ISRCTN16231169 https://doi.org/10.1186/ISRCTN16231169

Empowering better end of life dementia care

Submission date
22/01/2021

Recruitment status
No longer recruiting

Registration date
08/02/2021

Overall study status
Completed

Last Edited
20/09/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Dementia is the commonest cause of death in the UK. By 2040 it is estimated that annually 220,000 people will die with dementia, with many experiencing distressing symptoms like pain and agitation. Access to good care for people with dementia towards the end of life is highly unequal. In the UK, those who make decisions about care and develop policy do not have sufficient information to deliver solutions to improve care that focuses on the person and their needs or to plan future services, for which there will be increasing demand.
EMBED-Care brings together collaborators, clinicians, policymakers, patients and families to form a network, which will inform this work. Six interconnected projects will lead to the development and testing of an intervention, which people with dementia, informal carers and health and social care professionals will help design. The intervention will prioritise comfort and what is important to each person to ensure the right services are in the right place at the right time. People with young-onset and rapidly progressive prion dementia will benefit from a better understanding of their needs. EMBED-Care will provide evidence and generate a step-change in how care is provided for people of any age with any type of dementia to maximise their quality of life.
It will spark public conversations on dying with dementia, and engage the public by combining art and science through policy and public engagement work.
The aim is to deliver timely person-centred care, improving outcomes, including comfort and quality of life, towards the end of life. The researchers will develop new knowledge and pilot an innovative intervention to empower people with dementia of all ages, carers and staff, to identify and act upon changing physical, psychosocial and spiritual needs, addressing these across care settings and transitions. They will leverage sustained improvement in care by working with the public, commissioners and policymakers and by creating a network for care, engagement and research capacity.

Who can participate?
People living with dementia, their family carers and healthcare professionals

What does the study involve?
The study consists of six work streams. Work stream 1 will synthesise health and social care evidence on palliative care for people with dementia towards the end of life, and review policy on the priorities for palliative care to understand the context, processes and components of palliative care for people with dementia, evidence of benefit and levers for change. Work Stream

2 will add to knowledge about how people with dementia use health services towards the end of their lives. This workstream takes a societal approach, exploring health inequalities experienced by people with dementia at a population level. The researchers are using large datasets of routinely collected information about people's characteristics, the areas they live in, their health, the services they access and receive, and information about their death. Work Stream 3 will explore why the care needs of people living with dementia and their carers are not being met. The researchers will look at the physical, psychological, social and spiritual needs of people living with dementia and their carers. They will use this information to look at the links between needs and quality of life, transitions between care settings as they happen and carer experiences. In addition there are two smaller cohort studies looking as Young Onset Dementia and Prion Disease. Work Stream 4 brings together the findings from Work Streams 1-3 organising and combining the data to see the unmet dementia palliative care needs. In turn, this will help develop the new intervention. Work Stream 5 is the co-design of a new model of palliative dementia care. This means the researchers will work with people with dementia, carers and people who work in health and social care to develop an intervention that helps staff and carers to assess and monitor needs and concerns about a person with dementia and support decision making to manage distressing symptoms by providing the right care. Work Stream 6 aims to understand how the intervention may work, what is needed to support its use, and to test the methods for a future large-scale trial.

What are the possible benefits and risks of participating?
The benefit of taking part in the study is that the information participants provide will help to improve understanding and knowledge of the needs of people living with dementia and their carers. The information will inform new and better ways of providing care to people living with dementia and their carers at the end of life. The researchers do not anticipate any risks or harm to participants from taking part in this study, although it is possible that discussions may touch on some difficult subjects. Participants can request to have a break or stop participation. The study team can signpost participants to further advice or support from relevant organisations or resources.

