The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

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

Final Version 5.0
7 June 2017

Short title: Falls in Care Homes

Acronym: FinCH

ISRCTN: ISRCTN34353836

IRAS Project ID: 199492

Trial Sponsor: University of Nottingham

Sponsor reference: 16020

Funding Source: National Institute for Health Research HTA Programme (NIHR HTA Project 13/115/29) is providing funding for research costs for the project duration to cover trial set up, trial conduct, analysis and report writing.

1. TRIAL / STUDY PERSONNEL AND CONTACT DETAILS

Sponsor: Contact name	University of Nottingham Ms Angela Shone Head of Research Governance Research and Graduate Services King's Meadow Campus Lenton Lane Nottingham NG7 2NR Email: sponsor@nottingham.ac.uk
Chief investigator: `	Professor Pip Logan UoN job title: Professor of Rehabilitation Research University of Nottingham Medical School Room B96, School of Medicine Division of Rehabilitation & Ageing Queen's Medical Centre Derby Road Nottingham NG7 2UH Phone: 0115 823 0235 Email pip.logan@nottingham.ac.uk
Co-investigators:	Maureen Godfrey Public Coordinator c/o Gail Arnold University of Nottingham Medical School Room B96, School of Medicine Division of Rehabilitation & Ageing Queen's Medical Centre Derby Road Nottingham NG7 2UH 0115 823 0239 Professor John Gladman Professor of the Medicine of Older People University of Nottingham Medical School Room B111 Medical School Queen's Medical Centre Derby Road Nottingham NG7 2UH 0115 823 0242 Dr Paul Leighton Deputy Director, NIHR Research Design Service for the East Midlands University of Nottingham Medical School Room 2104 South Block Queen's Medical Centre Derby Road Nottingham NG7 2UH 0115 924 9924 ext 70710 Dr Sarah Armstrong Associate Professor and Reader in Medical Statistics University of Nottingham Medical School Room 2101 NICRC C Floor South Block Queens Medical Centre Derby Road

Nottingham NG7 2UH
0115 924 9924 ext 70705

Dr Adam Gordon
Consultant & Honorary Associate Professor in Medicine of Older People
University of Nottingham Medical School
B Floor Medical School
Queens Medical Centre Derby Road
Nottingham NG7 2UH
0115 823 0236

Professor Simon Conroy (also site PI for Leicester)
Geriatrician, University Hospitals of Leicester & Honorary Professor
University of Leicestershire
Department of Health Sciences
22-28 Princess Road West
Leicester LE1 6TP
0116 252 5992

Dr Tracey Sach
Reader in Health Economics
University of East Anglia
Rm 2.37 Norwich Medical School
Norwich Research Park
Norwich NR4 7TJ
01603 591936

Kate Robertson (also site PI for Nottinghamshire)
Consultant Therapist in Falls Prevention, Nottinghamshire Healthcare NHS Foundation Trust
University of Nottingham Medical School
Room A03, Duncan Macmillan House
Porchester Road
Nottingham NG3 6AA
01159691300 x 10763

Dr Allan Clark
Medical statistician, Senior Lecturer
University of East Anglia
Rm 2.23 Norwich Medical School
Norwich Research Park
Norwich NR4 7TJ
01603 593629

Marie Ward (also site PI for Nottingham City)
Clinical specialist in falls prevention and bone health and a nurse
Nottingham City Care NHS
Room 43a New Brook House
385 Alfreton Road
Nottingham
NG7 5LR
0115 883 8307

Professor Ann Marie Swart
Director of the Norwich Clinical Trials Unit
University of East Anglia
Rm 2.10 Norwich Medical School
Norwich Research Park
Norwich NR4 7TJ
01603 597306

Mrs Wynne Williams
Skylarks Nursing Home
Adbolton Lane
West Bridgeford
Nottingham
NG2 5AS

Dr Erika Sims
CTU Clinical Trial Operational Manager
University of East Anglia
Rm 2.17 Norwich Medical School
Norwich Research Park
Norwich NR4 7TJ
01603 597178

Trial / Study Statistician:

Dr Sarah Armstrong
Director, NIHR Research Design Service for the East Midlands
University of Nottingham Medical School
Room 2101 NICRC C Floor South Block
Queens Medical Centre Derby Road
Nottingham NG7 2UH
0115 924 9924

Dr Allan Clark
Medical statistician, Senior Lecturer
University of East Anglia
Rm 2.23 Norwich Medical School
Norwich Research Park
Norwich NR4 7TJ
Phone: 01603 593629
Email: allan.clark@uea.ac.uk

Trial / Study Coordinating Centre:

University of Nottingham Medical School
Room B96, School of Medicine Division of Rehabilitation & Ageing
Queen's Medical Centre Derby Road
Nottingham NG7 2UH

CTU:	Norwich Clinical Trials Unit Norwich Medical School University of East Anglia Norwich NR7 4TJ 01603 591035

2. SYNOPSIS

Title	A multi-centre cluster randomised controlled trial to evaluate the Guide to Action Care Home fall prevention programme in care homes for older people (FinCH)
Acronym	FinCH
Short title	Falls in Care Homes
Chief Investigator	Professor Pip Logan

Objectives	Primary objective is to compare the rate of falls per participant in the 2 trial arms (GtACH arm and usual practice control arm) during the 3 month period comprising 4, 5 and 6 months post randomisation.
	
	Secondary objectives are to:
	• compare the rate of falls per participant during the :
	  ○ 3 month period comprising months 7, 8 and 9 post randomisation
	  ○ 3 month period comprising months 10, 11 and 12 post randomisation
	• compare between the trial arms at 6 months and 12 months post randomisation
	  ○ Frequency of fall injuries
	  ○ Frequency and type of fractures
	  ○ Number of days in hospital
	  ○ Number of deaths
	  ○ Health and social service use
	  ○ Physical activity
	  ○ Functional ability
	  ○ Quality of life
	  ○ Medication use
	• perform a within trial cost effectiveness and utility analysis from both a NHS and a personal social service perspective
	• complete a process evaluation to explain the findings from the perspectives of residents, staff.

Trial Configuration	Multi-centre, single blinded, cluster randomised controlled trial
Setting	The study setting is adult care homes (with and without nursing) in England with the option of extending to include Scotland, Wales and Northern Ireland.
Sample size estimate	This is based on the primary outcome of falls rate over the 3 month period, months 4, 5 and 6, post randomisation. Assuming a falls rate of 2.5 falls per year (0.625 falls in 3 months) in the control group (Whitney 2012b), 80% power and a two-sided significance level of 5%, 189 residents per group are required in order to detect a 33% reduction in falls rate in the

	intervention group. The sample size has been calculated using the Whitney study as the feasibility study population on which the sample size calculation was based, had a falls rate of 15 falls per year (Walker 2015) but only recruited residents who had fallen recently. The adjustment for clustering assumes an average cluster size of 20 residents (Dyer 2004) and an intra-cluster coefficient (ICC) of 0.1 (Dyer 2004), giving a sample size of 549 residents per group. Incorporating a further 16% to the sample size to account for potential attrition (Gordon 2014), the aim is to recruit a total of 1308 residents (654 to intervention group and 654 to control group).
Number of participants	1308 care home residents in 66 care homes. Care homes will be randomised on a one to one basis with resident's participation being based on the care homes randomisation with the aim of having 50% of residents in each arm. All residents will be consented to observations by researchers at baseline and prior to randomisation. 30 - Process Evaluation Observations (Care Home Staff) of GtACH Assessments and Actions 48 - Process Evaluation Focus Group participants. A staff focus group (comprising of an estimated 8 staff) will take place in each of the 6 care homes. Each focus group will be run twice, but with the same participants where possible. Where numbers dictate, multiple focus groups will be held in a care home to facilitate full participation 36 - Process Evaluation Interview participants. In each of the 6 evaluation care homes key stakeholders will be interviewed. This will include care home staff, falls leads, care home management and (when appropriate) care home residents (or resident/relative dyads). At least 6 interviews will take place in each setting.
Eligibility criteria	Care Home inclusion criteria: • Long stay with old age and or dementia registration • 10 or more potentially eligible residents • Routinely record falls in resident personal records and on incident sheets • Consent of care home manager to comply with the protocol and identify a care home fall champion Care Home exclusion criteria: • Participated in GtACH pilot/feasibility studies • Homes exclusively providing care for those with learning difficulties or substance dependency • Homes with contracts under suspension with health or social providers, or that are currently subject to safeguarding investigations or homes under CQC special measures • Homes with a significant proportion of beds taken up by health-service commissioned intermediate-care services • Trained and routinely using a systematic falls prevention programme

	Resident inclusion criteria: • All long term care home residents Resident exclusion criteria • Residents on short-term care (e.g. respite), • Residents identified to be in the last few days of life. Staff Inclusion Criteria (Process Evaluation Only) • Employed by a Care Home participating in FINCH and selected for participation in the Process Evaluation • Employed in a caring role. Staff Exclusion Criteria (Process Evaluation Only) • Have a significant proportion of time caring for residents in health-service commissioned intermediate-care services funded beds
Description of interventions	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 assessment takes 15 minutes and actions take up to 2 hours per resident. The comparator to the intervention will be usual care, where usual care is defined as the absence of a systematic and coordinated falls prevention process.
Duration of study	Study Duration: 36 months (planned start date May 2016); Care Home participation: 13 months per care home (1 month prior to randomisation and 12 months post randomisation) Resident/Consultee participant duration: 13 months per resident/consultee (1 month prior to randomisation and 12 month from date of randomisation of care home) Process evaluation duration (resident/consultee/staff): 4-6 months immediately post-randomisation (limited to 6 care homes randomised to GtACH intervention)
Randomisation and blinding	RANDOMISATION 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 un-blinded. The sequence of treatment allocations will be concealed from the study statistician until all interventions have been assigned and recruitment, data collection, and all other study-related assessments are complete.

	UNBLINDING As only the researcher collection baseline and outcome data is blinded to the intervention, emergency un-blinding is not required. Access to the randomisation sequence will be confined to the Norwich CTU data management team. Only appropriate members of the trial team will be aware of the allocation to intervention or control group. The independent Data Monitoring Committee may request and will be provided with whatever data it deems necessary or useful for it to carry out its duties, including the provision of un-blinded data.
Outcome measures	**Primary Outcomes measure:** Falls recorded during the 3 month period comprising months 4, 5 and 6 post randomisation. **Secondary Outcomes measures:** Falls recorded during the 3 month period comprising months 7, 8 and 9 post randomisation. Falls recorded during the 3 month period comprising months 10, 11 and 12 post randomisation. **The following measures will be collected at baseline, 3, 6, 9 and 12 months:** Number of fall injuries Number and type of fall injuries Physical activity and mobility in residential care (using PAM-RC) Functional ability (using Barthel Index) Quality of life (using DEMQOL-U-5D, andEQ-5D-5L reported bythe resident where they have capacity to consent Quality of life (using DEMQOL-P-4D and EQ-5D-5L) reported by a member of staff with a good knowledge of the resident for all participants. Medication use from MAR sheets Health service and social service resource use Days in hospital Number of deaths Date of death **Process evaluation outcome measures:** Contextual factors and processes which impact upon the implementation of the GtACH, extent to which GtACH is being used consistently within and across care home settings, and views and opinions of key stakeholders about the adoption of GtACH as derived from observations, stake holder interview and staff focus groups .
Statistical methods	The primary outcome is the rate of falls per participant in the 3 months prior to 6 months post randomisation. This will be collected at the 6 month time point. Data will be collected from care home records and incident report forms. The primary outcome, rate of falling over the 3 month period prior to 6 months post-randomisation, will be expressed as the number of falls per

	1,000 resident days for each group. The number of falls per resident will be compared between groups using a two-level Poisson or negative binomial model with resident at level one and care home at level two, with length of residence in care home as an offset. The primary analysis will adjust for type of care home (residential, nursing, dual registration) and site. Two additional models will be fitted in order to assess the robustness of the model. In addition to adjusting for care home type and site, these will adjust for i) baseline fall rate; ii) baseline fall and other variables that are associated with falling (these are to be confirmed after discussion with the trial IDMC). Fall rates during the 3 month period prior to 9 and 12 month follow-up will be analysed and presented in the same way as for the primary outcome variable. For other secondary outcomes, groups will be compared using multi-level regression analysis for continuous outcomes and multi-level logistic regression for binary outcomes.

3. ABBREVIATIONS

AE	Adverse Event
CI	Chief Investigator overall
CIS	Consultee Information Sheet
COMET	Common Outcome Measures in Efficacy Trials
CQC	Care Quality Commission
CRF	Case Report Form
DEMQOL	Dementia Specific Quality of Life
DMC	Data Monitoring Committee
GCP	Good Clinical Practice
GtACH	Guide to Action fall prevention in Care Homes
HSCIC	Health and Social Care Information Centre
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
InterRAI	International collaborative to improve the quality of life of vulnerable persons through a seamless comprehensive assessment system
IRB	Institutional Review Board
ITT	Intention to Treat
MAR	Medication Administration Record
NHS	National Health Service
Norwich CTU	Norwich Clinical Trials Unit
PAM-RC	Physical Activity and Mobility in Residential Care
PI	Principal Investigator at a local centre
PIS	Participant Information Sheet
QA	Quality Assurance
QC	Quality Control
QMMP	Quality Management and Monitoring Plan
QOL	Quality of Life
R&D	Research and Development Department
REC	Research Ethics Committee
RfPB	Research for Patient Benefit
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SSA	Site Specific Approval
TMF	Trial Masterfile
TMG	Trial Management Group
TMT	Trial Management Team
ToR	Terms of Reference
TSC	Trial Steering Committee
UEA	University of East Anglia

TABLE OF CONTENTS

4. TRIAL / STUDY BACKGROUND INFORMATION AND RATIONALE

Falls in older care home residents (1.5-2.8 per year) (Rapp 2012, Whitney 2012a, Whitney 2012b) are at least five times more frequent than in community dwelling adults (WHO 2007) and have higher direct costs (Heinrich 2010). In care homes, nearly 1 in 10 people who fall sustain a fracture (Rapp 2009), 1 in 5 are admitted to hospital (Scuffham 2003) and 1 in 5 will die within a year (Leibson et al., 2002) due to a fall related injury. One third of the UK's hip fractures occur in care home residents (Scuffham 2003), which is devastating to patients and their carers, and costly to the NHS. At present, hip fractures cost the NHS £1.4 billion per year with the figure set to double by 2050 (Becker 2003). An important strategy in preventing fractures, alongside improving bone health, is to prevent the falls which cause the fractures.

Even when falls do not result in fractures, they frequently result in other forms of injury, which are important to the NHS, with or without admission to hospital. They cause fear of falling which contributes to a cycle of functional decline and increasing dependency with associated care costs. 400,000 people in the UK live in care homes (LaingBuisson, 2009). At a rate of 2.5 falls per year (Whitney 2012b) there are 160,000 falls per year in care home residents. Based upon conservative projections by the Joseph Rowntree Foundation, the number of care home places in the UK will increase by 150% by 2051, which implies that the number of falls occurring in care homes is set to increase over time.

Preventing falls and injuries in those over 65 years of age is a public health priority (RoSPA 2013) and The King's Fund recommends structured patient-centred care in care home settings (Naylor 2013). The recently published NICE Quality Standard 86, 'Falls in older people: assessment after a fall and preventing further falls' (NICE, 2015), recommends that all health and social care practitioners involved in assessing, caring for and treating older people who experience a fall should have sufficient and appropriate training and competencies to deliver the actions and interventions.

Community fall prevention interventions reduce falls by about 30%, but literature to date has found no conclusive reduction in falls in care homes (Gillespie 2012, Cameron 2012). Care home research is scarce but suggests that fall-related injuries might be prevented by fall prevention interventions (AlFaisal, 2006, Kannus 2005). However, care home staff have been found to expect older people to fall (Larson 2008) which may result in fear and activity reduction (Fletcher 2010). Current fall interventions rely on patient engagement, risk recall and adherence to advice. This is difficult in care homes, where 75% of residents are cognitively impaired (Gordon 2014) and non-targeted interventions with cognitively impaired older adults have lacked success (Jensen 2011, Jensen 2003). To decrease fall rates it has been suggested that interventions need to be targeted at high risk groups such as elderly care home populations and include specific components (Close, 2005). They need to be delivered by the whole team (Bouwen 2008, Jensen 2004) to the whole environment.

Implementing healthcare interventions in care homes is challenged by lack of clarity about staff roles and responsibilities, unequal power relationships between healthcare and care home staff and inadequate time and space to conduct detailed assessments (Robbins 2013). As a result, novel healthcare interventions in this setting are often short-lived (Goodman 2011). A suggested solution has been to effectively engage care home staff in the development, implementation and delivery of healthcare interventions to ensure that delivery of the intervention does not depend upon long-term involvement by highly trained or motivated NHS staff (Gage 2012).

The GtACH intervention aims to reduce fall rates by facilitating change in practice of care home staff. It was co-produced by a group of care home staff, clinicians, researchers, public,

voluntary and social care organisations and includes care home staff training, support and documentation. With training, the GtACH takes on average 20 minutes to complete for each resident, compared to 2 hours per resident without training (Robertson 2012). An introductory GtACH paper has been published (Robertson 2012) and its content and delivery have been refined through a proof of concept study (Logan 2010) and a Research for Patient Benefit (RfPB) funded randomised controlled feasibility trial (Walker 2015; REC number: 12/WM/0091).

5. TRIAL / STUDY OBJECTIVES AND PURPOSE

5.1 PURPOSE

The purpose of the trial is to determine the clinical and cost effectiveness of the Guide to Action (GtACH) process for fall prevention in care homes compared to usual care. A process evaluation will run concurrent with the trial to explain the findings from the perspectives of residents and staff.

5.2 PRIMARY OBJECTIVE

The primary objective of the trial is to compare the rate of falls per participant in the 2 trial arms (GtACH arm and usual practice control arm) during the 3 month period comprising months 4, 5 and 6 post randomisation.

5.3 SECONDARY OBJECTIVES

The secondary objectives are to:

- compare the rate of falls per participant during the :
    - 3 month period comprising months 7, 8 and 9 post randomisation
    - 3 month period comprising months 10, 11 and 12 post randomisation
- compare between the trial arms at 6 months, 9 months and 12 months post randomisation
    - Frequency of fall injuries
    - Frequency and type of fractures
    - Number of days in hospital
    - Number of deaths
    - Health and social service use
    - Physical activity
    - Functional ability
    - Quality of life
    - Medication use
- perform a within trial cost effectiveness and utility analysis from both a NHS and a personal social service perspective
- complete a process evaluation to explain the findings from the perspectives of residents and staff.

6. DETAILS OF INTERVENTION TOOL

6.1 Description

The Guide to Action in Care Homes (GtACH) Tool is a systematic falls risk assessment and action process, co designed by University of Nottingham researcher in conjunction with care home and NHS staff, based on NICE clinical guidelines. It was developed by the NIHR grant applicants utilising Trent RDSU grant funding and consists of 33 domains related to falls risk

factors under four domains: falls history, medical history, movement/environment and personal needs. 30 corresponding suggested actions are included alongside the relevant risk factors to prompt action to be taken to reduce, reverse, modify or manage that risk factor. The GtACH feasibility study, sponsored by the University of Nottingham (Sponsor's reference number 12051), has been published although the GtACH manual (comprising assessment and action materials) has not been published.

The GtACH Intervention Tool comprises of a training package for Falls Leads to deliver to Care Homes, a GtACH manual (comprising assessment and action materials) and a GtACH Poster.

6.2 Train the Trainer

Falls Clinical Specialists, Kate Robertson and Marie Ward, will provide GtACH training for the site nominated Falls Leads at a one day Training Session to be held in Nottingham. This training will include background information regarding the GtACH development, how to deliver GtACH training in care homes and use case studies to practice completing the GtACH. The Falls Leads will be provided with a Training Manual to be given to the care homes post training and the one hour training package to be used in the intervention homes. The site Falls Lead will train care home staff in the intervention homes, ideally within two weeks of the home being randomised to use the GtACH. It is recognised that there are circumstances where training within the two week window will not be possible and reasons will be recorded for homes where training has been delayed. The training will be one hour in duration, conducted in small group sessions in the care home. Care Home staff who have a role caring for residents are expected to attend the training session as well as the Manager and the nominated care home Falls Champion. The Falls Lead will aim to train at least 80% of the care home staff. A log of care home staff in a caring role that have completed the GtACH training will be held and maintained at each care home.

6.3 Care Home Training

The one hour care home training includes: purpose of the study, purpose of the training, and prevalence of falls in care homes, GtACH history, how to complete and where to file completed forms. It emphasises consistent delivery, resources for the homes (Manual) and follow up support from the site Falls Lead. Case studies and role play will be used in the training. The training programme is not publically available to avoid contamination. The Falls Champion and the Falls Lead will support the Care Home with any queries they have following the training.

6.4 GtACH Manual

Following the training, the care home will be given two Manuals to support the implementation of the GtACH process within the home. The Manuals will include information about the study; a copy of the training session slides; falls information including definition of a fall; why falls are important and causes of falls; how to complete the GtACH; Falls Incident Analysis; and a Medication and Falls Chart. Information on how to contact the Falls Lead will also be included as well as Master copies of the GtACH Tool. Staff who attend the training sessions will be given attendance certificates.

6.5 GtACH Poster

Once the training is complete, the home will be given an A4 sized poster to display with information about the study. This is designed to be a visible reminder for staff and visitors of GtACH being implemented within the Home.

6.6 GtACH Intervention

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 GtACH will be completed ideally within 4 weeks of randomisation (and within 2 weeks of staff training being completed in the care home if this has been delayed) 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.

6.7 Manufacture

The current version of the GtACH materials will be printed by the Study Coordinating Centre and provided to the care home during the training session.

7. TRIAL / STUDY DESIGN

7.1 TRIAL / STUDY CONFIGURATION

A cluster randomised controlled, 2 arm, parallel group trial comparing the GtACH fall prevention intervention against usual care for people living in care homes (with and without nursing).
The study setting is adult care homes (with and without nursing). All care homes will be recruited initially from England but may be extended to include Wales and Northern Ireland.
66 care homes in total will be recruited as the unit of randomisation.

7.1.1 Primary endpoint

The primary efficacy endpoint is the rate of falls per participant in the 3 month period comprising months 4, 5 and 6 post randomisation.

7.1.2 Secondary endpoint

Secondary efficacy endpoints are:

Falls recorded during the 3 month period comprising months 7, 8 and 9 post randomisation.
Falls recorded during the 3 month period comprising months 10, 11 and 12 post randomisation.
Physical activity (measured using physical activity and mobility in residential care questionnaire (PAM-RC) and completed by care home staff)
Activities of daily living (measured using Barthel Index and completed by care home staff)
Quality of life (DEMQOL-U-5D and EQ-5D-5L) for participant completion where the participant has capacity.
Quality of life (DEMQOL-P-4D and EQ-5D-5L proxy completed by a member of care home staff with a good knowledge of the resident for all residents (this is necessary in case a resident loses the capacity to self-complete during the study)) (Mulhern 2013, Rowen 2012, Herdman, 2011)

Medication (as recorded on care home Medication Administration Record sheets
Frequency and type of fractures
Days in hospital
Deaths

7.1.3 Safety endpoints

No additional endpoints will be collected for safety over and above the primary and secondary efficacy endpoints.

The intervention being evaluated is a care home wide falls reduction intervention for care home staff to implement. In view of the nature of the care home population (which is pre-terminal and in which a high number of events are expected and recorded in care home records), the intervention (which is not a medicinal product, or novel physiological or surgical procedure) and the trial primary and secondary outcomes including safety outcomes, we do not intend to collect any additional safety endpoints.

7.1.4 Stopping rules and discontinuation

Residents and relatives/consultees where appropriate will be made aware that they can withdraw their consent at any time during the trial, without it affecting their or their relatives' usual care. If a participant chooses to leave the study prematurely the primary reason for discontinuation will be determined and recorded, if at all possible. Withdrawn participants will not be replaced. Participants will be made aware (via the information sheet and consent form) that should they withdraw, the data collected to date cannot be erased and may still be used in the final analysis.

In the event a care home withdraws participation (or is unable to continue following a regulatory inspection) after randomisation, the care home will not be replaced. The care home will be made aware that data collected on the care home AND participants at that care home to date cannot be erased and may still be used in the final analysis. Participants will be advised that their care home has withdrawn

Recruitment will be undertaken over a 12 month period, and recruitment progress will be reviewed at 6 months following start of recruitment. A stop / go time point at month 6 of the recruitment phase will be applied this will be the successful recruitment of 33 care homes and 654 residents. The Trial Management Group (TMG) and the Trial Steering Committee (TSC) will review recruitment targets, training of care home staff and delivery of the GtACH intervention. Strategies to increase recruitment and adherence will be implemented if required. After six months the TSC will formally review recruitment and provide recommendations. The sponsor and funder reserve the right to discontinue this study at any time for failure to meet expected recruitment goals, for safety or any other administrative reason. The Sponsor and Funder shall take advice from the TSC as appropriate in making this decision. Should the trial be terminated, the research data will not be destroyed.

7.2 RANDOMIZATION AND BLINDING

Care homes will be randomised on a 1:1 basis to one of two parallel arms: intervention (which will be GtACH fall prevention programme) or control (which will be usual care). Participants, care home staff, site Fall Lead and research assistants undertaking the process evaluation at the care homes will not be blinded to allocation. The research assistant responsible for recruiting care homes, consenting patients and carers and collecting care home and patient level outcome data will remain blinded to the home allocation.

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.

The sequence of treatment allocations will be concealed from the study statistician until all interventions have been assigned and recruitment, data collection, and all other study-related assessments are complete.

Randomisation will be based on a bespoke computer generated pseudo-random code using variable block randomisation within strata (site, care home type [nursing/residential/dual registration]) provided by the Norwich CTU via a secure web based randomisation service.

Trial management group and the data monitoring committee will be un-blinded to the intervention. Chief investigator and principle investigators will have direct contact with the randomised care homes, although not with the participants. Independent members of the data monitoring committee will not have contact with either care homes or participants.

7.2.1 Maintenance of randomisation codes and procedures for breaking code

As the care home and the trial team except for the research assistant, will be aware of which arm the care home is randomised to, no emergency un-blinding procedure will be required. Norwich CTU will retain the randomisation codes for care homes for the duration of the trial. At the end of the study the blinded allocation will be provided to the study statistician. Once the analysis has been completed, the study statistician will be provided with the un-blinded allocation.

Interim analyses required to populate recruitment and data monitoring for harm reports for the data monitoring committee will be conducted on un-blinded data by the Norwich CTU Senior Statistician and Nottingham Trial Statistician.

7.3 TRIAL/STUDY MANAGEMENT

The Trial will be managed from a central coordinating centre at University of Nottingham supported by Norwich Clinical Trials Unit.
A Trial Management Group composed of all co-applicants and Norwich Clinical Trials Unit staff (operations, data management, statistical and health economic representatives) will meet monthly to oversee day to day management of the study.
A Data Management Committee, including three independent members, will meet on a 6 monthly basis to review care home and participant recruitment, and safety data.
The Trial Team will submit recruitment and safety reports to the Data Monitoring Committee on a 6 monthly basis.
The Trial Management Group and Data Monitoring Committee will submit 6 monthly reports to an HTA appointed Trial Steering Committee comprising of three independent members, who will meet on a 6 monthly basis.

The first meeting of the data monitoring committee and trial steering committee will be prior to starting care home recruitment in November 2016. The second meeting will be approximately six months later to evaluate recruitment into the pilot phase of the study, and 6 monthly after that.

University of Nottingham template terms of reference will be used for the Trial Management Group, Data Monitoring Committee and Trial Steering Committee and will be agreed by the sponsor, University of Nottingham.

The Chief Investigator has overall responsibility for the study and shall oversee all study management.

The data custodian will be the Chief Investigator.

7.4 DURATION OF THE TRIAL / STUDY AND PARTICIPANT INVOLVEMENT

Study Duration: 36months ending April 2019

Participant Duration:

Care Homes: 13 months comprising 1 month prior to randomisation (to recruit residents/consultees) and 12 months post randomisation

Residents/Consultees: 13 months comprising 1 month prior to randomisation to consent and collect baseline data and 12 months post randomisation

Care Home Staff (Process Evaluation): 4-6 months post randomisation

7.4.1 End of the Trial

Care homes will be closed according to Norwich CTU procedures once all outcome data recorded for the outcome period (12 months following randomisation) has been collected. Trial sites will be closed once all care homes associated with that site have been closed.

The end of the study will be the last data collection (at 12 months post randomisation) of the last participant.

