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Finch: Falls in care homes study

Submission date
22/03/2016

Recruitment status
No longer recruiting

Registration date
14/04/2016

Overall study status
Completed

Last Edited
15/08/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Falls are one of the leading causes of death and injury in people over the age of 65. Studies have shown that care home residents fall five times more often than elderly frail people living in their own homes. Of those residents who fall nearly 1 in 10 suffer a broken bone, 1 in 5 is admitted to hospital and 1 in 5 will die within the year as a result of this injury. These people suffer pain, immobility and fear of further falls with high personal and financial costs. Currently hip fractures cost £1.4 billion per annum and the number of fractures is set to double by 2050 and so it is vital to find a way to reduce the high level of falls in care homes. The physical environment and the decline in residents' memories have prevented this from being achieved through the traditional falls prevention programmes. The Guide to Action Care Home (GtACH) falls prevention is a unique process which involves falls prevention experts, usually employed by the NHS, training care home staff in small groups to systematically assess residents fall risk and then provide actions to reduce falls risks. Previous studies have shown that care homes are keen to take part in studies looking at GtACH, staff are willing to attend GtACH training, GtACH processes can be implemented with residents and fall rates can be reliably established from care home records. However, it is still not known whether the GtACH process can reduce falls rates in care home residents and what the casts would be for the NHS. The aim of this study is to compare the number of falls in care homes where staff are trained to use the GtACH process with homes that are providing usual care.

Who can participate?
Long-term care residents of care homes which are registered to look after the elderly and those with dementia.

What does the study involve?
If a care home resident decides they would like to take part in the research a researcher makes arrangements to visit the care home and explain the study and make sure the resident understands what is involved. The resident is given an information sheet to keep and is asked to sign a consent form. The consent allows the researcher to:
1. Collect information from the care home records about their current health, any previous falls they may have had and how they manage each day.
2. Notify the residents GP (or other health care practitioner) of their participation in the FinCH study and to allow clarification of medication data from GP records where necessary.
3. Observe care home staff assessing residents for the new treatment and delivering actions

arising from the assessment. The assessment may be repeated every 3 months, or more often if a participant has a fall.
Once all data from everyone who wishes to participate in the care home has been collected, the participating care homes are randomly allocated to receive either the new treatment or usual care. If the care home is allocated to receive the new treatment, care home staff are trained to carry out a personal assessment and suggest changes that may prevent residents having falls in the future. At 3, 6, 9 and 12 months after the care home has been allocated to the new treatment or care as usual, the researcher visits each participant to complete some questionnaires and collect information from the care home records about the participants current health, any falls they have had in the previous three months and how they manage each day.

What are the possible benefits and risks of participating?
There are no direct benefits or risks to participants taking part in this study.

Where is the study run from?
Sixty six care homes across Nottingham City, Nottinghamshire County, Sheffield, Leicester, Derby and Norwich (UK)

When is the study starting and how long is it expected to run for?
January 2014 to September 2020

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

Who is the main contact?
1. Mrs Gail Arnold (public)
gail.arnold@nottingham.ac.uk
2. Professor Pip Logan (scientific)
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
FinCH (Falls in Care Homes): A multi-centre cluster randomised controlled trial to evaluate the Guide to Action Care Home fall prevention programme in care homes for older people

Acronym
FINCH

Study objectives
Training care home staff to deliver the Guide to Action to reduce falls which is an evidence based falls prevention intervention will reduce the rate of falls in care home residents and be cost effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - Bradford Leeds Research Ethics Committee, 11/04/2016, ref: 16/YH/0111

Study design
Multi-centre single blinded cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Prevention

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
Falls prevention in care home residents

Interventions
Care homes will be randomised on a 1:1 basis to one either: intervention (which will be GtACH fall prevention programme) or control (which will be usual care). Randomisation of homes to allocation will occur after all participants have given consent and all baseline data have been collected. The research assistant who gathered the baseline information will confirm to the site Falls Lead (not individual care home falls champion) that the care home is ready to be randomised. The Falls Lead will use a remote, internet-based randomisation system to obtain the allocation for each home, and will inform the Falls Champion within the care home of the allocated intervention arm. This is to maintain the blinding of the research assistants to home allocation: the site Falls Lead will necessarily be unblinded.

Intervention arm: The intervention is the Guide to Action Care Home (GtACH) process delivered to care home residents by care home staff who have been trained and are supported. GtACH is a systematic falls risk assessment and action process, co-designed by care home and NHS staff, based on NICE clinical guidelines. The intervention involves care home staff completing the GtACH Tool with residents in a private area of the care home. The results will be discussed with family, friends and other care home staff. Completed GtACH documentation will be placed in the residents care records and updated when necessary according to the re-assessment schedule outlined below. The actions might require changes within the care home, changes to residents' personal care, referral to other services, or purchase of equipment. The actions will be written in the GtACH documentation. The assessment takes 15 minutes and actions take up to 2 hours per resident. The GtACH will be completed within 4 weeks of randomisation for all trial participants in the care home. Actions will be started immediately after the identification of risk. As part of GtACH training, re-assessment is undertaken if the participant develops a new medical or cognitive condition, if they fall, or every 3-6 months if there are no other changes.

Control arm: Participants receive usual care, where usual care is defined as the absence of a systematic and coordinated falls prevention process.

The study duration will be 36 months. Care Home participation will be for a duration of 13 months per care home (1 month prior to randomisation and 12 months post randomisation), Resident/Consultee participant will be for a duration of 13 months per resident/consultee (1

month prior to randomisation and 12 month from date of randomisation of care home). The Process evaluation duration (resident/consultee/staff) will be 4-6 months immediately post-randomisation (limited to 6 care homes randomised to GtACH intervention).

Intervention Type
Other

Primary outcome measure
Falls rates recorded by the care homes during the 3 month period comprising months 4, 5 and 6 post randomisation. This will be collected at the 6 month time point. Data will be collected from care home records and incident report forms.

Secondary outcome measures
1. Physical activity is measured using the Physical Activity and Mobility in Residential Care Scale (questionnaire) completed by care home staff and collected at baseline and 3, 6, 9 and 12 months post randomisation
2. Fracture rate is measured using fractures recorded in care home records and incident report forms at baseline and 3, 6, 9 and 12 months post randomisation. Fractures will be cross checked with hospital episode statistics (HES) data to ensure maximal data collection.
3. Days in hospital is measured using care home records and incident report forms at baseline and 3, 6, 9 and 12 months post randomisation and HES data.
4. Functional ability is measured using the Barthel Index of Activities of Daily Living completed by care home staff and, completed by care home staff at baseline, 3, 6, 9 and 12 months.
5. Economic evaluation is conducted by Tracey Sache at University of East Anglia. Economic evaluation will use health care resource use data collected for the 3 months prior to baseline and 3, 6, 9 and 12 months post randomisation and Quality of life using the DEMQOL-U-5D, DEMQOL-U-4D, EQ-5D-5L, EQ-5D-5L-P.
6. Process evaluation is conducted by Paul Leighton at University of Nottingham. The evaluation will use information from 12 focus groups and a minimum of 30 interviews. The evaluation will cover Training of Fall prevention Leads, training of care home staff and implementation of the GtACH will be observed and assessed against a standard fidelity checklist. Care home records will be reviewed to consider broad compliance with GtACH. Key stakeholders will be interviewed to explore the experience of introducing GtACH.
7. Falls recorded in the care home records and incident report forms will be recorded during the 3 months periods comprising months 7, 8 and 9 and 10, 11 and 12 post randomisation. This will be collected at the 9 and 12 month time point.
8. Fall injuries recorded during the 3 months periods comprising months 4,5 and6, 7 ,8 and 9 and 10, 11 and 12 post randomisation. This will be collected at the 6, 9 and 12 month time point. Data will be collected from care home records and incident report forms.
9. Quality of life is measured using DEMQOL-U-5D and EQ-5D-5L questionnaires (or DEMQOL-P-4D and EQ-5D-5L proxy questionnaires if reported by consultee). Collected at baseline, 3, 6, 9 and 12 months from the resident/consultee

Overall study start date
01/01/2014

Completion date
14/09/2020

Eligibility

Key inclusion criteria
Care Home inclusion criteria:
1. Long stay with old age and/or dementia registration
2. 10 or more potentially eligible residents
3. Routinely record falls in resident personal records and on incident sheets
4. Consent of care home manager to comply with the protocol and identify a care home fall champion

Resident inclusion criteria:
All long term care home residents.

