), including two residential care home settings and two Primary Care Network (PCN) Teams. Residential care homes are settings that provide 24-hour residential care but do not employ registered nurses. PCN teams are multi-disciplinary teams of health and social care professionals providing care to people at home with complex or long-term care needs. As this is a single-arm study, all settings will receive the EMBED-Care Framework intervention, and no randomisation will take place.

## Sampling and sample sizes:

We aim to recruit 50 participants, with a minimum of 10-12 per setting. We assume 15% attrition and therefore we anticipate 40 participants will complete the study.

#### Procedure and EMBED-Care Framework:

The EMBED-Care Framework aims to enhance 'usual care' and is based on best practice and evidence. This means that it needs to be implemented at an organisational (or cluster) level for the six-month duration of the feasibility study.

As such, all residents or patients in participating care homes or PCN Teams will receive the EMBED-Care Framework regardless of whether they are recruited to the study. Anonymous data will be collected on use of the EMBED-Care Framework for all users (including people with dementia, carers and health and social care professionals). These data include use of the EMBED-Care Framework (collected through the app - aggregated and anonymous), anonymous feedback of the training provided, feedback on how the framework supports care (collected through the app - aggregated and anonymous), and use of support provided (e.g. telephone helplines). Throughout the six-month feasibility study, observations of care provision and MDT meetings of all recruited and non-recruited health and social care staff using the the EMBED-Care Framework.

Recruited residents and/or carers (family or friends) will participate in the study for 12 weeks. Recruited health and social care professionals will be recruited for the six-month feasibility study. Identifiable data will only be collected from recruited people with dementia, carers, and /or health and social care professionals. It is anticipated that where data collection is face to face, this will occur in the individuals' homes or places of care or work. However, researchers may interview participants over the phone or through teleconferencing technology if preferred

or required due to COVID-19

restrictions. Informed consent will be obtained either in person or remotely depending on preference and according to any restrictions.

The EMBED-Care Framework comprises a comprehensive assessment, the Integrated Palliative care Outcome Scale (IPOS-Dem) administered in the form of a questionnaire, linked to evidence-based decision support tools. The framework intends to support identification of need, shared decision-making between people with dementia, their carers, and health and social care professionals; and management of identified symptoms and concerns based on best evidence. Frequency of use will be determined based on clinical need, but as a minimum, will be once a month. It can be used more frequently if there is a clinical deterioration or suspected unstable conditions or untreated needs.

The EMBED-Care Framework will be delivered digitally through the ATouchAway app (powered by Aetonix), which also includes training videos. A non-app version will be provided if preferred, comprising paper/electronic copies and training videos. All sites will be provided with training prior to the EMBED-Care Framework being introduced into routine care and support will be provided through the course of the feasibility study.

Training is provided to care homes and PCN teams. Training will be delivered to care home staff champions and champions working in PCN teams of different grades, who then cascade to other team members. It will also be offered to any other staff who are interested in attending and will be offered at multiple times if required to accommodate shift work. Training may be delivered at site settings or online. This comprises part of the intervention which is implemented into routine care for all people with dementia under participating sites.

Multiple methods will be used to ensure that sufficient training/support is provided for health and social care professionals, people with dementia and carers. Ahead of implementing the framework, a pack of training resources including instructions on how to use the tablet, a manual for the intervention and links to other helpful services such as technical support will be provided. A series of instructional videos which will be built into the app will also be provided. These will be 'bitesize' (max 5 minutes) so they can be easily and regularly accessed. Fortnightly support sessions are provided to champions either in-person or online.

Timetable for the feasibility study:

Month 1-3: Main recruitment.

Month 1-6: Data collection with each participant. Participants will be involved in the feasibility study for 12 weeks each.

During this time period there will be analysis of the data and refinement of the EMBED-Care Framework.

Participant pathway - people with dementia (study enrollment: 12 weeks):

All people with dementia participating in the study will receive the EMBED-Care Framework, administered as part of their routine care. People with dementia and their carers can be recruited as dyads, or individually. This means that people with dementia may be recruited without their carers, or carers can be recruited without people with dementia being recruited. Where people with dementia are recruited without their carers, or if carers choose not to be proxies, we will ask health and social care staff to be proxy reporters.

