

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 05/10/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/11/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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 People with dementia may become distressed if medication is withdrawn and the other support mechanisms do not work.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
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Study website
<http://www.aston.ac.uk/medrev/>

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design**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

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/01/2015

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

Age group

Senior

Sex

Both

Target number of participants

45

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**

England

United Kingdom

Study participating centre

Aston University

Aston Triangle

Birmingham

United Kingdom

B7 4ET

Sponsor information**Organisation**

Aston University

Sponsor details

Aston Triangle

Birmingham

England
United Kingdom
B4 7ET

Sponsor type
University/education

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

Publication and dissemination plan
1. Protocol published in: <https://www.ncbi.nlm.nih.gov/pubmed/27009145>, full detailed protocol on: <https://www.aston.ac.uk/medrev>
2. Planned publication of the results in high-impact peer reviewed journals

Intention to publish date
31/12/2017

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?
Protocol article	protocol	23/03/2016		Yes	No
Results article	results	19/10/2018	10/09/2019	Yes	No
Results article		02/03/2020	08/11/2023	Yes	No