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?
ESRC-NIHR Dementia Research Initiative (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
268797

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 44953, IRAS 268797

Study information

Scientific Title
Empowering Better End of Life Dementia Care (EMBED-Care Programme)

Acronym
EMBED-Care

Study objectives
The hypothesis is that unmet palliative care needs are associated with decreased comfort and QoL, and increased service utilization, care transitions and career adverse experiences.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/05/2020, London - Queen Square REC (Friends Meeting House, Euston, NW1 2BJ, UK; +44 (0)207 104 8061; queensquare.rec@hra.nhs.uk), REC ref: 20/LO/0295

Study design
Randomized; Both; Design type: Process of Care, Complex Intervention, Cohort study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Work stream 1 (systematic review) and work stream 2 (data set analysis) do not involve any research participants. Work stream 3 (cohort study) involves research participants and is outlined in detail below. Work streams 4, 5 and 6 will involve research participants. However, their final design will be influenced by the findings from workstreams 1, 2 and 3 of the programme grant and substantial amendments will be used in due course to provide detail about the final design and methodology of these work streams.

Design and methodology of work stream 3, cohort study.
Current analysis of existing data sets can be used to demonstrate factors that predict hospitalisation of people living with dementia. However, this data cannot indicate how unmet needs of PwD and their carers might result in avoidable burdensome transitions at the end of life and if and how a palliative care approach may address unmet needs and reduce unnecessary transitions in place of care.

This cohort study will explore unmet needs experienced by 294 people living with dementia (and their carers) at all stages and across all dementias and determine how these impact on comfort, quality of life, service utilization, care transitions, carer experiences and health and social costs. By doing this the researchers will produce new knowledge on unmet needs and this will be used to inform the latter work streams in the programme.

Participant pathway
Identification and screening:
Local clinical research staff identify PwD within 72 hours of unplanned admission to acute setting and screen using eligibility criteria of ≥1 unplanned admissions and have a diagnosis of dementia.

The local clinical team approach the PwD or carer if they lack the capacity to establish interest in research and provide information on the study. The participant will be given 24 hours to consider the information. After this point, a member of the local clinical staff or EMBED-Care team will re-contact the participants to see if they have any questions and if they would like to participate.

Consent
Whilst an inpatient, the local clinical research staff or EMBED-Care team assess capacity and consent for the person with dementia including advanced consent to study or obtain a declaration from personal or nominated consultee if PwD lacks capacity.
It is anticipated that informal carers will have the capacity to provide informed consent.
Month 0 – Baseline:
7-14 days Post-discharge. It is anticipated that where data collection is face to face for baseline and subsequent timepoints, this will occur in the place of residence of the participants. Alternatively, a room at University College London or King's College London could be arranged if this is preferred by the participant.
Assess capacity and obtain a declaration from personal/nominated consultee if PwD has lost capacity since first consent taken.

PwD and informal carer measures completed face-to-face 1 week after PwD returns to place of residence
Eligible PwD and carers invited to take part in a qualitative interview. Qualitative interview with a subsample of 15 dyads including PwD and carers
Month 2:
Basic quantitative assessments of PwD conducted over the telephone
Month 4:
Assess capacity and obtain a declaration from personal or nominated consultee if PwD has lost capacity since baseline assessment
PwD and informal carer measures completed face-to-face
Month 6:
Basic quantitative assessments of PwD conducted over the telephone
Repeat qualitative interview with sub-sample of 15 dyads
Month 8:
Assess capacity and obtain a declaration from personal or nominated consultee if PwD has lost capacity since month 4 assessment
PwD and informal carer measures completed face-to-face
Month 10:
Basic quantitative assessments of PwD conducted over the telephone
Month 12:
Assess capacity and obtain a declaration from personal or nominated consultee if PwD has lost capacity since month 8 assessment
Final face-to-face assessments with PwD and informal carers
Post-Death:
Retrospective assessment of PwD and carers using quantitative measures with carers
Qualitative interviews with bereaved carers
Timetable for work stream 3 [post REC/HRA approval and local site approval]
Month 1-6: Main recruitment at each site
Month 1-18: Data collection with each participant. Participants will be involved in the study for up to 12 months each.
During this time period there will be an interim analysis of data.
Month 12-36: Data analysis leading to informing work streams 4 ,5 and 6. Dissemination of the findings.

