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Improving person-centred care for people with dementia in care homes

Submission date
07/02/2011

Recruitment status
No longer recruiting

Registration date
10/05/2011

Overall study status
Completed

Last Edited
06/09/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
250,000 people with dementia in the UK live in care homes. These individuals have complex mental health problems, disabilities and social needs, which are made worse by widespread prescription of sedative drugs. The inconsistent quality of care, the poor management of mental health problems and the widespread overuse of sedative drugs are matters for serious concern. The launch of the National Dementia Strategy (2009) and a parallel Department of Health report (2009) regarding the use of sedative drugs provides an opportunity to move forward on a national basis to provide a better trained workforce that can improve the mental health of people with dementia living in care homes and reduce the use of sedative drugs.
The main goal of the WHELD programme is to develop an effective, simple and practical programme (intervention), which improves the mental health of, and reduces sedative drug use in, people with dementia in care homes; which can be rolled out nationally. This study will determine the most effective elements of existing approaches. This will be achieved by training care staff to provide care that is focused on an understanding of the individual and their needs; and by using additional elements such as exercise, activities and social interaction to improve mental health, reduce the use of sedative drugs and improve quality of life. The interventions studied will be Person Centred Care training either alone or in combination with Antipsychotic Review, Exercise and Social Interaction.
The main aim of the study is to determine whether the combination of Person Centred Care and Antipsychotic Review results in the reduction of antipsychotic prescribing and improvement of participant outcomes compared to Person Centred Care training alone.
The secondary objective is to establish the specific impact of each therapy (Antipsychotic Review, Social Intervention and Pleasant Activities, Exercise) in addition to Person Centred Care training on a range of outcomes including: mental health; psychotropic drug use; physical health; and quality of life. We also aim to determine the impact on potentially important mediating factors such as: activities; social interactions; staff attitudes; and the quality of the interaction between care staff and people with dementia.
The findings from this study will be used to develop the programme further for a larger study.

Who can participate?
All individuals with dementia living in the care homes participating in the study, aged between 40 and 120 years, will be invited to participate. Individuals for whom consent has not been obtained will not be included in the study.

What does the study involve?
This study will be conducted in 16 care homes recruited into the study across Oxfordshire, Buckinghamshire, North & South London. A minimum of 12 participants from each care home will be recruited into the study. Data will be collected on all consenting residents who meet the inclusion criteria at each participating care home. Each care home will receive a randomly allocated intervention for 9 months. Evaluations will be undertaken to understand the breadth of benefits conferred by the 3 key interventions to be assessed when used in addition to the Person Centred Care training package, which has already been shown to work. The interventions involve the following:
Person Centred Care: This intervention uses best practice guidelines to improve care. It provides ways of reviewing and adapting individual residents care to ensure that it reflects their needs and choices and includes elements of leadership training and approaches that address common team concerns about change.
Antipsychotic Review: This involves a specific review of antipsychotic drugs based on expert opinion and guidelines. Ideas for assessment and alternative approaches are also included.
Social Interaction: This intervention aims to develop skills and techniques amongst the care team for delivering individual and group activities to enhance interactions between staff and residents.
Exercise: This intervention aims to promote exercise through encouraging enjoyable positive activities that involve exercise, through implementing exercise plans, which are realistic and appropriate to residents level of dementia, and designed to increase balance, strength, endurance and flexibility.

What are the possible benefits and risks of participating?
Participants will receive benefits as a result of training of care staff. There are minimal risks or burdens for participants.

Where is the study run from?
Oxford Health NHS Foundation Trust and Kings College London.

When is the study starting and how long is it expected to run for?
The study started in August 2011 and ended in November 2012, running for 16 months

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

Who is the main contact?
Professor Clive Ballard, Wolfson Centre for Age Related Diseases, Kings College London

Contact information

Type(s)
Scientific

Contact name
Prof Clive Ballard

Contact details
Kings College London
Guy's Campus
London
United Kingdom
SE1 1UL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01855152

Secondary identifying numbers
RP-PG-0608-10133

Study information

Scientific Title
An optimised person-centred intervention to improve mental health and reduce anti-psychotics amongst people with dementia in care homes

Acronym
WHELD

Study objectives
The overarching goal of the programme is to provide an effective, simple and practical intervention, which improves the mental health and reduces sedative drugs in people with dementia in care homes, and which can be rolled out nationally to all UK care homes as an National Health Service (NHS) intervention. The current study is the pilot study and qualitative evaluation to help to develop a larger randomised controlled clinical trial, which will establish the value of (Well-being and health for people with dementia) WHELD.

We hypothesise that each intervention will significantly improve several key outcomes, but none of the interventions will improve all outcomes on their own. This pilot study is not powered to answer these questions definitively. The role of these hypotheses are to guide the analysis and to generate firm hypotheses for testing in the main trial.