7.5 SELECTION AND WITHDRAWAL OF PARTICIPANTS

7.5.1 Recruitment

Care Home Recruitment to Trial
On the basis of the sample size calculation in section 9.1.3 the aim is to recruit 1308 residents from 66 care homes. The areas of recruitment of care homes are currently anticipated to be covered by, but maybe extended beyond, Nottinghamshire Healthcare NHS Foundation Trust, Bradford District Care NHS Foundation Trust, Norfolk Community Health and Care NHS Trust, Derby Hospitals NHS Foundations Trust/Derbyshire Community Health Services NHS Foundation Trust, Nottingham City Care Partnership and Leicester Partnership NHS Trust. It is anticipated that each site will recruit 12-13 care homes and 218 participants in a 12 month period. Across all sites, it is anticipated that the rate of recruitment of care homes and residents will be 5-6 care homes and 18-19 residents per month. In the event that 1308 residents are not recruited from the 66 care homes, additional care homes may be recruited until the sample size has been reached. Care Homes will be identified from local health and social care commissioners. Eligible care homes will be telephoned to introduce the study and a formal invitation to participate sent by e-mail and letter. From the homes that volunteer to participate, a review of the home against the eligibility criteria will be undertaken to confirm that the care home meets the entry criteria.

Resident recruitment to the trial

Once a Care Home has agreed to take part in the study and consent has been obtained from the Care Home Manager, the Care Home Staff will provide information to the residents who meet the eligibility criteria. Details of those who have confirmed that they are happy to take part will be provided to the Researcher who will then arrange to meet with the resident and their consultee as appropriate at a mutually agreeable time in order to provide further information about the study and take consent. This will happen prior to the Care Home being randomised.

Process Evaluation
From the 33 care homes randomised to receive the GtACH intervention, 6 Care Homes will be identified according to the purposive selection criteria and invited to participate in a process evaluation. After obtaining consent from the care home manager, care home staff will be invited to consent to researcher observations of GtACH implementation. Staff taking part in the Process Evaluation will be provided with information through the Care Home Manager and the researcher will meet with those who agree to explain the study and take consent.

Residents/consultees in care homes participating in the process evaluation will be asked to consent to researcher observations as part of the consent to participate in the trial.

Care home staff and resident/consultee dyads may also be invited to participate in focus groups and/or stakeholder focus groups. The qualitative researchers undertaking the process evaluation will provide information to the staff/residents/consultees, explain the study and take consent. It will be explained to the potential participant that entry into the trial is entirely voluntary and that their treatment and care will not be affected by their decision. It will also be explained that they can withdraw at any time but attempts will be made to avoid this occurrence. In the event of their withdrawal, it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

7.5.2 Eligibility criteria

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

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

Resident eligibility criteria

Resident eligibility criteria are:

- All long term care home residents providing informed consent
- Residents without capacity to provide informed consent must have a relative/consultee who will provide advice on their behalf

Resident exclusion criteria

- Residents in receipt of end of life care or in the home for short term care, respite care or for rehabilitation

Staff eligibility criteria (Process Evaluation)

Staff Eligibility Criteria (Process Evaluation Only)

- Employed by a Care Home participating in FinCH and selected for participation in the Process Evaluation
- Employed in a caring role.

Staff Exclusion Criteria (Process Evaluation Only)

- Have a significant proportion of time caring for residents in health-service commissioned intermediate-care services funded beds

7.5.3 Expected duration of participant participation

Study Duration: 36months ending April 2019

Participant Duration:

Care Homes: 13 months comprising 1 month prior to randomisation (to recruit residents/consultees) and 12 months post randomisation

Residents/Consultees: 13 months comprising 1 month prior to randomisation to consent and collect baseline data and 12 months post randomisation

Care Home Staff (Process Evaluation): 4-6 months post randomisation
Study participants will be participating in the study for 12 months following randomisation

7.5.4 Removal of participants from therapy or assessments/Participant Withdrawal

Residents may be withdrawn from the trial either at their own request, consultee request or at the discretion of the Investigator. The participants will be made aware that this will not affect their future care. Participants and consultee where appropriate will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

Care Homes may withdraw from the trial at their own request or at the discretion of the investigator.

7.5.5 Informed consent

Three levels of consent are required: care home consent and individual resident consent. Where a participant is considered not to have the capacity to give consent, a consultee will be sought.

Care home consent

Consent of the care home manager is required to assure compliance with the trial process.

Individual resident consent

Consent of residents is required to permit the collection and use of data about them. Potential participants will be assessed by the researcher (in consultation with the care home manager and staff) to determine whether they have the mental capacity to give informed consent. Researchers will receive training on evaluating capacity, taking informed consent from participants, informed consent from consultees, and taking assent from participants considered unable to give consent.

Residents who have the mental capacity to do so will be asked to read the Patient Information Sheet and sign a written consent form.

Residents who are deemed not to have the mental capacity to consent, a personal family or friend consultee will be sought if possible. The following process will be followed:

- Where there is a personal consultee who is in frequent contact with the resident who lacks capacity – The consultee will be provided with the Consultee Information Sheet and asked to sign a personal consultee advice form.
- Where the resident has no identifiable potential family or friend consultees - a nominated consultee will be asked to provide advice and sign a consultee advice form.
- Where family/friends live a long distance away and/or are not in frequent contact with the person who lacks capacity the Care Home Manager will agree that one of the following two processes will be followed:
    - A Consultee Information Sheet will be posted out to the consultee with a covering letter offering the options of the consultee providing advice or nominating the Care Home Manager or another nominated consultee to provide advice. If no response has been received within 2 weeks from posting the information, a nominated consultee will be identified and asked to sign a nominated consultee form.
    - A nominated consultee will be identified and asked to provide advice and sign a consultee advice form.

In all cases, with agreement from the consultee and care home staff, and with the consultee or care home staff present, the researcher will provide the resident with the short version of the participant information sheet and discuss the trial with the resident in order to gain assent to participate wherever possible.

The personal and nominated consultee processes are as described by the Mental Capacity Act and Department of health Guidance for nominated consultees (OPSI 2005, DH 2008). The assent process is consistent with Alzheimer Europe Ethics of Dementia Research (http://www.alzheimer-europe.org/Ethics/Ethical-issues-in-practice/Ethics-of-dementia-research/Informed-consent-to-dementia-research) and has the support of Alzheimer's UK.

The provision of informed consent to participate in the trial includes consenting data collection and to participating in trial follow up as described in the protocol and the participant information sheet. Participants will be requested to consent to their medical records, including GP records,

being accessed as part of the trial, for supplementary data to be collected on their health service use, fractures and admissions to hospital.

The Principal Investigator (PI) retains overall responsibility for the informed consent of participants at their site and will ensure that any person delegated responsibility to participate in the informed consent process is duly authorised, trained and competent to participate according to the ethically approved protocol, principles of Good Clinical Practice (GCP) and Declaration of Helsinki.

The right of a participant or consultee to refuse participation without giving reasons will be respected. The participant and their consultee as appropriate will remain free to withdraw from the trial at any time without giving reasons and without prejudicing his/her further treatment and will be provided with a contact point where he/she may obtain further information about the trial. The PI takes responsibility for ensuring that all vulnerable subjects are protected and participate voluntarily in an environment free from coercion or undue influence.

Informed consent will be collected from each participant before they undergo any interventions (including physical examination and history taking) related to the study. The original consent form will be kept in the Site File and three copies will be taken. One copy of this will be kept by the participant, one will be retained in the resident's care home file and a third will go to Norwich Clinical Trials Unit for checking. This copy will be stored securely in a locked office until checked and will then be destroyed. Consent, and assent where appropriate, will be recorded in the resident care home notes.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the trial, continuing consent will be obtained using an amended Consent form which will be signed by the participant (or consultee as appropriate).

Staff consent (Process Evaluation)

Staff who agree to take part in the process evaluation will provide written informed consent. The Informed Consent Form will be signed and dated by the participant before they enter the trial. The Investigator will explain the details of the trial and provide a Participant Information Sheet, ensuring that the participant has sufficient time to consider participating or not. The Investigator will answer any questions that the participant has concerning study participation.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the trial, continuing consent will be obtained using an amended Consent form which will be signed by the participant.