Location of data collection
Data collection will be face to face in the residence of the participant, which may be their home or a care home at baseline and months 4,8 and 12. Data will be collected over the telephone at months 2,6 and 10. All data collection will be arranged for a date/time to suit the participant.

Planned interim analyses
There will be an interim analysis of the data to inform further data collection and to begin to inform work stream 4.

Sampling and sample sizes
The researchers estimate that care transition occurs in 50% of people with dementia in the last year of life. Based on previous studies, they will screen 420 PwD to allow for 30% attrition and to ensure that the target of 294 PwD (and were possible their carers) will be assessed at baseline. Allowing for 25% attrition, they 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.

People with dementia will be identified during a hospital admission. Screening will be undertaken by a Research Nurse or equivalent role at each of the participating hospitals. Those who are eligible will be approached by a member of their clinical team and informed about the study. They will be provided with an information sheet and given at least 24 hours to consider their participation. For those who would like to participate they will be consented whilst they are an inpatient. Baseline data will be collected after discharge from the hospital.

Patient and public involvement (PPI)
The researchers 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 information sheets and consent forms to be used with people living with dementia and their family carers to ensure that the content and format is appropriate.

Intervention Type
Other

Primary outcome(s)
1. WS3: Care transitions are measured by recording any care transitions in the previous two months on a form devised by the study team at baseline, 2, 4, 6, 8,10,12 months and post-death (this information will be provided by the participant, either a person living with dementia with capacity or a family carer)
2. WS5: Symptoms are measured by the Integrated Palliative care Outcome Scale for Dementia (IPOS-Dem) at baseline, 2, 4, 6, 8, 10 and 12 months

Key secondary outcome(s))
Person with dementia:
1. Demographic information will be collected at baseline
2. Dementia Severity is measured using the Clinical Dementia Rating Scale (CDR) at baseline
3. Preferences for End of life and goals of care are measured using EOLC preferences at baseline
4. Co-morbidities are measured using Charlson co-morbidity Index (CCI) at baseline
5. Religious and spiritual needs are measured using the Duke University Religion Index (DUREL) at baseline
6. Experience of COVID-19 are measured using COVID-19 questions devised by the study team at baseline, 2, 4, 6, 8, 10 and 12 months
7. Medication is measured by medication use at baseline, 2, 4, 6, 8, 10, 12 months and post-death
8. Strategies used to address needs are measured using Addressing unmet needs at baseline, 2, 4, 6, 8, 10 and 12 months
9. Behavioural and Psychological Symptoms in Dementia (BPSD) are measured using The Neuropsychiatric Inventory Questionnaire (NPI-Q) at baseline, 2, 4, 6, 8, 10 and 12 months
10. Resource use and care transitions are measured using Client Services Receipt Inventory (CSRI) at baseline 4, 8 and 12 months
11. Quality of life is measured using Quality of Life for people with dementia (DEMQOL /DEMQOL-Proxy) at baseline, 2, 4, 6, 8, 10 and 12 months
12. Quality of life is measured using EQ-5D-5L at baseline, 2, 4, 6, 8, 10 and 12 months
13. Pain is measured using Pain Assessment in Advanced Dementia (PAINAD) at baseline 4, 8 and 12 months
14. Frailty is measured using FRAIL at baseline 4, 8 and 12 months
15. Symptom Management is measured using Symptom Management at the End of Life in Dementia Scale (SM-EOLD) at baseline, 2, 4, 6, 8, 10 and 12 months
16. Unmet needs are measured using Camberwell Assessment of Need for the Elderly (CANE) at

baseline 4,8 and 12 months
17. Integrated and continuity of care at measured by Walker's measure of integrated care at baseline and 12 months
18. Place of death, cause of death are measured by Information about death at post-death
19. Quality of dying and death is measured by Comfort Assessment in Dying with Dementia Scale (CAD-EOLD) at post-death
20. Severity of dementia is measured by Bedford Alzheimer Nursing-Severity Scale (BANS-S) at post-death