Staff Inclusion Criteria (Process Evaluation Only)
1. Employed by a Care Home participating in FINCH and selected for participation in the Process Evaluation
2. Employed in a caring role

Participant type(s)
Other

Age group
Senior

Sex
Both

Target number of participants
1308

Total final enrolment
1657

Key exclusion criteria
Care Home exclusion criteria:
1. Participated in GtACH pilot/feasibility studies
2. Homes exclusively providing care for those with learning difficulties or substance dependency
3. Homes with contracts under suspension with health or social providers, or that are currently subject to safeguarding investigations or homes under CQC special measures
4. Homes with a significant proportion of beds taken up by health-service commissioned intermediate-care services
5. Trained and routinely using a systematic falls prevention programme

Resident exclusion criteria
1. Residents on short-term care (e.g. respite),
2. Residents identified to be in the last few days of life

Staff Exclusion Criteria (Process Evaluation Only)
3. Have a significant proportion of time caring for residents in health-service commissioned intermediate-care services funded beds

Date of first enrolment
01/11/2016

Date of final enrolment
31/10/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nottingham Healthcare NHS Trust
The Resource
Trust HQ
Duncan Macmillan House
Nottingham
United Kingdom
NG3 6AA

Study participating centre
Nottinghamshire City PCT
1 Standard Court
Park Row
Nottingham
United Kingdom
NG1 6GN

Study participating centre
Norfolk Community Health and Care NHS Trust
Elliot House
130 Ber Street
Norwich
United Kingdom
NR1 3FR

Study participating centre
Derby Hospitals NHS Foundation Trust
Derby City General Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Derbyshire Community Health Serves NHS Trust
Newholme Hospital
Baslow Road
Bakewell
United Kingdom
DE45 1AD

Study participating centre
Airedire NHS Foundation Trust
Airedale General Hospital
Skipton Road
Steeton
United Kingdom
BD20 6TD

Study participating centre
Leicester City PCT
St. Johns House
30 East Street
Leicester
United Kingdom
LE1 6NB

Study participating centre
Leicestershire County and Rutland PCT
Lakeside House
4 Smith Way
Grove Park
Enderby
Leicester
United Kingdom
LE19 1SS

Sponsor information

Organisation
University if Nottingham

Sponsor details
Research and Graduate Services
Kings Meadow Campus
Lenton Lane
Nottingham
England
United Kingdom
NG7 2NR

Sponsor type
University/education

ROR
https://ror.org/01ee9ar58

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. The trial is due to complete in April 2019. The study team will seek to disseminate in a way likely to support best practice and will liaise with ProFouND (The Prevention of Falls Network for Dissemination) to identify potential research users: other researchers, policy makers, commissioners, providers, clinicians, care home managers and staff, care home residents and relatives.
2. Plans to engage in networks of the above stakeholders locally and internationally. This could

include identifying a knowledge broker to work between the research team and CLAHRC-EM/EM AHSN to facilitate this. Dissemination outputs will be tailored towards each group including peer reviewed journal articles (e.g. Clinical Rehabilitation), video clips, DVD. Dissemination of findings will be prioritised to study participants (residents/care home staff) who will receive quarterly newsletter updates. At the end of active involvement participants will receive thank you letters. A summary document research brief will be distributed to relevant organisations due to relative successes a neighbouring organisation CLAHRC EM (Collaboration for Leadership in Applied Health Research and Care East Midlands) has had with their "CLAHRC Bite". Oral/poster presentations and workshops at sponsor hosted events, community meetings and national /international conferences will be one method.
3. Dissemination will be target audience specific with appropriate language and information. Written text dissemination will also include illustrations, graphs and figures. Media coverage will be sought in the form of local newspapers, television and radio outlets. This will be enabled further via connecting with the university's specialist experts in Information technology and communication departments.
4. Requests will be sent to relevant agencies to feature the research project in their newsletters and websites. A study web page will feature on the Nottingham University Rehabilitation and Ageing Department website. Social media networks; Facebook, Twitter and Pinterest will be used to provide the public with information and updates about study progress which will link to the University's webpage. If the trial is positive we will apply to the Academic Health Science Network to roll the technology out across clinical services via training workshops.

Intention to publish date
30/04/2020

Individual participant data (IPD) sharing plan
Not provided at time of registration

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?
Results article		07/12/2021	20/12/2021	Yes	No
Protocol (other)			15/08/2022	No	No
Results article		01/01/2022	15/08/2022	Yes	No
HRA research summary			26/07/2023	No	No