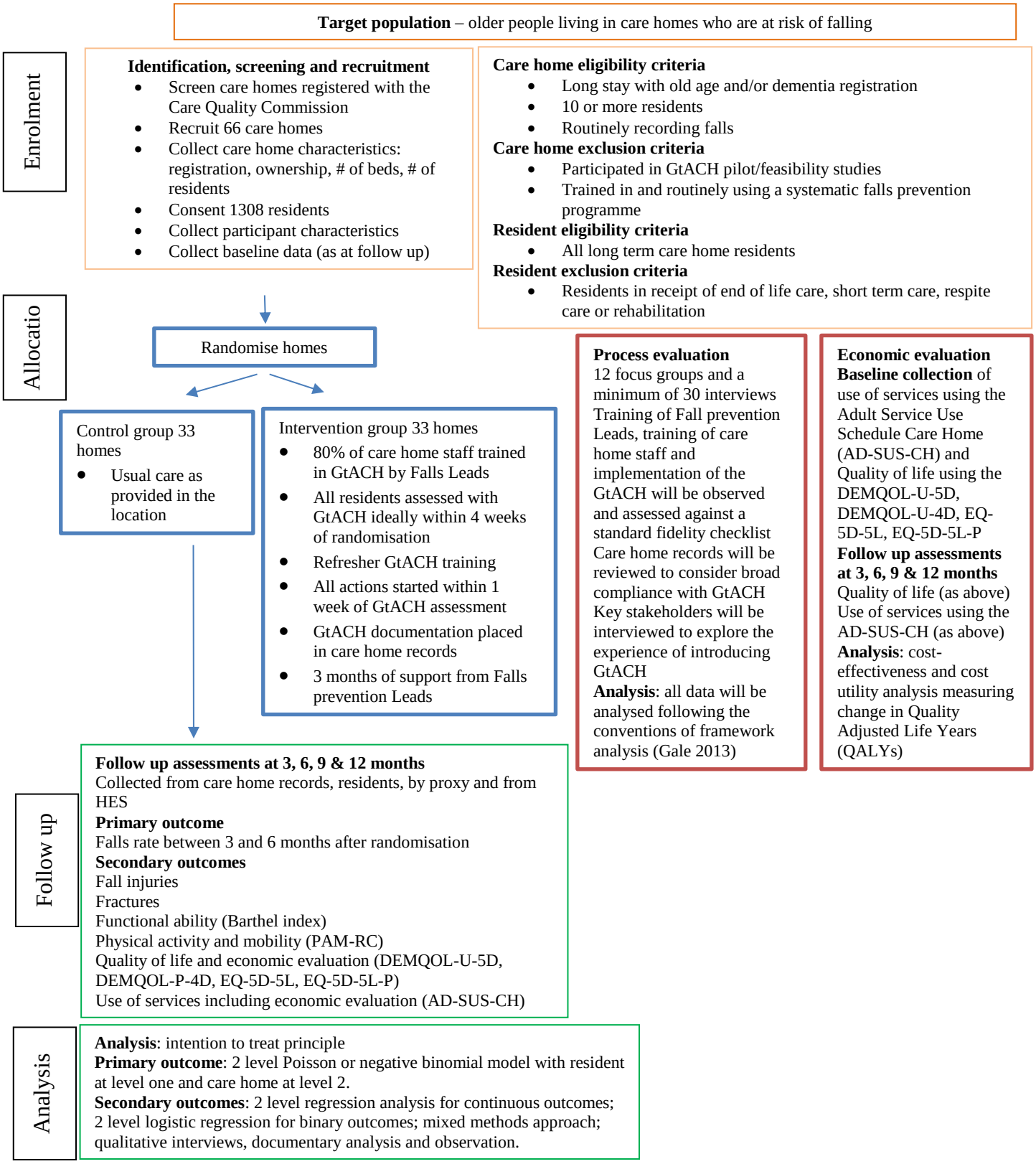
7.5.6 Consent in Ancillary Studies

There is no intention to collect any specimens for storage or use in future studies. There is no current intention to perform any ancillary studies but should plans emerge they will require additional funding and ethics applications to be made.

8. TRIAL / STUDY TREATMENT AND REGIMEN

A schematic diagram of the trial design is shown on Page 24

Schematic diagram of trial design



Regimen for care homes and care home staff
Care home eligibility criteria will be requested when care homes express an interest to participate in the study. Once care home eligibility is confirmed, care home managers will be consented to participate.

Characteristics of care homes will be collected on:

- Number of staff in caring role,
- Number of beds
- Number of residents
- Falls monitoring processes
- Name and contact details of allocated care home Falls Champion

Care homes randomised to the intervention:

Care Homes randomised to the intervention will receive the training as described in Section 6 of this Protocol.

Care homes randomised to usual care

Fall recording will be conducted as routinely performed in care homes for the duration of the study. Referral to community falls prevention services will be captured. After the 12 month follow up, control homes will get 1 GtACH training session and manual.

Participants (Care Home Residents)

Study regimen for residents who have consented to data collection is shown in the Assessment Timeline.

All residents at all care homes will participate in the following trial regimen.

All residents will be consented to participate or a consultee will give consultee advice on their behalf. A short version of the Participant Information Sheet will also be used by the researcher to explain the study to residents who are unable to consent in the presence of the consultee with the aim of getting assent of the resident wherever possible.

At baseline, and 3, 6, 9 and 12 months post randomisation, the following measures will be undertaken in the care home by the research assistant:

- Health related quality of life in dementia validated questionnaires for participant (where they have capacity to consent) (DEMQOL-U-5D), and completion by a member of care home staff(DEMQOL-P-4D)
- Validated heath assessment questionnaire for completion by participant(where they have capacity to consent) (EQ-5D-5L) and completion by a member of care home staffEQ-5D-5L)
- Physical activity and mobility in residential care questionnaire (PAM-RC)
  Validated questionnaire comprised of 2 domains – ability (2 questions assessing mobility and balance); activity (3 questions assessing walking frequency, wandering and outdoor mobility). Questionnaire will be completed by a member of care home staff who regularly cares for the participant.
- Activities of daily living assessment (Barthel index)

Validated 10 question questionnaire to assess participant's current level of ability for each of 10 activities of daily living. This will be completed by a member of care home staff who regularly cares for the participant.

Routinely collected data will be obtained from the following record source by the research assistant:

- Care home records (to collect data on falls, fractures, use of aids, health and social care service use, referral to secondary care, death).
- Incident report forms (alternative source of data on falls)
- Medication administration record (consent will be sought to allow clarification of medication data from GP records where necessary)
- Care home financial records to collect data on NHS funding received by the care home
- Hospital episode statistics (to collect data on deaths, fractures and type of fracture occurring in secondary care and from HSCIC)

Participants in intervention Homes

Care home staff will receive a 1 hour training session on the GtACH manual including assessments and actions delivered in small groups by Site Falls Leads. Care home staff who have attended the GtACH training will use the GtACH in the assessment and care planning of all residents. The risk identification and action checklists will be completed by the care home staff face to face with the participant. The risk identification checklist includes 33 fall risks in the domains of: fall history, medical history, movement/environment and personal needs. The action checklist includes 30 activities directly related to the assessment checklist that might reduce falls rates. Information sheets to support the actions have been produced by experts. These include medication use, medication reviews, nutrition, dehydration, incontinence, cognition, lighting of rooms, vision, trip hazards, equipment and fall sensors. Each component of the risk assessment and action checklists validated and indicated for use in routine practice, although this is the first systematic assessment and action toll that brings these elements together. The risk assessment takes up to 20 minutes. Implementation of the action checklist activities identified is anticipated to take between 20 minutes and 2 hours to implement.

If appropriate the results will be discussed with family, friends and other care home staff. GtACH documentation will be placed in the residents care records and updated when necessary. 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 initial assessment will take place in a private area of the care home. The ongoing actions could take place in any area of the care home.

The GtACH will ideally be completed within four weeks of randomization for all participants (within 2 weeks of staff training being completed in the care home if this has been delayed). 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.

Integrated Process Evaluation

A process evaluation will run concurrently during the implementation of the intervention as shown in trial schematic.

Six care homes where GtACH is being implemented will be purposively selected to take part in the process evaluation. Selection will be purposive to include:

1. Care homes without nursing provision; care homes with nursing provision (inc. care homes which offer intermediate care).
2. Small care homes (less than 20 beds); medium sized care homes (20-40 beds); larger care homes (more than 40 beds).
3. Independently owned care homes; corporate owned care homes.
4. Care homes in different locations (we will recruit in at least 4 or our geographic locations).

It is anticipated that there will be an even distribution in each category, for example: three care homes with nursing provision, three care homes without nursing provision, although this may change if outcome or process data indicates interest/value in focusing upon a particular characteristic(s) All staff and residents in these care homes who meet the eligibility criteria will be invited to participate in the process evaluation.

Observations, care home staff focus groups and stakeholder interviews will be undertaken:

- Observations will be undertaken to record the implementation of GtACH (frequency of observations will vary depending on the care home setting (e.g. number of residents, number of staff, etc.) but effort made to observe at least five staff on multiple occasions in each setting. It is anticipated that approximately 20 observations per care home will be undertaken during a 4-6 month window.

- Field notes will be made to record discussion of GtACH in staff meetings.

- 2 staff focus groups will take place in each evaluation care home. Focus group (1) following completion of the local GtACH training and (2) 3 months after the introduction of GtACH. All staff trained in the use of GtACH will be invited to participate in both focus groups. Where numbers dictate, multiple focus groups will be held in a care home to facilitate full participation.

- In each care home key stakeholders will be interviewed. This will include care home staff, Falls Leads, care home management and (when appropriate) care home residents (or resident/relative dyads). Interview topics will reflect upon stakeholder experience of using GtACH. At least 6 interviews will take place in each setting.

Observations, interviews and focus groups will be conducted by qualitative researchers trained in process evaluation.

At each of the 6 care homes recruited to participate in the process evaluation, care home staff in a caring role will be consented to permit researcher observations of the GtACH assessment and actions arising to residents, and to take field notes during staff meetings at which GtACH is discussed. Resident consent for observations will be collected during baseline consent and confirmed prior to each researcher observation.

Consent will be obtained prior to focus group participation and prior to stakeholder interviewers.

Participants in intervention Homes participating in the process evaluation.

Participants, or participant/consultee dyads, will be consented to allow researchers to observe the delivery of the GtACH assessment and actions arising.

Participants, or participant/consultee dyads, may be invited to participate in stakeholder interviews conducted by qualitative researchers trained in process evaluation. Interview topics will reflect upon stakeholder experience of being exposed to GtACH.