Specifically we hypothesise that, compared to person-centred care alone:
1. The combination of person-centred care and antipsychotic review will result in the reduction of antipsychotic prescribing
2. The combination of person-centred care and social interaction will result in additional improvements in agitation/aggression, especially in individuals already experiencing these symptoms at the baseline evaluation
3. The combination of person-centred care and exercise will improve the overall mood and will reduce the number of falls

Please note that as of 21/01/2013, the following changes were made to the record:
1. The anticipated start date for this trial was updated from 03/05/2011 to 03/08/2011
2. The anticipated end date for this trial was updated from 03/02/2012 to 09/11/2012

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending as of 10/05/2011

Study design
Cluster randomised 2 x 2 x 2 factorial pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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
Dementia

Interventions
Evaluations will be undertaken to understand the breadth of benefits conferred by three key interventions to be assessed when used in addition to the person-centred care (PCC) training package, whose efficacy has already been established:
1. Person-centred care (PCC): PCC training will be delivered using the operationalised FITS manual. This will be further augmented by additional elements of leadership training on the basis of input from an expert therapy development group.
2. Antipsychotic review: This will involve specific review of antipsychotic drugs by an expert clinician, based upon the principles outlined in the National Institute for Health and Clinical Excellence (NICE) dementia guidelines. In addition, for all participants continuing to receive antipsychotics after the initial review or where antipsychotics are started or re-started, a detailed medical antipsychotic care plan will be developed. This will include planned dates for further antipsychotic review.
3. Social Intervention and Pleasant Activities: An intervention manual will be developed based upon three evidence based approaches and specific communication skills training to enhance staff resident interactions. The approaches will include:
3.1. The Positive Events Schedule, developed and demonstrated to be effective in the treatment of agitation and depression in people with dementia in non-care home settings
3.2. The Social Interaction intervention demonstrated to be effective for the treatment of

agitation in people with dementia in care homes
3.3. The NEST programme
Minor adaptations will be undertaken, in collaboration with the authors who developed the manuals, to ensure that they are suitable and practical for administration in a UK care home setting.
4. Exercise: The main focus will be to promote exercise through encouraging enjoyable positive activities that involve exercise. People will be offered enjoyable individual and group exercise activities to augment activities identified specifically as hobbies or enjoyable activities by individual participants.

Please note that this trial is co-sponsored; the contact details for the co-sponsor are as follows:
Oxford Health NHS Foundation Trust
c/o Jane Fossey
Clinical Head of Psychological Services
Chancellor Court
4000 John Smith Drive
Oxford Business Park South
Oxford OX4 2GX
T: +44 (0)18 6573 8445
E: jane.fossey@obmh.nhs.uk
Website: http://www.obmh.nhs.uk

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Antipsychotic use (number and proportion of people and dose) - measured at baseline and post intervention using records search and drug chart
2. Agitation - measured at baseline and post intervention using the Cohen-Mansfield Agitation Inventory

Secondary outcome measures
1. Use of psychotropic drugs (number and proportion of people and dose) - measured at baseline and post intervention using records search and drug chart
2. Other (not including agitation) behavioural and neuropsychiatric symptoms including apathy and psychosis - measured at baseline and post intervention using the NeuroPsychiatric Inventory - Nursing Home version (NPI NH)
3. Mood - measured at baseline and post intervention using the Cornell Depression Scale
4. Unmet Needs - measured at baseline and post intervention using theCamberwell Assessment of Need in the Elderly (CANE)
5. Quality of Life - measured at baseline and post intervention using a measure of health-related quality of life for people with dementia (DEMQOL) and Quality Of Life in Alzheimer's Disease (QoL AD)
6. Quality of interactions between staff and residents - measured at baseline and post intervention using the Quality of Interaction Scale (QUIS)
7. Falls - measured on an on-going basis using falls records

Overall study start date

03/08/2011

Completion date
09/11/2012

Eligibility

Key inclusion criteria
Current inclusion criteria as of 21/01/2013:
All individuals residing in participating care homes who score 1 or greater on the CDR and score 4 or greater on the FAST in the 16 participating care facilities will be eligible to participate.

Previous inclusion criteria until 21/01/2013:
All individuals (aged 40 - 120 years, either sex) with dementia residing [Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM IV) criteria, FAST staging] in the 16 participating care facilities will be eligible to participate

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
16 suitable homes will be identified, recruited, randomised and the intervention delivered to all residents.

Key exclusion criteria
Absence of dementia. Data will not be collected from individuals for whom consent has not been obtained.

Date of first enrolment
03/08/2011

Date of final enrolment
09/11/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Kings College London
London
United Kingdom
SE1 1UL

Sponsor information

Organisation
King's College London (KCL) (UK)

Sponsor details
c/o Professor Clive Ballard
Professor of Age Related Diseases
The Strand
London
England
United Kingdom
WC2 2LS

Sponsor type
University/education

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

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Programme Grant for Applied Research (PGfAR) (ref: RP-PG-0608-10133)

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	10/01/2013		Yes	No
Results article	results	06/02/2018	06/09/2019	Yes	No