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The impact of a structured education reminiscence-based programme for staff on the quality of life of people with memory problems living in long-stay units

Submission date 30/07/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/08/2010	**Overall study status** Completed	
Last Edited 12/09/2011	**Condition category** Mental and Behavioural Disorders	

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

Study information

Scientific Title
A cluster randomised trial on the effectiveness of a structured education reminiscence-based programme for staff on the quality of life of residents with dementia in long-stay units

Acronym
DARES (DementiA Education Programme Incorporating REminiscence Therapy for Staff)

Study objectives
Aims:
1. To develop a comprehensive structured education reminiscence-based programme for staff (SERPS) that is specifically orientated toward incorporating reminiscence in the care of residents with dementia
2. To evaluate the effectiveness of the SERPS within the context of a cluster randomised trial
3. To understand participants (staff and people with dementia) perceptions of the SERPS, its impact on their lives and experience of care

Please note that as of 19/10/10 the primary and secondary outcomes sections of this record have been updated. Please also note that these changes have been implemented prior to any post randomisation data collection. More information can be found in the relevant field with the above update date.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Research Ethics Committee of the National University of Ireland, Galway approved on the 20th of November 2008.
2. Ethics approval was also obtained from the appropriate ethics committees responsible for trials within the selected public clinical sites

Study design
Two arm single blind cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

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

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

Interventions
Staff participants in long-stay units randomised to the experimental arm will attend the DARES structured education reminiscence-based programme for staff (SERPS), which will be delivered over three days; starting with two consecutive days and a third day, 6 weeks later. The DARES research team will provide telephone support to staff participants during the study period (22-25 weeks post randomisation) and will conduct one support visit to each unit within this period. The SERPS is founded on the DARES programme philosophy of empowerment of staff participants, including identifying what participants perceive to be important and what they feel they need to know. The concepts of learner-centeredness and adult learning are at the core of the programme, and those teaching the programme will adopt a facilitator-participant role, as this is considered central to modelling an empowerment philosophy. Staff participants will be trained to enable them to incorporate reminiscence in the care of residents with dementia.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Quality of Life of residents as measured by the Quality of Life-AD (QOL-AD) instrument (Logsdon et al 1999).
Current information as of 19/10/10:
All outcomes will be assessed at baseline and at 18 to 22 weeks post randomisation.

Initial information at time of registration:
All outcomes will be measured at baseline and at 22 to 25 weeks post randomisation.

Secondary outcome measures
1. Agitation, measured using the Cohen-Mansfield Agitation Inventory (CMAI)
2. Depression, measured using the Cornell Scale for Depression in Dementia
3. Staff attitudes to residents with dementia and perceived care burden will be assessed using a modified version of the Zarit Burden Interview
Current information as of 19/10/10:
All outcomes will be assessed at baseline and at 18 to 22 weeks post randomisation.

Initial information at time of registration:
All outcomes will be measured at baseline and at 22 to 25 weeks post randomisation.

Overall study start date
01/12/2008

Completion date
30/11/2011

Eligibility

Key inclusion criteria
Patients:
1. Residents who have lived in the residential unit for at least one month and are likely to be there for the duration of the study
2. Residents with dementia. Diagnosis may be determined in any of the following ways:
2.1. A formal diagnosis of dementia determined by the DSM-1V criteria for dementia (American Psychiatric Association 1995)
2.2. Any other diagnosis of dementia by a medical clinician
2.3. Resident is on anti-Alzheimers medications, including Aricept (donepezil), Ebixa (memantine) and Exelon (rivastigmine)
2.4. Nurses judgement and/or nursing records advise that the person has dementia

Study sites:
Public and private long-stay units across the Western seaboard of the Republic of Ireland who meet the eligibility criteria will be invited to participate.
1. Have 17 residents with dementia who agree to take part
2. A commitment from management of the long-stay unit and the clinical staff to participate in the study

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
18 residential units (clusters) each containing 17 people with dementia

Key exclusion criteria
Patients:
1. Has a sensory impairment that, in the judgment of the nursing staff, impairs their ability to participate
2. Has an acute physical illness that, in the judgment of the nursing staff, impairs their ability to participate

Date of first enrolment
01/12/2008

Date of final enrolment
30/11/2011

Locations

Countries of recruitment
Ireland

Study participating centre
School of Business and Public Policy
Galway
Ireland
-

Sponsor information

Organisation
Health Research Board (Ireland)

Sponsor details
73 Baggot Street
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Sponsor type
Research council

ROR
https://ror.org/003hb2249

Funder(s)

Funder type
Research council

Funder Name
Health Research Board (Ireland) (RP/2008/64)

Alternative Name(s)
HRB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location

Ireland

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?
Protocol article	protocol	14/02/2011		Yes	No