

Prevention of falls in older people with cognitive impairment

Submission date 26/03/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 26/03/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 05/06/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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

United Kingdom

England

Study participating centre

Clinical Age Research Unit

London

United Kingdom

SE5 9RS

Sponsor information

Organisation

King's College Hospital (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

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