#### Identification and screening:

Once participating care homes and PCN Team have been recruited to the study, people with dementia will be identified and approached as detailed in question A29.

#### Consent:

We will assess capacity and obtain consent of the person with dementia. This includes advanced consent to participate should they lose capacity during the study. Those providing advanced consent will be asked whether there is anyone who they would prefer to act as a personal

consultee. For those lacking capacity to consent we will obtain declaration from personal or nominated consultees. Due to the nature of dementia/cognitive impairment, many eligible individuals may have impaired capacity but may be able to consent in the moment. This means that they will be able to understand and retain information long enough to provide consent at the start of the moment, but may not be able to retain this information for the duration of the study. For these individuals, we will obtain written informed

consent at the start of the study, and this will be verbally reaffirmed, and recorded by a member of the research team at each data collection point. Should any individuals lose capacity during the study, then the process for individuals who lack capacity will be followed. Individuals may also have fluctuating capacity. For this reason, if individuals lose capacity during the course of the study, we will reassess capacity at subsequent data collection time points. If individuals have regained capacity, then verbal consent will be attained as detailed if written informed consent has been obtained, or written informed consent obtained if not already collected.

#### Baseline:

For people with dementia with capacity to consent and self report: Where possible and to minimise participant burden, baseline data collection with the person with dementia will occur at the same time as informed consent is signed.

Data collection with the person with dementia comprises two interview-administered questionnaires:

- EQ-5D-5L
- Edmonton Symptom Assessment Scale (ESAS)

For all people with dementia participants, we identify a proxy. The proxy may either be a carer or health/social care professional (not necessarily recruited to the study). We obtain a proxy reported:

- Clinical Dementia Rating
- Australia-modified Karnofsky Performance Status
- Bristol Activities of Daily Living
- FRAIL
- The General Medical Health Rating
- EQ-5D-5L
- ESAS
- Neuropsychiatric Inventory agitation subscale
- Adapted Client Service Receipt Inventory (CSRI)
- Walker's Measure of Integrated Care

For all people with dementia participants, we extract the following data from their case/care notes:

- Demographic data including DOB, ethnicity, gender, marital status, education, first language, religion, sexual orientation, postcode
- Health data including dementia diagnosis, psychiatric and medical history, medication, care plans and medical/social reviews and/or meetings, Charlson Co-morbidity Index
- Intervention data (if applicable at baseline)

Approximately 4 and 8 weeks from baseline:

For those people with dementia who provided informed consent, we re-assess capacity and obtain verbal consent to proceed. If any individuals, lose capacity, we follow the process for individuals who lack capacity to consent, and get advice from a personal or nominated consultee. For people with dementia with capacity to consent and self-report: Where possible and to minimise participant burden, data collection with the person with dementia will occur at the same time as capacity is assessed and verbal consent to proceed is obtained. A member of the research team records capacity and consent. Data collection with the person with dementia comprises two interview-administered questionnaires:

- EO-5D-5L

- ESAS

For all people with dementia participants, we obtain a proxy reported:

- The General Medical Health Rating
- EQ-5D-5L
- ESAS
- Neuropsychiatric Inventory agitation subscale

For all people with dementia participants, we extract the following data from their case/care notes:

- Current symptoms and concerns, medication, care plans and medical/social reviews and/or meetings
- Intervention data

Final timepoint (approximately 12 weeks):

For those people with dementia who provided informed consent, we re-assess capacity and obtain verbal consent to proceed. If any individuals, lose capacity, we follow the process for individuals who lack capacity to consent, and get advice from a personal or nominated consultee. For people with dementia with capacity to consent and self report: Where possible and to minimise participant burden, data collection with the person with dementia will occur at the same time as capacity is assessed and verbal consent to proceed is obtained. A member of the research team records capacity and consent. Data collection with the person with dementia comprises two interview-administered questionnaires:

