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Challenge FamCare: Behaviours that challenge in dementia care

Submission date	Recruitment status	[ ] Prospectively registered
17/02/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/10/2017	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

Protocol serial number
N/A

Study information

Scientific Title
Challenge FamCare: An observational study of people with dementia and challenging behaviour living at home and their carers

Acronym
Challenge FamCare

Study objectives
As of 24/02/2016:
The main aims are to investigate the following questions in respect to people with dementia and challenging behaviour (CB) living at home, supported by a carer.
Research questions:
1. Do levels of reported CB, and carer reaction to this, change over time as measured by the frequency and reaction domains of the RMBPC?
2. What is the level of specialist support provided to families, measured by the number of specialist mental health care service contacts and time spent with the family?
3. What are the predictors of change in CB in family care settings?
4. What are the patterns of health and social care service use and associated costs?
5. What are the estimated extent and costs of family care?
6. What are the patterns of prescribing medications measured by change over time, for people living at home with dementia and CB and their carers, and the costs of these?

Original study hypotheses:
Using a web-based training and decision support system will:
1. Enhance the quality of life of people with dementia and their relationship with their family caregiver
2. Reduce the frequency and severity of challenging behaviours
3. Reduce the level of carer distress associated with challenging behaviours
4. Improve coping and effectiveness in the family carer
5. Be cost effective in terms of reducing challenging behaviour and its cost per Quality Adjusted Life Year (QALY) relative to usual care

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval for revised protocol:
National Research Ethics Service Committee Yorkshire & The Humber – Leeds West, 22/11/2013

Initial approval:
National Research Ethics Service, York Research Ethics Committee, Learning and Research Centre, York Hospital, 12/05/2009, ref: 09/H1311/28

Study design
Observational naturalistic cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Dementia with behaviours that challenge

Interventions
Interventions as of 24/02/2016:
A cohort of people with a dementia and challenging behaviour and their carers in six NHS organisations, was followed up over a six month period. The information collected focussed specifically on challenging behaviour in family care settings, the stress experienced by family carers, the quality of life of people with dementia and their carers and the range, frequency and cost of health and social care services (including prescribing) accessed by participants recruited to the study.

Original interventions:
Community Mental Health Nurses (CMHNs) whose team has been randomised will use a functional analysis-based intervention (i.e., web-based training and decision support system) to support carers of people with dementia who display behaviours that challenge. The randomised control group will have treatment as usual from the CMHN.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Primary outcome measure as of 24/02/2016:
Revised Memory and Behaviour Problem Checklist (RMBPC) frequency and RMBPC reaction.

Original primary outcome measures:
Incidence of behaviours that challenge, quality of life and stress and burden measured by:
1. Revised Memory and Behaviour Problem Checklist (RMBPC)
2. Euroqol-5D (EQ-5D)
3. Quality Of Life in Alzheimers Disease (QOL-AD)
4. Short Form-12 (SF-12,)
5. Quality of Relationships (QoR) Scale
6. Neuropsychiatric Inventory including Caregiver Distress Scale (NPI-D)
7. Clinical Dementia Rating (CDR)
8. (Adapted) General Health Questionnaire - 12
9. Hospital Anxiety and Depression scale (HADS)
10. The Short Sense of Competence Questionnaire (SSCQ)
11. Guilt Scale Relatives Stress Scale (RSS)

Key secondary outcome(s))
Secondary outcome measures as of 24/02/2016:
1. Frequency and severity of CB assessed using the NPI, with its caregiver distress domain
2. Emotional impact of CB on carers using: the NPI distress score where carers report how distressing they find a CB; the 17-item Guilt Scale; the Hospital Anxiety and Depression Scale and the 12-item General Health Questionnaire (GHQ-12)
3. Coping and effectiveness in caring for someone with CB using the Short Sense of Competence Questionnaire (SSCQ), and the Relative Stress Scale which measures stress specific to dementia caregiving
4. Quality of life of the person with dementia using the European Quality of Life-5 Dimensions (EQ-5D) with its Index and Visual Analogue Scale (VAS) scorings, in which participants are able to indicate their health; the Quality of Life in Alzheimer’s Disease (QOL-AD), and the ICEpop

CAPability measure for older people (ICECAP-O) where those people who are able to can report on their perceived quality of life (for EQ-5D and QOL-AD the carers also provide their perception of the person with dementia's quality of life - proxy report); and the quality of relationship, assessed by both the person with dementia and the carer using the Quality of Caregiver/Patient Relationship (QCPR) scale
5. Quality of life of the carer using: EQ-5D using the Index scoring, ICECAP-O and QCPR
6. Costs in relation to CB using: the adapted Client Service Receipt Inventory (CSRI) to establish the level of health and social care services and medication being accessed for the couple
7. Specialist mental health service contacts: data were collected retrospectively from patient administration systems about the number and duration of contacts with all mental health practitioners over the six month period in which participants were in the study

Original secondary outcome measures:
To examine cost effectiveness of intervention tool measured by:
1. Client Service Receipt Inventory (CSRI)
2. Structured Medication Inventory (SMI)

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. People fulfilling the DSM-IV diagnostic criteria for dementia that have a positive score of 5 or more on the Revised Memory and Behaviour Problem Checklist (RMPBC)
2. Community dwelling with a family or unpaid carer with whom they have regular contact who is a willing participant and informant
3. There are no age limits for participants

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Participants with dementia residing in a care home or in receipt of in-patient respite care at the time of recruitment
2. In receipt of palliative or end of life care
3. Non-English speaking

Date of first enrolment
01/02/2010

Date of final enrolment
31/01/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Institute of Rehabilitation
Kingston Upon Hull
United Kingdom
HU3 2PG

Sponsor information

Organisation
Humber NHS Foundation Trust (UK)

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK)

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes