Multi-professional clinical medication reviews in care homes for the elderly

Submission date Recruitment status [X] Prospectively registered 21/10/2010 No longer recruiting [X] Protocol [] Statistical analysis plan Registration date Overall study status 21/10/2010 Completed [X] Results Individual participant data **Last Edited** Condition category 01/10/2018 Other

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

8221

Study information

Scientific Title

Multi-professional clinical medication reviews in care homes for the elderly: a randomised controlled trial with cost effectiveness study

Acronym

CARE MED

Study objectives

To determine whether a multi-professional clinical medication review leads to a reduction in falls and potentially inappropriate prescribing in care homes for the elderly. Thirty care homes will be recruited and randomised into two groups: the control group will receive usual care and the intervention group will receive two multi-professional clinical medication reviews.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Norfolk Research Ethics Committee approved on the 22nd February 2010 (ref: 09/H0310/96). Approval of amendment #1 given on the 4th October 2010.

Study design

Single centre randomised interventional trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions

The intervention group will receive two multi-professional clinical medication reviews at baseline and 6 months, with follow-up for a further 6 months. Residents' medications will be reviewed by pharmacist, pharmacy technician, GP and care home staff. Agreed action plan will

be implemented by the medicines management team. The control group (15 care homes) will receive usual care (support they currently receive from the NHS), with data collection at baseline and 12 months. Both control and intervention homes are in the study for a total of 12 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Number of falls, measured at 6 months prior to baseline (T0), T0 to 6 months (T1) and T1 to 6 months (T2)

Secondary outcome measures

Potentially inappropriate prescribing, measured at baseline, 6 months and 12 months

Overall study start date

01/11/2010

Completion date

31/07/2011

Eligibility

Key inclusion criteria

- 1. Care homes for older people (average age greater than 65 years)
- 2. Care homes which have been registered for at least 6 months

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

Planned sample size: 824; UK sample size: 824

Key exclusion criteria

- 1. Care homes specifically for people with dementia
- 2. Care homes specifically for people with learning difficulties
- 3. Care homes specifically for people with sensory impairment
- 4. Care homes specifically for people with mental health problems
- 5. Care homes specifically for people with physical disabilities
- 6. Care homes specifically for people with alcohol dependence

- 7. Care homes which have received a medication review service from the PCT in the last six months
- 8. Residents who self-medicate

Date of first enrolment

01/11/2010

Date of final enrolment

31/07/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre University of East Anglia

Norwich United Kingdom NR4 7TJ

Sponsor information

Organisation

University of East Anglia (UK)

Sponsor details

School of Pharmacy Earlham Road Norwich England United Kingdom NR4 7TJ

Sponsor type

University/education

Website

http://www.uea.ac.uk/

ROR

https://ror.org/026k5mg93

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (ref: PB-PG-0808-16065)

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?
<u>Protocol</u> <u>article</u>	study protocol	05/10 /2011		Yes	No
Abstract results	results presented at British Geriatrics Society Spring Meeting	01/10 /2014		No	No