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Improving the management of behaviour that challenges associated with dementia in care homes: testing the feasibility of a combined pharmacy-health psychology intervention

Submission date
30/12/2015

Recruitment status
No longer recruiting

Registration date
05/10/2017

Overall study status
Completed

Last Edited
08/11/2023

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
Older people take many different medicines. Anti-psychotics (powerful tranquilisers) can help to control behaviours – such as aggression – that occur in people with dementia and which may be difficult for carers to manage. However, because benefits are limited and anti-psychotics can cause significant harm, the Department of Health would like to reduce their levels of use by two-thirds. However, the sole focus on reducing anti-psychotics may simply shift prescribing to equally harmful, other mood-altering medicines (psychotropics), such as benzodiazepines (e.g. lorazepam). This study aims to assess the feasibility of a medication review combined with staff training in limiting the use of all psychotropics in care homes and consider if a larger study should be undertaken.

Who can participate?
Residents of a long-term care facility who have dementia and are receiving medication to treat behaviour that challenges

What does the study involve?
People with dementia undergo a medication review to support appropriate prescribing by an experienced specialist pharmacist. There is a follow-up at 6 months to assess the impact of the medication review. Care staff receive education and training to support them in managing challenging behaviour without medication.

What are the possible benefits and risks of participating?
People with dementia may benefit from by having unneeded medication stopped, reducing the risk of side effects. Care staff may benefit from training in the management of behavioural symptoms including using medication correctly. People with dementia may become distressed if medication is withdrawn and the other support mechanisms do not work. To reduce this risk, people with dementia with severe symptoms are excluded and the researchers work with the GP and care home staff.

Where is the study run from?
Aston University (UK)

When is the study starting and how long is it expected to run for?
January 2015 to June 2017

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

Who is the main contact?
Dr Ian Maidment
i.maidment@aston.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Ian Maidment

Contact details
Aston University
Birmingham
United Kingdom
B4 7ET
+44 (0)121 204 3002
i.maidment@aston.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
v8

Study information

Scientific Title
Improving the management of behaviour that challenges associated with dementia in care homes: a pharmacy-health psychology intervention feasibility study

Acronym
MEDREV

Study objectives
This study aims to determine whether it is feasible to implement and measure the effectiveness of a combined pharmacy-health psychology intervention incorporating a medication review and staff training package to limit the prescription of psychotropics to manage behaviour that challenges in residential and nursing home residents.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands (Nottingham 1) Research Ethics Committee, 15/09/2015, ref: 15/EM/3014

Study design
Mixed methods feasibility study with embedded qualitative arm

Primary study design
Observational

Study type(s)
Treatment

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

Interventions
The study involves:
For people with dementia - a medication review to support appropriate prescribing by an experienced specialist pharmacist. Follow-up to assess the impact of the medication review
For care staff - 3-hour training session for care staff to support them in managing challenging behaviour without medication

Total follow-up period: 6 months

Intervention Type
Mixed

Primary outcome(s)
Neuropsychiatric symptoms, assessed using the Neuropsychiatric Inventory (NPI). A specific nursing home version (NPI-MH) designed for interviewing professional care staff will be used. The decrease in the NPI-MH change score between baseline and 3 months will be the primary measure; it will also be collected at 6 weeks and 6 months. A decrease in 4 points, or more will be considered a clinically meaningful change in the NPI-NH.

Key secondary outcome(s))
Collected at baseline (before the medication review), 6 weeks and 3 and 6 months (unless stated):
1. Quality of life (QoL), measured using DEMQoL and EuroQoL EQ-5D (proxy versions). Participants may not be able to respond and to reduce any “proxy effect” caregivers will be requested to respond “as if” they were the person with dementia (EQ-5D only collected at baseline, 3 and 6 months; DEMQoL collected at all time points)
2. Cognitive test: standardised Mini-Mental State Examination (sMMSE) collected at baseline, 6

weeks and 3 months)
3. All prescribed medication
4. Costs: a modified version of the Client Services Receipt Inventory (CSRI) will be used to monitor levels of resource use associated with the medication review (including preparation and recommendations) and the use of other NHS and PSS (Personal Social Services) resource items e. g. medication utilisation, GP services and hospital visits/admissions. This will be completed by proxy. Only collected at baseline, 3 and 6 months

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Receiving medication (including but not limited to medicines in British National Formulary [BNF] sections 4.1/4.2/4.3/4.11) to treat behaviour that challenges
2. Resident within a long-term care facility
3. Registered with a West Midlands GP (who has also agreed to participate)
4. Dementia confirmed (dementia register, documentation of relevant read codes, confirmation of diagnosis via communication from old age psychiatry, memory clinic or clinical psychologist)
5. Patient or personal consultee willing to provide consent/assent
6. A proxy informant (key worker or staff member with close working relationship) who can clearly communicate in English available

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
34

Key exclusion criteria
1. Patient or personal consultee unable or unwilling to provide consent or lacks necessary English-language skills
2. On palliative care register, or has pathology requiring complex specialist medication
3. Risk of harm in line with Alzheimer Society guidance (guidelines published in 2011, currently being updated and therefore not available)
4. Severe mental illness (e.g. schizophrenia) where psychotropic treatment should be continued

Date of first enrolment
01/02/2016

Date of final enrolment
01/08/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Aston University
Aston Triangle
Birmingham
United Kingdom
B7 4ET

Sponsor information

Organisation
Aston University

ROR
https://ror.org/05j0ve876

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

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/10/2018	10/09/2019	Yes	No
Results article		02/03/2020	08/11/2023	Yes	No
Protocol article	protocol	23/03/2016		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