- EQ-5D-5L
- ESAS
- Experiences of taking part in the study

For all people with dementia participants, we obtain a proxy reported:

- The General Medical Health Rating
- EQ-5D-5L
- ESAS
- Neuropsychiatric Inventory agitation subscale
- Adapted Client Service Receipt Inventory (CSRI)
- Walker's Measure of Integrated Care

For all people with dementia participants, we extract the following data from their case/care notes:

- Current symptoms and concerns, medication, care plans and medical/social reviews and/or meetings
- Intervention data

Observational data collection (throughout 12 weeks):

Observations of care provision including, for example, the use of the EMBED-Care Framework, observations of consultations and care provision, and observations of MDT meetings. Qualitative interviews or focus groups (approximately weeks 8-12):

For those people with dementia who provided informed consent, we re-assess capacity and obtain verbal consent to proceed.

Semi-structured qualitative interviews with recruited PWD and/or carers together or separately depending on preference. Qualitative interviews follow topic guides and ask questions pertaining to usefulness and acceptability of the EMBED-Care Framework and the experiences of participating in the study. Topic guides are developed in consultation with PPI members to ensure the acceptability of the questions.

Participant pathway – carers (study enrollment: 12 weeks)

People with dementia and their carers can be recruited as dyads, or individually. This means that

people with dementia may be recruited without their carers, or carers can be recruited without people with dementia being recruited.

## Identification and screening:

Once participating care homes and PCN Team have been recruited to the study, people with dementia will be identified and approached as detailed in question A29.

#### Consent:

Carers of people with dementia will be asked to sign informed consent at one point for participation for the 12-week duration in the study.

#### Baseline:

Where possible and to minimise participant burden, baseline data collection with carers will occur at the same time as informed consent is signed. If carers are also acting as proxies, we will collect carer data and person with dementia data at the same time or over multiple sessions according to the carer wishes.

For all carers, we collect:

- Demographic data postcode, ethnicity, DOB, age, gender, marital status, education, work history, relationship to person with dementia, living situation, accommodation, first language, religion, sexual orientation, type of dementia
- Neuropsychiatric Inventory agitation subscale, carer distress
- Scales Measuring the Impact of Dementia on Carers (SIDECAR) Direct Impact on Caring (D)
- SIDECAR Support and information (S)
- Kessler Psychological Distress Scale
- Decisional Conflict Scale
- HowRWe

#### Approximately 4 and 8 weeks: from baseline:

- Neuropsychiatric Inventory agitation subscale, carer distress
- Scales Measuring the Impact of Dementia on Carers (SIDECAR) Direct Impact on Caring (D)
- SIDECAR Support and information (S)
- Kessler Psychological Distress Scale
- Decisional Conflict Scale
- HowRWe

#### Final timepoint (approximately 12 weeks):

- Neuropsychiatric Inventory agitation subscale, carer distress
- Scales Measuring the Impact of Dementia on Carers (SIDECAR) Direct Impact on Caring (D)
- SIDECAR Support and information (S)
- Kessler Psychological Distress Scale
- Decisional Conflict Scale
- HowRWe
- Experiences of taking part in the study

Observational data collection (throughout 12 weeks):

Observations of care provision including for example, use of the EMBED-Care Framework, observations of consultations and care provision, and observations of MDT meetings

Qualitative interviews or focus groups (approximately weeks 8-12):

Semi-structured qualitative interviews with recruited PWD and/or carers together or separately depending on preference. Qualitative interviews follow topic guides and ask questions pertaining to usefulness and acceptability of the EMBED-Care Framework and experiences of participating in the study.

Participant pathway – health and social care professionals (study enrollment:6 months):

## Identification and screening:

Once participating care homes and PCN Team have been recruited to the study, health and social care professionals will be identified and approached as detailed in question A29.

Health and social care professionals will be asked to sign informed consent at one point for participation for the 6-month duration in the study.

