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Improving Well-being and HEaLth for people with Dementia

Submission date
04/10/2013

Recruitment status
No longer recruiting

Registration date
04/10/2013

Overall study status
Completed

Last Edited
14/08/2019

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
800,000 people in the UK have dementia, of which 250,000 are living in care homes. These people have complex mental health problems, disabilities and social needs, which needs to be met by qualified care staff to improve their quality of life. The government wants to try and improve training of staff working in care homes and reduce the unnecessary use of sedative drugs. We are trying to find out whether a new training programme that we have developed to help staff in care homes benefit the residents within the care homes receiving the training, by improving quality of life and mental health. This training will combine person-centred care, promoting person-centred activities and interactions and provide care home staff and general practitioners with updated knowledge regarding correct use of medications for persons with dementia in care homes. If this training successfully improves life of people with dementia in care homes, it can be rolled out nationally to all UK care homes.

Who can participate?
Nursing home resident with dementia in participating nursing homes will be invited to participate in the study.

What does the study involve?
The participating care homes will be randomly allocated to two groups where one group of care homes taking part will receive the training and the other group will continue to provide their usual care for 9 months. The homes that receive the training will have an additional part-time specialist nurse or similar health professional to look at ways of developing specific aspects of care. This will include training for care staff to improve the understanding of dementia, person-centred activities and interactions. This will also include education for care home staff and general practitioners to enable the best review and best use of medication to treat any behavioural or psychiatric symptoms.

What are the possible benefits and risks of participating?
The research will be very valuable in helping us to improve training of care staff and care for people with dementia in the future. There may be benefits for residents in the care homes who receive the extra training. Also sometimes people with dementia may benefit from interactions with researchers. There are limited disadvantages to taking part and no risks. There will be a

short assessment for the participant which will include some questions about how they are feeling, their needs and their quality of life. This would be undertaken sensitively and with breaks as appropriate, but can sometimes be tiring or occasionally cause mild distress. No residents will receive any less care than they currently receive.

Where is the study run from?
The study will be run from 80 care homes across the UK.

When is study starting and how long is it expected to run for?
The study started in September 2013 and is expected to run until February 2015.

Who is funding the study?
National Institute for Health Research (NIHR), UK.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01855152

Secondary identifying numbers
15116; RP-PG-0608-10133

Study information

Scientific Title
An optimized person-centred intervention to improve quality of life for people with dementia living in care homes: a cluster randomized controlled trial

Acronym
WHELD

Study objectives
The principal research question is to determine whether the optimised intervention, combining training on person centred care, promoting person centred activities and interactions and provide care staff and general practitioners with updated knowledge regarding the optimal use of psychotropic medication for people with dementia in care homes would significantly improve quality of life of people with dementia in comparison to the usual care provided in care homes.

Key secondary objectives will be to determine the specific impact of the WHELD programme on a range of outcomes including mental health and unmet needs, physical health and use of psychotropic drugs; staff attitudes and the quality of the interaction of care staff with people with dementia, person centred environment in care home settings and overall provide a cost effective, simple and practical intervention.

The secondary hypotheses are that the optimized WHELD intervention will:
1. Reduce agitation, other behavioural and neuropsychiatric symptoms
2. Reduce the use of antipsychotic and other psychotropic drugs use
3. Reduce unmet needs
4. Reduce mortality
5. Improve mood and depression
6. Improve the quality of interactions between staff and residents
7. Provide person centred environment in care home settings
8. Provide a cost-effective intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Application will be submitted to the NRES Committee - South Central - Oxford A; favourable ethical opinion was granted on 11/07/2013 and ethical approval for amendment to study protocol was approved 19/12/2013; ref:13/SC/0281

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Quality of life

Participant information sheet
Patient information not available in web format, please use contact info to request a patient information sheet

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

Interventions
Care homes are randomised to two arms: Intervention and control arms
Homes in the intervention arm will receive the WHELD intervention training for 9 months. The homes within the control arm will continue to provide their usual care.
The intervention consists of a combination of elements taken from the interventions trialled in the factorial study. The WHELD intervention training will focus on person centred care, promoting person centred activities and interactions and provide care home staff and general practitioners with updated knowledge regarding the optimal use of psychotropic medications for persons with dementia in care homes.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Quality of Life as measured by DEMQOL proxy. DEMQOL-Proxy is a 31 item interviewer-administered questionnaire answered by a caregiver with the score range of 31 to 124.

