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An awareness-based intervention to enhance quality of life in severe dementia

Submission date	Recruitment status	[X] Prospectively registered
17/03/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/03/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/08/2018	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
85327

Study information

Scientific Title
Development of an awareness-based intervention to enhance quality of life in severe dementia: a cluster randomised trial across 8 care homes

Study objectives
Providing care staff with an observational tool that can help to identify evidence of awareness in residents with severe dementia, supported by appropriate training and supervision, will lead to improvements.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West Wales Research Ethics Committee approved on the 17th October 2008 (ref: 08 /WNo01/60)

Study design
Cluster randomised trial of an observational measure of awareness

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please contact catherine.quinn@bangor.ac.uk to request a patient information sheet

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

Interventions
Care staff in homes allocated to the intervention condition will be trained and mentored in using an observational measure of awareness with selected residents over an 8-week period.

The control group will consist of 4 care homes, which will be paired with 4 care homes receiving the intervention. Baseline assessments will be conducted at the control homes after which they will receive no additional input for the 8 week period in which other homes will be receiving the intervention.

Follow-up assessments will be conducted at both homes after the end of the intervention period.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Care staff:
1.1. Staff attitudes: Approaches to Dementia Questionnaire (ADQ)
1.2. Care practice: The Dementia Care Practitioner's Assessment (DCPA)
1.3. Well-being: Maslach Burnout Inventory (MBI); General Health Questionnaire (GHQ-12)

2. Assessment of the person with dementia:
2.1. Behaviour: Behavioural Assessment Scale Of Later Life (BASOLL)
2.2. Well-being: Positive Response Scale (PRS)
2.3. Quality of life: Quality of Life in Late-stage Dementia (QUAL-ID)

All measured at baseline and at the end of the 8 week intervention period.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/06/2010

Completion date
28/02/2012

Eligibility

Key inclusion criteria
1. Care staff:
1.1. Working in the identified homes
1.2. All ages, either sex
1.3. Permanent employees
1.4. Have been in post for at least six months
1.5. Work at least 15 hours per week

2. Individuals:
2.1. All ages, either sex
2.2. Severe dementia
2.3. Have no, or only very limited, verbal communication

Participant type(s)
Patient

Age group
Other

Sex
Not Specified

Target number of participants

Up to 80 care staff, observing in total 80 residents with severe dementia

Key exclusion criteria
1. Agency staff
2. Staff who are unable to communicate effectively in English
3. Individuals with dementia who are wholly or largely confined to bed

Date of first enrolment
01/06/2010

Date of final enrolment
28/02/2012

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
School of Psychology
Bangor
United Kingdom
LL57 2AS

Sponsor information

Organisation
Bangor University (UK)

Sponsor details
School of Psychology
Brigantia Building
Bangor University
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Wales
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Sponsor type
University/education

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

ROR
https://ror.org/006jb1a24

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK) (ref: 85327)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

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?
Protocol article	protocol	25/06/2010		Yes	No
Results article	results of tool development	01/06/2012		Yes	No
Results article	results of RCT	01/01/2013		Yes	No