ISRCTN00695885 https://doi.org/10.1186/ISRCTN00695885

Prevention of falls in older people with cognitive impairment

Submission date
26/03/2013

Recruitment status
No longer recruiting

Registration date
26/03/2013

Overall study status
Completed

Last Edited
05/06/2017

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
Falls are a common and serious problem for older people living with dementia, particularly those who live in care homes. Not enough is known about the best ways to prevent falls in those living in care homes. The aim of this study is to investigate whether an assessment followed by an individualised plan of care and therapy is effective in reducing falls.

Who can participate?
The managers of care homes in South East London are invited to take part. All permanent residents of participating care homes are then asked if they wish to participate. If a resident has difficulty making the decision, relatives may be asked to help with this.

What does the study involve?
Walking, balance, memory and mood are assessed and a blood sample is taken at the start of the study and again 6 months later. The care homes are randomly allocated to either deliver the intervention or to continue to deliver care as normal. The intervention involves an assessment of factors which may increase the chance of falling and making recommendations for each person. These may include exercise, occupational therapy and review of medications.

What are the possible benefits and risks of participating?
Those who receive the intervention may find that their walking and balance improve, they feel better and have fewer falls. The risks are small: the blood test may be uncomfortable and it is possible to lose balance while doing the exercises. However, the physiotherapists providing exercise will supervise the exercise closely to minimise this risk.

Where is the study run from?
King's College Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2012 to April 2014

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

Who is the main contact?
Julie Whitney
julie.whitney@nhs.net

Contact information

Type(s)
Scientific

Contact name
Ms Julie Whitney

Contact details
Clinical Age Research Unit
Denmark Hill
London
United Kingdom
SE5 9RS
-
julie.whitney@nhs.net

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13484

Study information

Scientific Title
Prevention of falls in cognitively impaired older adults living in residential care (PROF-COG). A pilot multi-factorial intervention to prevent falls in older people living in care homes tailored towards risk factors related to cognitive impairment

Acronym
PROF-COG

Study objectives
Falls are a serious public health problem. The resultant injuries put immense strain on public resources and individuals who fall often go on to suffer difficulties with mobility, fear of further falls and loss of confidence and independence. Fall prevention trials on care home dwellers have been conflicting possibly because some have failed to adequately consider the effect of dementia in this physically frail population. Falls are twice as common in those with dementia and to date, despite a wealth of evidence to support preventative interventions in the

cognitively intact, there have been no effective interventions specifically for those with dementia.

A multi-factorial intervention has been designed to address falls risk factors specific to those with cognitive impairment living in care homes and will be tested in a pilot cluster randomised controlled trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Camberwell St Giles Research Ethics Committee, 13/08/2012, ref: 12/LO/1099

Study design
Randomised; Interventional; Design type: Process of Care

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Dementias and Neurodegenerative Diseases Research Network; Subtopic: Dementia; Disease: Dementia

Interventions
212 residents will be recruited from 6 care homes and randomised by care home into intervention and control groups. All participants will undergo screening to identify known risk factors for falls and appropriate referrals will be made for all participants in the intervention group. Interventions include review by a geriatrician, balance training exercise and management of dementia related behaviours. The control group will receive usual care.

Data will be collected on the clinical efficacy of the intervention in terms of its effect on falls risk factors including measures of balance, mobility, behaviour and quality of life. Information will also be collected to determine the safety, acceptability and feasibility of the intervention to ensure the development of a robust protocol for a future larger trial powered to detect differences in falls and fallers. While this intervention has been designed to address falls, it may have many other beneficial effects such as reduced hospital admissions, health and social care costs.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Standing balance; Timepoint(s): Baseline and at 6 months

Secondary outcome measures
1. Anxiety, assessed using the Goldberg Anxiety Scale at baseline and follow up
2. Cognition, assessed using the Addenbrooke's Cognitive Examination at baseline and follow up
3. Concern over falling, assessed using the Falls Efficacy Scale international at baseline and follow up
4. Physical assessment, including measure of walking (timed up and go), a standing balance test, sit to stand function and grip strength, at baseline and follow up

Overall study start date
03/09/2012

Completion date
07/04/2014

Eligibility

Key inclusion criteria
Living in the selected care home as a permanent resident
Care homes local to King's College Hospital will be recruited based on nearest first and:
1. Manager's consent to participate
2. Not involved in other interventional research (affecting the majority of residents)
3. Target Gender: Male & Female

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 212

Key exclusion criteria
1. Refusal to consent
2. Personal or nominated consultee advised against participation
3. Temporary resident in the selected care home
4. Unable to understand enough English to participate

Date of first enrolment
03/09/2012

Date of final enrolment
07/04/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Age Research Unit
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
King's College Hospital (UK)

Sponsor details
Paediatric Liver centre
London
England
United Kingdom
SE5 9RS

Sponsor type
Hospital/treatment centre

Website
http://www.kch.nhs.uk/

ROR
https://ror.org/01qz4yx77

Funder(s)

Funder type

Government

Funder Name
National Institute for Health Research (UK) - Research for Patient Benefit (RfPB); Grant Codes: PB-PG-0211-24140

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	30/05/2017		Yes	No