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The MARQUE project: Managing agitation and raising quality of life to improve agitation for people with dementia in care homes

Submission date
11/09/2014

Recruitment status
No longer recruiting

Registration date
11/09/2014

Overall study status
Completed

Last Edited
18/03/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Changes in the behaviour of people with dementia are very common, and usually get worse as the disease progresses. More than half of patients with dementia who are living in care homes regularly experience feelings of agitation. There is evidence to show that these feelings can be linked to a lower quality of life for the patient, as well as higher care costs compared to patients who are not agitated. Although agitation is common in dementia patients, many staff in care homes are not trained to deal with these behaviours. The aim of this study is to find out whether introducing new training practices in care homes to help deal with agitated patients can help to improve their quality of life and lower levels of agitation.

Who can participate?
1. Care homes with at least 17 patients with dementia who will allow training sessions for the study.
2. Paid carers who provide face-to-face care for people with dementia.
3. Patients with a diagnosis of dementia
4. Family members of patient with dementia involved in the study who see their relatives at least once a month.

What does the study involve?
Staff and managers in care homes are interviewed in order to find out the main things that help and hinder changes in policies. This information is then used in the development of a programme for the care homes. Paid carers are then trained, using the manual, to reduce agitation in patients with dementia, as well as prevent new cases of agitation from developing. After 8 months, a questionnaire (Cohen-Mansfield Agitation Inventory) is completed in order to assess the levels of agitation in the residents.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Charles Bell House, University College London (UK)

When is the study starting and how long is it expected to run for?
July 2014 to September 2018

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

Who is the main contact?
Ms Debbie Livingston
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Study website
https://www.ucl.ac.uk/psychiatry/marque

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17341

Study information

Scientific Title
The MARQUE project: Managing Agitation and Raising QUality of Life: Cluster RCT to improve agitation for people with dementia in care homes

Acronym
MARQUE

Study objectives
Our manual based intervention and strategy for changing care home culture decrease the mean level of agitation (measured by Cohen-Mansfield Agitation Inventory; CMAI) in residents with dementia eight months later, compared with usual practice?

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Queen Square Research Ethics Committee, 02/10/215, ref: 14/LO/0697

Study design
Multi-centre randomised controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Dementia

Interventions
Care homes are randomly allocated to one of two groups.

Intervention group: Staff take part in the manual based training package to teach staff in care home about managing agitation in dementia. This involves all day staff who are involved in personal care of residents from Managers down taking part in 6, 2 hours group sessions over 12 weeks. The intervention sessions will follow a manual with practical homework. Supervision sessions for care home staff will be available following training.

Control group: Staff will continue with their TAU training, we expect the TAU to be similar to good “TAU” throughout the UK

Eight months from baseline, follow up assessments will be carried out in both groups.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Cohen-Mansfield Agitation Inventory (CMAI) total is measured at 8 months.

Secondary outcome measures
1. Cost effectiveness in terms of agitation (CMAI) is measured at 8 months
2. Cost effectiveness in terms of QALYS is measured at 8 months
3. Quality of life of residents in the intervention group compared to the control group is measured at 8 months
4. Reducation in clinically significant agitation(CMAI>45)in intervention group compared to control group is measured at 8 months
5. Reduction in neuropsychiatric symptoms overall in intervention group compared to control group is measured at 8 months

Overall study start date
17/07/2014

Completion date
01/09/2018

Eligibility

Key inclusion criteria
Care homes inclusion criteria:
1. The minimum number of residents required for a homes inclusion in the study have dementia (17)
2. Care home is willing to be randomised
3. Care home will commit to allow mandatory training sessions, training staff champions to continue implementation (two per home to take account of possible staff turnover) and changing management procedures, to integrate the new techniques into care

4. Care home will commit to approaching residents and relatives
5. No plans to close over the following year

Inclusion criteria for paid carers:
1. Paid carer who provides face to face care for residents, at least some of whom have dementia.
2. Carer willing to complete the questionnaires about residents with dementia whom they know well
3. Carer willing to answer questions about their own coping

Inclusion criteria for residents with dementia:
1. Dementia diagnosis according to Noticeable Problems Checklist or known dementia diagnosis

Inclusion criteria for family carer:
1. Identifies themselves as the primary family carer for a resident in the home who either consents to the study or if the resident does not have capacity to consent to the study then the family carer has agreed that they will be in the study
2. See their relative with dementia at least monthly

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 340; UK Sample Size: 340

Key exclusion criteria
Exclusion criteria for care homes:
Less than 70% of the staff consent to the study after the care home manager has agreed to the study but before randomisation.

Date of first enrolment
17/07/2014

Date of final enrolment
01/09/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Charles Bell House
67-73 Riding House Street
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Sponsor information

Organisation
University College London (UK)

Sponsor details
Gower Street
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Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (ESCR/NIHR) (UK); Grant Codes: ES/L001780/1

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	01/04/2019		Yes	No
HRA research summary			28/06/2023	No	No