Baseline:

- Demographic data Job title, years of clinical/care experience, number of years in current post, gender, ethnicity, age
- NOMAD
- Readiness for organisational change

Final timepoint (approximately 6 months):

- NOMAD
- Readiness for organisational change

Focus groups or semi-structured interviews (months 1-2 and months 5-6):

Focus groups/qualitative interviews follow topic guides and ask questions pertaining to usefulness and acceptability of the EMBED-Care Framework, how it works to support care processes and improve outcomes, its implementation and experiences of participating in the study. Topic guides are developed in collaboration with PPI members.

Serial interviews/focus groups with managers/champions (months 1-3):

Up to fortnightly serial interviews with those leading the EMBED-Care Framework implementation such as managers, clinical leads, and/or champions will be conducted in the first three months of the feasibility trial. These will follow topic guides and will explore the processes of implementation of the EMBED-Care Framework.

### PILOT STUDY:

The methods for the pilot study will be informed by the findings from the feasibility study. Details of participant's journey and data flow will be informed by the feasibility trial. However, the following design, procedures and methods are proposed:

#### Study design:

Type 2 hybrid pilot cluster randomised controlled trial

#### Setting:

The pilot study will be conducted in ten settings (clusters), including six residential care home settings and/or four Primary Care Network (PCN) Teams.

#### Randomisation:

The ten clusters will be randomised to receive the EMBED-Care Framework or Standard Care, with five clusters in each arm. Randomisation will be done at a cluster level ensuring the two arms (intervention and standard care) are balanced with respect to the types of settings. The trial statisticians will produce randomisation specification documents, which an independent PRIMENT statistician will use to generate a randomisation list. The randomisation list will be given to Sealed Envelope to implement. When a cluster is recruited, Sealed Envelope will use the randomisation list to inform the Programme Manager which arm the cluster should be allocated to. Only the Programme Manager will have access to the allocation. Allocation will be concealed from the research team involved in recruitment.

Sampling and sample sizes:

We aim to recruit 100 participants.

#### Procedures:

Clusters are randomised to receive the EMBED-Care Framework or standard care for nine months. As with the feasibility study, the EMBED-Care framework is implemented at an organisational level for nine months. Recruited PWD and/or family carers participate for 16 weeks.

#### Data collection:

All data collection is informed by the findings of the feasibility trial.

## FEASIBILITY AND PILOT TRIALS: data journey

Activities will be conducted by the EMBED-Care research team or by the sites participating in the study. Paper data sources, including, for example, CRFs, non-participant observation notes, email /telephone helpline notes and diary, will be stored in a designated locked cabinet at KCL. A member of the research team will transfer the data from the sites to KCL. When transferring data, research team members will keep data on them at all times until locked in the designated cabinet at KCL at the earliest opportunity. Electronic data including, for example, non-participant observation notes, encrypted audio recordings of interviews and focus groups, screening and recruitment log, utility questionnaire and anonymised routine intervention data will be stored on KCL SharePoint. Electronic CRFs will be entered on researcher laptop and entered and stored on Red Cap. Anonymised routine intervention data will be sent via secure email to the research team where it will stored on KCL secure folder and deleted from the emails.

Only the research team will have access to data. The exception may be the transcription of interviews, which will be carried out by Clear Voice. A framework agreement is in place between Clear Voice and King's College London.

Aetonix will develop the digital protocol for EMBED-Care as outlined in question A66 (contract in place). The health economics will be provided by the London School of Economics (contract under review, July 2022).

## Role of organisations:

- UCL/UCLH will be the study sponsor. No study activity will take place at UCLH
- UCL and KCL will be joint data controllers
- Study stuff are from UCL, KCL with health economics from LSE

## Intervention Type

Other

#### **Phase**

**Not Specified** 

## Primary outcome measure

Candidate outcome measures for people with dementia:

- 1. Quality of life will be measured using the EQ-5D-5L and proxy reported EQ-5D-5L at baseline, week 4, week 8 and week 12
- 2. Symptoms will be measured using the Edmonton Symptom Assessment Scale and the proxyreported Edmonton Symptom Assessment Scale at baseline, week 4, week 8 and week 12
- 3. Agitation will be measured using the proxy-reported Neuropsychiatric Inventory agitation subscale at baseline, week 4, week 8 and week 12