Assessment Timeline

RA Visit number	**1**	**2**		**3**	**4**	**5**	**6**	**7**
Visit timing		**Randomisation -4 weeks**	**0**	**3 months**	**6 months**	**9 months**	**12 months**	**13 months**
Visit	**Care Home Screening**	**Resident recruitment**	**Randomisation**	**FU1**	**FU2**	**FU3**	**FU4**	**Post study training**
Care home consent	X							
CQC assessment of care home characteristics	X							
Resident consent/consultee advice (as appropriate)		X						
Care home records and incident report forms assessed for falls #		X		X	X	X	X	
Physical activity and mobility in residential care (PAM-RC)		X		X	X	X	X	
Activities of daily living assessment (Barthel index)		X		X	X	X	X	
Quality of life assessment by DEMQOL-U-5D, DEMQOL-P-4D		X		X	X	X	X	
Heath assessment by EQ-5D-5L and EQ-5D-5L proxy		X		X	X	X	X	
Medication use on MAR sheets #		X		X	X	X	X	
Assessment of number of days in hospital #		X		X	X	X	X	
Care home records assessment of health and social care service use#		X		X	X	X	X	
GtACH Training of care home staff*				X – ideally within 2 weeks of randomisation				
GtACH assessment of residents**				X – ideally within 4 weeks of randomisation				
GtACH re-assessment***					X	X	X	
Process evaluation (observations, interviews focus groups) – Staff. Residents and Consultee				←	→			
HSCIC assessment of fractures and death records#							X	
GtACH training in care home for control practices								X

*GtACH training in care home should ideally take place within 2 weeks of randomisation, for those in the intervention arm

**GtACH assessment of residents should ideally take place within 4 weeks of resident randomisation and after GtACH training in care home, for those in the intervention arm
***GtACH re-assessment scheduled to occur every 3-6 months, or with a change in medical or cognitive condition, or with any fall, for those in the intervention arm
#Routinely collected data.

8.1 Compliance

Care home records for all care homes randomised to the intervention will be reviewed by the Falls Lead during the first three months post randomisation GtaCH training and implementation period to consider broad compliance with GtACH. Evidence that the GtACH manual is accessible; that the GtACH poster is displayed; and that GtACH paperwork is attached to care records, will be sought as part of this evaluation.

Compliance with the intervention will also be evaluated as part of the process evaluation.

8.2 Criteria for terminating trial

Recruitment will be undertaken over a 12 month period, and recruitment progress will be reviewed at 6 months following start of recruitment. A stop / go time point at month 6 of the recruitment phase will be applied this will be the successful recruitment of 33 care homes and 654 residents. The Trial Management Group (TMG) and the Trial Steering Committee (TSC) will review recruitment targets, training of care home staff and delivery of the GtACH intervention. Strategies to increase recruitment and adherence will be implemented if required. After six months the TSC will formally review recruitment and provide recommendations. The sponsor and funder reserve the right to discontinue this study at any time for failure to meet expected recruitment goals, for safety or any other administrative reason. The Sponsor and Funder shall take advice from the TSC as appropriate in making this decision. Should the trial be terminated, the research data will not be destroyed.

In the event a care home withdraws participation (or is unable to continue following a regulatory inspection) after randomisation, the care home will not be replaced. The care home will be made aware that data collected on the care home AND participants at that care home to date cannot be erased and may still be used in the final analysis. Participants will be advised that their care home has withdrawn participation.

9. ANALYSIS

9.1 Statistical Analysis

9.1.1 Methods

Analyses will be undertaken on an intention to treat basis (White 2011) in that care homes will be analysed in the group to which they were allocated regardless of their compliance with the intervention. Data will be analysed according to a pre-specified analysis plan. Two-sided tests will be used to test statistical significance at the 5% level. Baseline characteristics of care homes and residents, outcome measures at baseline and each follow up time point will be summarized by treatment arm using descriptive statistics. The baseline fall rate will be expressed as the number of falls per 1,000 resident days for each group.

9.1.2 Sample size and justification

This is based on the primary outcome of falls rate over the 3 month period, months 4, 5 and 6, post randomisation. Assuming a falls rate of 2.5 falls per year (0.625 falls in 3 months) in the control group (Whitney 2012b), 80% power and a two-sided significance level of 5%, 189 residents per group are required in order to detect a 33% reduction in falls rate in the intervention group. The sample size has been calculated using the Whitney study as the feasibility study population on which the sample size calculation was based, had a falls rate of 15 falls per year (Walker 2015) but only recruited residents who had fallen recently. The adjustment for clustering assumes an average cluster size of 20 residents (Dyer 2004) and an intra-cluster coefficient (ICC) of 0.1 (Dyer 2004), giving a sample size of 549 residents per

group. Incorporating a further 16% to the sample size to account for potential attrition (Gordon 2014), the aim is to recruit a total of 1308 residents (654 to intervention group and 654 to control group).

9.1.3 Assessment of efficacy

The primary outcome is the rate of falls per participant in the 3 months prior to 6 months post randomisation. This will be collected at the 6 month time point. Data will be collected from care home records and incident report forms.

The primary outcome, rate of falling over the 3 month period prior to 6 months post-randomisation, will be expressed as the number of falls per 1,000 resident days for each group. The number of falls per resident will be compared between groups using a two-level Poisson or negative binomial model with resident at level one and care home at level two, with length of residence in care home as an offset. The primary analysis will adjust for type of care home (residential, nursing, dual registration) and site. Two additional models will be fitted in order to assess the robustness of the model. In addition to adjusting for care home type and site, these will adjust for i) baseline fall rate; ii) baseline fall and other variables that are associated with falling (these are to be confirmed after discussion with the trial IDMC). Fall rates during the 3 month period prior to 9 and 12 month follow-up will be analysed and presented in the same way as for the primary outcome variable. For other secondary outcomes, groups will be compared using multi-level regression analysis for continuous outcomes and multi-level logistic regression for binary outcomes. .

9.1.4 Assessment of safety

Primary and secondary efficacy variables identified as safety endpoints will be analysed as detailed above.

9.1.5 Procedures for missing, unused and spurious data

The primary analysis will be based on the ITT population. The amount and distribution of missing data will be examined to determine the type of missing data. Multiple imputations will be used to impute data if data are missing at random unless the pattern suggests an alternative approach would be more appropriate (Yang 2002). If data are missing at random and the amount of missing data is small (less than 15%), imputations may not be required. This will be detailed in full in the Statistical Analysis Plan.

9.1.6 Definition of populations analysed

Populations to be analysed will be the care homes (and corresponding participants) in the group to which they were allocated regardless of their compliance with the intervention.

9.2 Economic evaluations

A within trial economic evaluation will be used to estimate the cost effectiveness of the GtACH approach to preventing falls compared to no such approach in UK care homes. An NHS and personal social services perspective will be adopted as used in the NICE reference case (NICE 2013). We will identify and measure resources used to deliver the intervention, as well as wider resource use that may change as a consequence of the intervention being delivered. Resource use will be captured from care home records at baseline, 3, 6, 9 and 12 months and valued using published unit costs for the most recent price year. A cost-effectiveness analysis using the primary trial outcome, fall rates and a cost utility analysis

measuring change in Quality Adjusted Life Years (QALYs) will be conducted. The health-related quality of life aspect will be measured using the EQ-5D-5L (where available) and EQ-5D-5L proxy (Herdman 2011) and the DEMQOL-U(where available) and DEMQOL-P-U as recommended by Mulhern (Mulhern 2013, Rowen et al., 2012). Both versions of the forms will be collected where possible for each participant and used for analysis. The choice to use both quality of life measures reflects the fact that the utility value sets, DEMQOL-U and DEMQOL-P-U, have only recently been published so have not been extensively used or validated as yet in funded trials. We are aware from previous research that measuring HRQL in care home populations can be problematic in terms of achieving good response rates due to high cognitive impairment (Gordon et al., 2010), however, the EQ-5D-5L has successfully been used in a care home population to inform the economic evaluation of exercise for depression (Underwood 2013).
A feasibility study showed that residents with capacity were accepting of completion of a relative self-report measure; the Barthel ADL (Collin 1988) and care staff were accepting of proxy completion. QALYs will be estimated using linear interpolation and area under the curve analysis with baseline adjustment (Ramsey 2015 and Manca 2005). Neither costs nor benefits will be discounted reflecting the 12 month time horizon of the trial. Since this economic evaluation will be undertaken alongside a cluster randomised trial the analysis will reflect the increased uncertainty of randomising clusters rather than individuals. A number of approaches have been proposed for this, with each found to generate similar findings (Gomes 2012b, Gomes 2012a, Bachmann 2007). Where appropriate (i.e. where costs and effects are greater or costs and effects are lower) an Incremental Cost Effectiveness ratio (ICER) will be estimated to compare the costs and QALYs with and without the GtACH approach. Non-parametric bootstrapping will be used to explore decision uncertainty, which will be explored graphically on the cost effectiveness plane and using cost-effectiveness acceptability curves.
A full health economics Analysis Plan (HEAP) will be developed between the trial health economist and Chief Investigator and agreed with the trial's governance committees.

9.3 Within trial concurrent process evaluation.

9.3.1 Process evaluation objectives.

The process evaluation will: 1) consider fidelity of GtACH in training and operation (i.e. is it delivered and used as intended?), 2) identify contextual influences which impact upon GtACH (i.e. what local factors facilitate or inhibit GtACH use) and, 3) consider acceptability of GtACH to care home staff and residents (i.e. do key stakeholders value GtACH).

9.3.2 Process evaluation design.

This is a multi-method process evaluation which will run concurrently with the main trial. Informed by the principles of realist evaluation it will focus upon a small number of sites where GtACH is being trialled to develop a detailed understanding of its implementation and outcomes in these settings.

9.3.3 Data collection.

At each site [n=6] data will be collected using a combination of fidelity checklists, observational diaries, staff focus groups and interviews with staff and residents.

- Fidelity checklists will be used to record GtACH training.
- Fidelity checklists and observational diaries will be used to record the implementation of GtACH. The number of observations will vary depending on the care home setting (e.g. number of residents, number of staff, etc.) but effort made to observe at least five staff on multiple

occasions in each setting, giving an estimated 20 observations per site undertaken over a 4-6 month window.

- Additional field notes will be made to record discussion of GtACH in staff meetings and to record evidence of GtACH in care homes (e.g. in care home records, display of FinCH poster, display of GtACH manual etc.).

- 2 staff focus groups will take place in each evaluation care home. Focus group (1) following completion of the local GtACH training and (2) 3 months after the introduction of GtACH. All staff trained in the use of GtACH will be invited to participate in both focus groups. Where numbers dictate multiple focus groups will held in a care home to facilitate full participation.