Secondary outcome measures
1. Quality of Life measured by DEMQOL rated with person with dementia, which is a 28 item interviewer-administered questionnaire with the score range of 28 to 112 and Quality of life in late stage dementia (QUALID), which measures 11 observable behaviours indicating activity and emotional states. Ratings are made for observations made over the preceding 7 days
2. Agitation and other behavioural and neuropsychiatric symptoms are measured by Cohen-Mansfield Agitation Inventory (CMAI) and Neuropsychiatric Inventory nursing home version, NPI-NH). The CMAI consists of 29 items related to agitated behaviour, each of which is rated on a 7-point scale of frequency, from 1 = never to 7 = several times an hour. NPI-NH is a 12-item version consisting of 10 behavioural and two neurovegetative areas. It provides both a total score as well as scores for a number of sub-scales.
3. Antipsychotic use and other psychotropic (sedative) drugs (number of people taking antipsychotics and dose, rated from drug charts)
4. Unmet needs are assessed by Camberwell Assessment of Need for the Elderly (CANE Version IV). CANE is a comprehensive assessment assessing 24 areas of social, medical, psychological, and environmental needs
5. Symptoms of mood and depression are measured by (Cornell Scale for Depression in Dementia - CSDD). Each item in CSDD is rated for severity on a scale of 0-2 (0=absent, 1=mild or intermittent, 2=severe)
6. Pain is rated using the Abbey Pain Scale, which is an observational brief indicator of pain for people with end-stage dementia. The scale is rated on six non verbal indicators of pain where 0 is none and 3 is severe.

7. The quality of interactions between staff and residents and person centred environment in care home settings are rated using the observational tool Quality of Interaction Scale (QUIS)
8. Economic health evaluation will be performed by using Client Service Receipt Inventory (CSRI). The data collected through the CSRI can be used to calculate service costs and total costs of care.

Overall study start date
01/09/2013

Completion date
28/02/2015

Eligibility

Key inclusion criteria
1. Care homes who identify themselves as catering for people with dementia within its literature
2. Care homes should be able to demonstrate a minimum acceptable standard of care according to Care Quality Commision (CQC)
3. All individuals residing in participating care homes who meet diagnostic criteria and/or scores 1 or greater, on the Clinical Dementia Rating Scale (CDR)
Target Gender: Male & Female; Upper Age Limit 110 years ; Lower Age Limit 35 years

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
960-1280

Key exclusion criteria
1. Less than 60% of the residents have dementia
2. Care home is receiving special support from their local authority
3. Care home has failed to meet the 5 CQC care home quality standards checks with no more than one black mark (at least one standard in this area was not being met and required improvements are required) and no red marks (at least one standard in this area was not being met and enforcement have been taken):
3.1. Standards of treating people with respect and involving them in their care
3.2. Standards of providing care, treatment & support which meets people's needs
3.3. Standards of caring for people safely & protecting them from harm
3.4. Standards of staffing
3.5. Standards of management
4. Care home unable to provide care staff champions or staff able to act as informants for participant assessments
5. Events or major changes anticipated to take place in the next 12 months, which might impact on involvement in the research
6. Care home involved in other research projects, which might affect their suitability to take part

in this study or place too much burden on staff and residents
7. Undergoing systematic programme of service improvement: Involved in a systematic programme of service improvement (e.g. intensive Dementia Care Mapping)
8. Any resident for whom consent is not obtained

Date of first enrolment
15/09/2013

Date of final enrolment
27/03/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

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

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	12/07/2014		Yes	No
Results article	results	06/02/2018		Yes	No
HRA research summary			28/06/2023	No	No