Family carer:
1. Demographic information will be collected at baseline
2. Experience of COVID-19 are measured using COVID-19 questions devised by the study team at baseline, 2, 4, 6, 8, 10, 12 months and post-death
3. Religious and spiritual needs are measured using Duke University Religion Index (DUREL) at baseline
4. Knowledge and use of healthcare information are measured using the Health Literacy Questionnaire (HLQ) at baseline
5. Quality of life is measured using EQ-5D-5L at baseline, 2, 4, 6, 8, 10 and 12 months
6. Carer burden is measured using Zarit Burden Interview (ZBI) at baseline, 2, 4, 6, 8, 10 and 12 months
7. Distress is measured using the Kessler Psychological Distress Scale (K-10) at baseline, 2,4,6,8,10,12 months and post-death
8. Pre-death grief is measured using Caregiver Grief Questionnaire (CGQ) at baseline 4,8 and 12 months
9. Service use is measured by support for grief questions developed by the study team at baseline 4,8 and 12 months
10. Social support is measured by Social Support (SS) at baseline 4, 8, 12 months and post-death
11. Self-compassion is measured by Self-Compassion Scale Short Form (SCS-SF) at baseline 4, 8 and 12 months
12. Satisfaction with care is measured by Satisfaction with Care at the End of Life Scale in Dementia Scale (SWC-EOLD) at baseline 4,8, 12 months and post death
13. Complicated grief is measured by the Prolonged Grief disorder tool (PG-13) at post-death

Completion date
31/12/2024

Eligibility

Key inclusion criteria
Workstreams 1 and 2 do not include any research participants

Workstream 3: cohort study
People living with dementia must:
1. Be aged ≥65 years
2. Have a recorded diagnosis of dementia in their medical records
3. Have experienced at least one unplanned medical admission to hospital in the last 6 months at the point of identification by clinical staff
4. Be able to provide written informed consent or has a personal or nominated consultee who is able to provide a declaration for the person to be included in the study

Family carers:
1. Are able to provide informed written consent
2. Are providing (unpaid) care to a person living with dementia who is taking part in the study

The researchers will add a substantial amendment for the principal inclusion criteria for workstreams 4, 5 and 6 as these will be informed by workstreams 1, 2 and 3.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
65 years

Sex
All

Key exclusion criteria
Workstreams 1 and 2 do not include any research participants

Workstream 3: cohort study
People living with dementia who:
1. Do not have a diagnosis of dementia or are undergoing tests for cognitive impairment at the time of screening
2. Are unable to respond to study assessments and do not have a proxy respondent
3. Indicate either verbally or non-verbally that they do not wish to participate
4. Are unable to communicate in English (i.e., require an interpreter for medical appointments)
5. Are moribund, comatose or those with medical concerns that the clinical staff feel should preclude them being approached (including PwD who are in the last few days of life and are not likely to survive to discharge)

Family carers who:
1. Are aged ≤18 years
2. Are unable to communicate in English (i.e., require an interpreter for medical appointments)
3. Do not have the capacity to provide informed written consent

The researchers will add a substantial amendment for the principal exclusion criteria for workstreams 4, 5 and 6 as these will be informed by workstreams 1, 2 and 3

Date of first enrolment
15/01/2021

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North Middlesex University Hospital NHS Trust
Sterling Way
London
United Kingdom
N18 1QX

Study participating centre
King's College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
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Study participating centre
Western Sussex Hospitals NHS Foundation Trust
Worthing Hospital
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Worthing
United Kingdom
BN11 2DH

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
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Sponsor information

Organisation
University College London

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)
Social Science Research Council, ESRC, SSRC, UKRI ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes