ISRCTN02553381 https://doi.org/10.1186/ISRCTN02553381

Challenge ResCare: Behaviours that challenge in dementia care

Submission date	Recruitment status
15/02/2010	No longer recruiting
Registration date	**Overall study status**
06/04/2010	Completed
Last Edited	**Condition category**
07/06/2023	Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.challengedemcare.com

Contact information

Type(s)
Scientific

Contact name
Ms Cathryn Hart

Contact details
Humber NHS Foundation Trust
Trust HQ
Willerby Hill
Beverley Road
Willerby
United Kingdom
HU10 6ED

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
A cluster randomised trial of a dementia challenging behaviour web-based training and decision support system, for staff working in residential and nursing homes.

Acronym
Challenge ResCare

Study objectives
Principle research question:
Does the experimental intervention reduce the frequency and severity of 'behaviours that challenge' in care homes?

Secondary research questions:
Does the experimental intervention:
1. Reduce the emotional impact of 'behaviours that challenge' on care home staff?
2. Result in care home staff having a more positive and person-centred attitude to people with dementia?
3. Improve staff self-efficacy in caring for people with dementia?
4. Enhance quality of life in care home residents as a whole (including those without dementia)?
5. How cost-effective is the experimental intervention in terms of:
5.1 reducing 'behaviours that challenge';
5.2. its cost per Quality Adjusted Life Year (QALY) relative to usual care?

Ethics approval required
Old ethics approval format

Ethics approval(s)
The York NHS Research Ethics Committee, 12/05/2009, ref: 09/H1311/29

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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

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

Interventions
1. Intervention arm: participants in the experimental arm (i.e. all residents in homes randomised to receive the intervention) will be cared for under a regime in which care staff have:
1.1. Access to the web-based training and decision support system designed for the trial
1.2. Continued access to the web-based system to guide their care plans for residents with challenging behaviour during the trial
2. Control arm: participants living in homes allocated to the control arm will receive long term care from care staff 'as usual'. Staff working in these homes may have access to training materials, as they would do usually, available commercially and from organisations such as the Alzheimer's Society as well as training courses that are offered by a variety of providers. Information on such training will be recorded and collated.

Total duration of intervention and follow-up is 12 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Neuropsychiatric Inventory with Caregiver Distress Scale (NPI–D) This is a validated measure based on informant interview and designed to rate frequency, severity and caregiver distress for 12 Challenging Behaviour categories - delusions, hallucinations, agitation/aggression, depression /dysphoria, anxiety, elation/euphoria, apathy/indifference, disinhibition, irritability/lability, aberrant motor behaviour, sleep, appetite/eating disorders. The primary research question will be addressed by analysis of the frequency and severity scores.
Outcome will be measured at baseline, 4 months and 12 months

Secondary outcome measures
Secondary outcome measures as of 24/02/2016:
1. Staff and resident quality of life is measured using the Euroqol–5D (EQ–5D)
2. Resident quality of life is measured using the Quality of Life in Alzheimer's Disease (QOL–AD)
3. Diagnostic criteria for dementia is measured using the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM–IV)
4. Frequency and severity of challenging behaviour in residents is measured using the Challenging Behaviour Scale (CBS)
5. Attitudes of staff towards people with dementia is measured using the Attitudes to Dementia Questionnaire (ADQ)
6. Perceived effectiveness of staff in caring for people with dementia is measured using the Self–Efficacy Scale
7. Resident health and social care resource use is measured using the (Adapted) Client Service Receipt Inventory (CSRI)
8. Resident medication use is measured using the Structured Medication Inventory (SMI)
9. Clinical Dementia Rating (CDR) is used as a covariate for analysis

10. Emotional impact of, or reaction to, challenging behaviour is measured using the Maslach Burnout Inventory (MBI) and the NPI caregiver distress score
11. Frequency and severity of challenging behaviour in residents is measured using the Cohen-Mansfield Agitation Inventory (CMAI)
12. Staff learning style is measured using the Visual Auditory Kinesthetic (VAK) Learning Styles Self-Assessment Questionnaire

All outcomes will be measured at baseline, 4 months and 12 months

Original secondary outcome measures:
1. Euroqol–5D (EQ–5D)
2. Quality of Life in Alzheimer's Disease (QOL–AD)
3. Short Form 12 (SF–12)
4. Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM–IV)
5. Challenging Behaviour Scale (CBS)
6. Attitudes to Dementia Questionnaire (ADQ)
7. 12 Item General Health Questionnaire (GHQ–12)
8. Self–Efficacy Scale
9. (Adapted) Client Service Receipt Inventory (CSRI)
10. Structured Medication Inventory (SMI)
11. Clinical Dementia Rating (CDR)
All outcomes will be measured at baseline, 4 months and 12 months

Overall study start date
01/02/2010

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Identification of homes (clusters):
Within the trial area, an invitation to participate in the trial will be sent to all care homes with 25+ beds listed on the website of the Care Quality Commission (CQC) as old age care homes, with a rating of 'good' or 'excellent', (a) with nursing care and (b) without nursing care. Homes specialising in care of residents with dementia will not be excluded.
2. Consent of care home residents

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
1200 residents (624 with dementia and challenging behaviour)

Key exclusion criteria
1. Residents whose stay in the home is not, in the judgement of the home manager, likely to be for long term care - for example those receiving respite care
2. Residents who are in the palliative stages of a disease at the time of recruitment
3. Residents who are unable to speak/understand English
4. Residents who enter the home part way through the study or who are out of the home (for example in hospital) at the time of data collection

Date of first enrolment
01/03/2011

Date of final enrolment
23/03/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Humber NHS Foundation Trust
Willerby
United Kingdom
HU10 6ED

Sponsor information

Organisation
Humber Teaching NHS Foundation Trust

Sponsor details
Trust HQ
Willerby Hill
Beverley Road
Willerby
England
United Kingdom
HU10 6ED

Sponsor type
Hospital/treatment centre

Website

http://www.humber.nhs.uk/templates/Homepage.aspx?id=1783

ROR
https://ror.org/016bnqk64

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) - programme grant (ref: NIHR RP–PG–1067)

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?
Results article	results	01/08/2017		Yes	No