- In each care home key stakeholders will be interviewed. This will include care home staff, Falls Leads, care home management and (when appropriate) care home residents (or resident/relative dyads). Interview topics will reflect upon stakeholder experience of using / being exposed to GtACH. At least 6 interviews will take place in each setting.

10. ADVERSE EVENTS

Adverse events (serious and non-serious) will not be collected in this study.

This is a low risk intervention. No specific risks, untoward incidents or adverse events were reported during feasibility work. The GtACH tool provides recommendation that actions are taken but does not stipulate what that action is other than recommend referral to health professionals as appropriate. If residents become distressed during the GtACH assessment or in actions, the process will be halted and event recorded and closely monitored until resolution, stabilisation, or until it has been shown that the study intervention is not the cause. The participant has the right to decline any intervention at any time.

Gentle exercises are one of the 30 activities included in the action checklist. If gentle exercises are recommended after the assessment the Care Home is advised to refer the resident to a Physiotherapist in order that a programme of exercise can be put in place. It is possible that participants might suffer an injury that they would not have if they had not taken part in the exercise. These will be recorded and monitored by the Fall Champion in the care home. If there is any concern the Falls Champion will refer to the Falls Lead for advice. If needed the exercises will be stopped.

Fall rates will be monitored for harm and reported to the IDMC and TSC every three months after they have been collected. The IDMC and TSC have the ability to recommend changes to the study protocol if fall rates are substantially higher than expected. The IDMC will review unblinded safety data including reported frequencies of primary and secondary outcomes by treatment arm every three months. This will be provided by the NCTU via a secure email.

As GtACH is copyrighted by Nottingham, Nottingham would be responsible for any issues which arise due to the design of the intervention, training given to Care Homes or any issues with the tool itself. However, in respect of the use of this in Care Homes, the Care Home would be responsible if the tool was incorrectly used. Care Homes will be requested to confirm that they have indemnity for this and, if the indemnity does not include Research, Care Homes will

be requested to seek indemnity from their insurance providers, making clear that all individual components of GtACH are currently used in routine care but in a consistent or structured manner.

10.1 Participant removal from the study due to adverse events

GtACH assessments and or actions may be stopped in the event that the participant shows evidence of distress. This will be documented. However the participant will not be withdrawn from the study.

11. ETHICAL AND REGULATORY ASPECTS

11.1 ETHICS COMMITTEE AND REGULATORY APPROVALS

The trial will not be initiated before the protocol, informed consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), and the respective National Health Service (NHS) Research & Development (R&D) department. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The trial will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the Department of Health Research Governance Framework for Health and Social care, 2005.

11.2 INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent or consultee advice will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. The investigator or their nominee and the participant or consultee shall both sign and date the Informed Consent Form/Consultee Advice Form before the person can participate in the study.

The resident or consultee will receive a copy of the signed and dated forms and the original will be retained in the Site File. A copy of the signed form will also be sent to Norwich Clinical Trials Unit who will verify that the form is correctly completed and will then destroy the form. Copies will also be filed in the participant's care home notes together with a signed and dated note made in the notes that informed consent was obtained for the trial, and in the care home file study file. Staff participants will receive a copy of the signed and dated forms, the original will be retained in the Site File, a second copy will be saved in the care home study file and a third copy will be sent to Norwich Clinical Trials Unit.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled. No trial-specific interventions will be done before informed consent has been obtained.

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the Informed Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Informed Consent Form by the REC and use of the amended form (including for ongoing participants).

11.3 RECORDS

11.3.1 Case Report Forms

Each participant will be assigned a trial identity code number, allocated at randomisation if appropriate, for use on CRFs, questionnaires, work books and other trial documents and the electronic database. The documents and database will also use their initials (of first and last names separated by a hyphen or a middle name initial when available) and date of birth (dd/mm/yy). The Trial identify code number will be a 7 digit number comprising of site number, care home number and participant number.

CRFs will be treated as confidential documents and held securely in accordance with regulations. The investigator will make a separate confidential record of the participant's name, date of birth, local hospital number or NHS number, and Participant Trial Number (the Trial Recruitment Log), to permit identification of all participants enrolled in the trial, in accordance with regulatory requirements and for follow-up as required. For each care home, a copy will be held at the care home and also at the corresponding site.

CRFs shall be restricted to those personnel approved by the Chief or local Principal Investigator and recorded on the 'Trial Delegation Log.'

CRFs are used to record consent, assent and clinical trial data and are an integral part of the study and subsequent reports. The CRFs, therefore, must be legible and complete.

All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialled and dated.
The Chief or local Principal Investigator shall sign a declaration ensuring accuracy of data recorded in the CRF.

11.3.2 Source documents

Participating investigators and care home managers must agree to allow trial related monitoring, including audits, by providing access to source data and other trial related documentation as required. Participant (or consultee where appropriate) consent for this will be obtained as part of the informed consent process for the trial.

A CRF may also completely serve as its own source data. Only trial staff as listed on the Delegation Log shall have access to trial documentation other than the regulatory requirements listed below. Sites will also retain a copy of the consent form, participant and consultee contact details and questionnaires completed by participants/consultee.

11.3.3 Direct access to source data / documents

The CRF and all source documents, including progress notes, shall made be available at all times for review by the Chief Investigator, Sponsor's designee and inspection by relevant regulatory authorities (as appropriate).

11.4 DATA PROTECTION

All trial staff and investigators will endeavour to protect the rights of the trial's participants to privacy and informed consent, and will adhere to the Data Protection Act, 1998. The CRF will only collect the minimum required information for the purposes of the trial. CRFs will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the trial staff and investigators and relevant regulatory authorities (see above). Computer held data including the trial database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one way encryption method).
Information about the trial in the participant's care home records will be treated confidentially in the same way as all other confidential medical information.

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

12. QUALITY ASSURANCE & AUDIT

12.1 INSURANCE AND INDEMNITY

Insurance and indemnity for trial participants and trial staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but trial participants may have recourse through the NHS complaints procedures.

The University of Nottingham as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials insurance. These policies include provision for indemnity in the event of a successful litigious claim for proven non-negligent harm.

12.2 TRIAL CONDUCT

Trial conduct may be subject to systems audit of the Trial Master File for inclusion of essential documents; permissions to conduct the trial; Trial Delegation Log; CVs of trial staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, correct randomisation, timeliness of visits); and accountability of trial materials.

12.3 TRIAL DATA

Monitoring of trial data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. Monitoring will be undertaken using centralised monitoring techniques. Where one or more criteria are met as defined in the Quality Management and Monitoring Plan on site monitoring will be undertaken. Norwich Clinical Trials Unit, nominated designee of the Sponsor, shall carry out monitoring of trial data as an ongoing activity.

Entries on CRFs will be verified by inspection against the source data. A sample of CRFs (10% or as per the study risk assessment) will be checked on a regular basis for verification of all entries made. In addition the subsequent capture of the data on the trial database will be checked. Where corrections are required these will carry a full audit trail and justification.

Trial data and evidence of monitoring and systems audits will be made available for inspection by REC as required.

12.4 RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Research Code of Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The Trial Master File and trial documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all trial databases and associated meta-data encryption codes.

12.5 DISCONTINUATION OF THE TRIAL BY THE SPONSOR

The Sponsor reserves the right to discontinue this trial at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice from the Trial Steering Committee and Data Monitoring Committee as appropriate in making this decision.

12.6 STATEMENT OF CONFIDENTIALITY

Individual participant medical and personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.
Participant confidentiality will be further ensured by utilising identification code numbers to correspond to treatment data in the computer files.

Such medical information may be given to the participant's medical team and all appropriate medical personnel responsible for the participant's welfare.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

13. PUBLICATION AND DISSEMINATION POLICY

The results of the trial will be reported first to the trial collaborators. The main report will be drafted by members of the Trial Management Group, and the final version will be agreed by the Trial Steering Committee before submission for publication, on behalf of the collaboration. The trial will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines. All publications will be subject to the forthcoming FinCH publications protocol, which will explicitly stipulate the requirements for authorship of publications. Findings will be disseminated to academic audiences through publication in academic journals and presentations at academic conferences. 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. Oral/poster presentations and workshops at sponsor hosted events, community meetings and professional/stake holder/user conferences will be targeted. The results of the trial will be disseminated regardless of the direction of effect.

The study team will seek to disseminate in a way to support best practice. They will liaise with ProFouND (The Prevention of Falls Network for Dissemination) and EnRICH to identify

potential research users, other researchers, policy makers, commissioners, clinicians, care home managers and staff, care home residents and relatives. JG is the lead for the programmes related to older people in Collaboration for Leadership in Applied Health Research and Care East Midlands and the East Midlands Academic Health Sciences Network which will enable dissemination through these regional and national networks and to prepare for subsequent adoption at pace and scale. Dissemination outputs will be tailored towards each group including peer reviewed journal articles, evidence summaries, briefing papers, video clips and a DVD. 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. 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 University of Nottingham Rehabilitation and Ageing divisional website.

14. USER AND PUBLIC INVOLVEMENT

A care home manager and user and public involvement representative will sit on the Trial Management Group. They will contribute to writing documents, study management, recruitment, finance, interpretations of findings and dissemination of outcomes. The Principal Investigator for each site will liaise with local PPI groups who will be asked to check documents for local nuances. Changes will be reviewed by the user and public involvement representatives to ensure they comply with the study protocol. PPI member will be appointed to the Trial Steering Committee acting as an independent and valuable member. Funding has been included as part of the HTA award for all PPI involvement.

15. STUDY FINANCES

15.1 Funding source

This study is funded by National Institute for Health Research HTA Programme (NIHR HTA Project 13/115/29) is providing funding for research costs for the project duration to cover trial set up, trial conduct, analysis and report writing.

