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A pilot study of a palliative care intervention for people with advanced dementia

Submission date	Recruitment status	[ ] Prospectively registered
30/01/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/03/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/03/2012	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
How can we best provide palliative care in advanced dementia? Phase II development of an intervention: phase IIa pilot study

Study objectives
Our aims are to assess and define the palliative care needs of patients with advanced dementia and their carers and to design and pilot an intervention to improve care.

Objectives:
Our objectives are to:
1. Assess the feasibility of implementing the palliative care needs assessment for patients and advanced care planning for their carers
2. Monitor the consistency of its functional implementation
3. Choose and measure outcomes
4. Examine recruitment rates
5. Assess the feasibility of randomisation
6. Demonstrate acceptable follow-up rates
7. Obtain further views from professionals and patients on the acceptability/practicality of delivering/receiving the intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Camden and Islington Local Research Ethics Committee on the 17th December 2007 (ref: 07/H0722/104).

Study design
A phase IIa pilot study: clustered design with 1 x intervention ward and 1 x control ward

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied

Advanced neurodegenerative dementia including Alzheimer's disease, Lewy body and vascular or mixed dementia

Interventions
Intervention group:
A structured nurse-led assessment of patients' physical and mental state with particular attention to pain and other features of advanced dementia such as swallowing and mobility. This is coupled with an educative structured discussion with the carer and, if the carer wishes, the construction of an advanced care plan for the patient.

Control group:
Usual hospital clinical care.

The duration of the intervention is a 1 x 1 hour patient assessment and a 2 x 1 hour care planning discussion with the patients main family carer. Follow up for both arms is six months. Assessment of outcomes will occur at six weeks, then six months. If the subject dies during the study period, their final hospital admission will be audited and their carer interviewed at three months post-bereavement.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
This is a pilot study and a number of potential outcomes will be explored:

Carer related outcomes:
1. Stress and wellbeing-Kessler Distress Scale (KD10)
2. Health status (EQ-5D)
3. Satisfaction with decision-making process:
3.1. Decision Satisfaction Inventory
3.2. Decision Conflicts Scale
4. Satisfaction with care: Satisfaction with End of Life Care in Advanced Dementia Scale
5. Visual Analogue Scale: a standard 10 cm Visual Analogue Scale to measure carer satisfaction with:
5.1. The process of the advanced care planning
5.2. The utility/usefulness of the advance care planning

Patient related outcomes:
1. Active interventions: Painful Interventions Scale
2. Other interventions:
2.1. Resuscitation status
2.2. Percutaneous endoscopic gastrostomy (PEG) feeding
2.3. Prescription of neuroleptics
3. Quality of end of life care:
3.1. Prescription of analgesia at time of death
3.2. Use of Liverpool Care Pathway
4. Survival times: time of intervention to time of death

System related outcomes:
1. Advanced care planning:
1.1. Numbers choosing to make advanced care plan
1.2. Adherence to advance care plan
2. Use of Gold Standards Framework (GSF): by GP (if practice participating in the GSF programme)
3. Referrals to and input from community palliative care
4. Number of contacts after the intervention, i.e., by telephone between carers and the research nurse
5. Readmission rates for emergency acute admissions
6. Place of death
7. Economic outcomes (Client Service Receipt Inventory [CSRI])

Secondary outcome measures
No secondary outcome measures as this is a pilot study, therefore only the establishment of which outcomes are of most utility is being explored.

Overall study start date
02/02/2008

Completion date
02/08/2008

Eligibility

Key inclusion criteria
We will recruit patients who have a high six-month mortality risk:
1. Unplanned emergency admission to general hospital ward with treatable acute medical illness
2. Over 70 years of age, either sex
3. Diagnosis of advanced primary degenerative dementia:
3.1. Functional assessment staging (FAST) stage 6e or worse
3.2. Doubly incontinent and needing assistance with all activities of daily living

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Imminently dying (prognosis less than 48 hours)
2. Patients without a clearly identified non-statutory carer

Date of first enrolment
02/02/2008

Date of final enrolment
02/08/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Mental Health Sciences
London
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Sponsor information

Organisation
University College London (UK)

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Sponsor type
University/education

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

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
BUPA Foundation (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/07/2008		Yes	No