Candidate outcome measures for family carers:

- 1. Direct impact on caring will be measured using the Scales Measuring the Impact of Dementia on Carers Direct Impact on Caring at baseline, week 4, week 8 and week 12
- 2. Carer support and information needs will be measured using the Scales Measuring the Impact on Carers Support and Information at baseline, week 4, week 8 and week 12
- 3. Carer distress will be measured using the Kessler Psychological Distress Scale at baseline, week 4, week 8 and week 12
- 4. Carer decision making will be measured using the Decisional Conflict Scale at baseline, week 4, week 8 and week 12
- 5. Carer experience of care will be measured using HowRWe measured at baseline, week 4, week 8 and week 12

## Secondary outcome measures

There are no secondary outcome measures

## Overall study start date

01/01/2019

## Completion date

31/12/2024

# Eligibility

## Key inclusion criteria

Person with dementia:

- 1. 18 years and older
- 2. All genders
- 3. Diagnosis or symptoms suggestive of dementia/cognitive impairment as a result of dementia in medical or care home records (any type/any severity)
- 4. Permanently resident in participating care home OR
- 5. New referral to Primary Care Network (PCN) team

#### Carer of person with dementia:

- 1. 18 years and older
- 2. All genders
- 3. Capacity to consent
- 4. Able to read and write in English
- 5. Identifies as family/friend carer of PWD
- 6. Minimum of fortnightly contact with PWD (by phone, in person)

#### Health and social care professionals:

- 1. All permanent care home staff involved in providing direct resident care
- 2. Care home managers
- 3. Bank and temporary staff care home staff
- 1. Those health/social care professionals with participating people with dementia on their active caseloads, and involved in delivery or using the EMBED-Care Framework
- 2. Primary/community health/social care professionals working with participating care homes and involved in the delivery or using the EMBED-Care Framework in conjunction with the care home staff

## Participant type(s)

Patient, Health professional, Carer

## Age group

Adult

## Lower age limit

18 Years

#### Sex

Both

## Target number of participants

Planned Sample Size: 140; UK Sample Size: 140

## Key exclusion criteria

Person with dementia:

- 1. Under 18 years of age
- 2. No cognitive impairment that is likely related to dementia
- 3. Those in care homes who are not permanently resident e.g. in respite care

## Carer of person with dementia:

- 1. Under 18 years of age
- 2. Less than two-weekly phone or in-person contact with person with dementia
- 3. Lacks the capacity to consent
- 4. Unable to read/write in English

## Health and social care professionals:

- 1. Those care home staff not in a managerial position or not involved in direct resident care
- 2. Those with no active involvement in the care of participating people with dementia

#### Date of first enrolment

01/09/2023

#### Date of final enrolment

30/09/2024

## Locations

#### Countries of recruitment

England

**United Kingdom** 

## Study participating centre Sussex Community NHS Foundation Trust

Brighton General Hospital Elm Grove Brighton

# Study participating centre

Derbyshire Community Health Services NHS Foundation Trust

Trust Hq, Ash Green Disability Ctr Ashgate Road Ashgate Chesterfield United Kingdom S42 7JE

# Sponsor information

## Organisation

University College London

## Sponsor details

Gower Street London England United Kingdom WC1E 6BT +44 (0)20 3447 5557 uclh.randd@nhs.net

## Sponsor type

University/education

#### Website

http://www.ucl.ac.uk/

#### **ROR**

https://ror.org/02jx3x895

# Funder(s)

## Funder type

Research council

### **Funder Name**

Economic and Social Research Council; Grant Codes: ES/S010327/1

## Alternative Name(s)

**ESRC** 

## **Funding Body Type**

Government organisation

## Funding Body Subtype

National government

## Location

**United Kingdom** 

## **Results and Publications**

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal by December 2025

## Intention to publish date

31/12/2025

## Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No