15.2 Care Home stipends and payments

Care homes will receive £200 for participating in the trial, £100 after recruitment of participants/consultees and collection of baseline data; £100 after collection of all outcome data.

15.3 Participant stipends and payments

Participants will not be paid to participate in the trial.

16. SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: (name) PHILIPPA A LOGAN.

Signature: Philippa Logan

Date: 7/8/17

Co- investigator: (name) Ann Swart

Signature: AS

Date: 17/7/17.

Trial Statistician: (name) Sarah Armstrong

Signature: SArmstrong

Date: 04/08/17

17. REFERENCES

AL-FAISAL, W. 2006. Falls Prevention for Older Persons. Eastern Mediterranean Regional Review [Online]. Available: http://www.who.int/ageing/projects/EMRO.pdf.

BACHMANN, M. O., FAIRALL, L., CLARK, A. & MUGFORD, M. 2007. Methods for analyzing cost effectiveness data from cluster randomized trials. Cost effectiveness and resource allocation, 5, 12.

BECKER, C., KRON, M., LINDEMANN, U., STURM, E., EICHNER, B., WALTER-JUNG, B. & NIKOLAUS, T. 003 .Effectiveness of a multifaceted intervention on falls in nursing home residents. Journal of American Geriatric Society, 51, 306-13.

BOUWEN, A., DE LEPELEIRE, J. & BUNTINX, F. 2008. Rate of accidental falls in institutionalised older people with and without cognitive impairment halved as a result of a staff-oriented intervention. Age and Ageing, 37, 306-10.

CAMERON, I. D., GILLESPIE,L. D., ROBERTSON, M. C.,MURRAY, G. R., HILL, K.D.,CUMMING, R. G. & KERSE, N. 2012. Interventions for preventing falls in older people in care facilities and hospitals. Cochrane Database of Systematic Reviews, 12.

CAMPBELL, M. K., PIAGGIO, G., ELBOURNE, D. R. & ALTMAN, D. G. 2012. Consort 2010 statement: extension to cluster randomised trials. BMJ: British Medical Journal, 345.

CARPENTER GI & M.,C. 1997. MDS/RAI provides real hope as an assessment model for older people. The Health Services Journal, 107, 20-26.

CHAN AW, Tetzlaff JM, Altman DG et Al. SPIRIT 2013 Statement: Defining Protocol Items for Clinical Trials. *Ann Intern Med* 2013; 158:200-207.

CHAN AW, Tetzlaff, Gotzsche et Al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ* 2013; 346: e7586.

CLARKE, D. J., GODFREY, M., HAWKINS, R., SADLER, E., HARDING, G., FORSTER, A., MCKEVITT, C., DICKERSON, J. & FARRIN, A. 2013. Implementing a training intervention to support caregivers after stroke: a process evaluation examining the initiation and embedding of programme change. Implementation Science, 8, 1-96.

CLOSE, J. C. T. 2005. Prevention of falls-a time to translate evidence into practice. Age and Ageing, 34, 98-100.

COLLIN, C., WADE, D. T., DAVIES, S. & HORNE, V. 1988. The Barthel ADL Index: a reliability study. Disability and Rehabilitation, 10, 61-63.

COMET. 2005. Development of a common outcome data set for fall injury prevention trials: the Prevention of Falls Network Europe consensus [Online]. [Accessed 31st March 2015].

COX, H., PUFFER, S., MORTON, V., COOPER, C., HODSON, J., MASUD, T., OLIVER, D., PREEDY, D., SELBY, P., STONE, M., SUTCLIFFE, A. & TORGERSON, D. 2008. Educating nursing home staff on fracture prevention: a cluster randomised trial. Age and Ageing, 37, 167-172.

DEPARTMENT OF HEALTH 2005. Research Governance Framework for Health and Social Care. Second Edition ed.www.dh.gov.uk: Crown Copyright.

DEVINE, A. M., TAYLOR, S. J. C., SPENCER, A., DIAZ-ORDAZ, K., ELDRIDGE, S. & UNDERWOOD, M. 2013. OP77 Proxy Reporting of Health-Related Quality of Life using the Euroqol-5D in Care Home Residents; how Good is it and how should we Deal with Clustering Effects? Journal of Epidemiology and Community Health, 67, A36-A37.

DH SCIENTIFIC DEVELOPMENT AND BIOETHICS DIVISION 2008. Guidance on nominating a consultee for research involving adults who lack capacity to consent. London: Crown copyright

DRABBLE, S. J., CATHAIN, A. O., THOMAS, K. J., RUDOLPH, A. & HEWISON, J. 2014. Describing qualitative research undertaken with randomised controlled trials in grant proposals: a documentary analysis. BMC Medical Research Methodology, 14.

DYER,C.A.E., TAYLOR,G.J., REED,M., DYER,C.A., ROBERTSON,D.R. & HARRINGTON,R. 2004. Falls prevention in residential care homes: a randomised controlled trial. Age and Ageing, 33, 596-602.

FLETCHER,P.C., GUTHRIE,D.M., BERG,K. & HIRDES,J.P. 2010.Risk factors for restriction in activity associated with fear of falling among seniors within the community. Journal of Patient Safety, 6, 187-191.

GAGE,H., DICKINSON,A., VICTOR,C., WILLIAMS,P., CHEYNEL,J., DAVIES,S.L., ILIFFE,S., FROGGATT, K., MARTIN, W. & GOODMAN, C. 2012. Integrated working between residential care homes and primary care: a survey of care homes in England. BMC Geriatrics, 12, 71.

GILLESPIE, L. D., ROBERTSON, M. C., GILLESPIE, W. J., SHERRINGTON, C., GATES, S., CLEMSON, L. M. & LAMB, S. E. 2012. Interventions for preventing falls in older people living in the community. Cochrane Database of Systematic Reviews, 9, 1-416.

GOMES,M., GRIEVE,R., NIXON,R. & EDMUNDS,W. 2012a. Statistical Methods for Cost-Effectiveness Analyses That Use Data from Cluster Randomized Trials A Systematic Review and Checklist for Critical Appraisal. Medical Decision Making, 32, 209-220.

GOMES, M., NG, E. S.-W., GRIEVE, R., NIXON, R., CARPENTER, J. & THOMPSON, S. G. 2012b. Developing appropriate methods for cost-effectiveness analysis of cluster randomized trials. Medical Decision Making, 32, 350-361.

GOODMAN, C., DRENNAN, V., SCHEIBL, F., SHAH, D., MANTHORPE, J., GAGE, H. & ILIFFE, S. 2011. Models of inter professional working for older people living at home: a survey and review of the local strategies of English health and social care statutory organisations. BMC Health Service Research, 11, 1-337.
GORDON,A., ROBBINS,I., GLADMAN,J.R.F., AVERY,A.J. & LOGAN,P.A. 2010. Care Home Outcome Study (CHOS). University of Nottingham

GORDON, A. L., FRANKLIN, M., BRADSHAW, L., LOGAN, P., ELLIOTT, R. & GLADMAN, J. R. 2014. Health status of UK care home residents: a cohort study. Age Ageing, 43, 97-103.

HEINRICH, S., RAPP, K., RISSMANN, U., BECKER, C. & KÖNIG, H.-H. 2010. Cost of falls in old age: a systematic review. Osteoporosis International, 21, 891-902.

HERDMAN, M., GUDEX, C., LLOYD, A., JANSSEN, M. F., KIND, P., PARKIN, D., BONSEL, G. & BADIA, X. 2011. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D5L). Quality of Life Research, 20, 1727-1736.

HOFFMANN,T.C.,GLASZIOU,P.P.,BOUTRON,I.,MILNE,R.,PERERA,R.,MOHER,D.,ALTMAN,D.G., BARBOUR, V., MACDONALD, H., JOHNSTON, M., LAMB, S. E., DIXON-WOODS, M., MCCULLOCH, P., WYATT, J. C., CHAN, A. W. & MICHIE, S. 2014. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ, 348, g1687.

HOPEWELL,S., HIRST,A., COLLINS,G.S., MALLETT,S., YU,L.-M. & ALTMAN,D.G. 2011. Reporting of participant flow diagrams in published reports of randomized trials. Trials, 12, 253.

JENSEN, J., Lundin-Olsson L, Nyberg L, Gustafson Y. Fall and injury prevention in older people living in residential care facilities. A cluster randomized trial. Ann Intern Med 2002:136:733-41

JENSEN, J., NYBERG, L., GUSTAFSON, Y. & LUNDIN-OLSSON, L. 2003. Fall and injury prevention in residential care-effects in residents with higher and lower levels of cognition. Journal of American Geriatric Society, 51, 627-635.

JENSEN, J., NYBERG, L., ROSENDAHL, E., GUSTAFSON, Y. & LUNDIN-OLSSON, L. 2004. Effects of a fall prevention program including exercise on mobility and falls in frail older people living in residential care facilities. Ageing Clinical and Experimental Research, 16, 283-292.

JENSEN, L. E. & PADILLA, R. 2011. Effectiveness of interventions to prevent falls in people with Alzheimer's disease and related dementias. The American Journal of Occupational Therapy, 65,532-540.

KANNUS,P., SIEVÄNEN,H., PALVANEN,M., JÄRVINEN, T. & PARKKAR I, J.2005. Prevention of falls and consequent injuries in elderly people. The Lancet, 366, 1885-1893.

KERSE,N.,KATHYPERI,K.,ROBINSON,E.,WILKINSON,T.,VONRANDOW,M.,KIATA,L.,PARSONS,J., LATHAM, N., PARSONS, M., WILLINGALE, J., BROWN, P. & ARROLL , B. 2008. Does a functional activity programme

improve function, quality of life, and falls for residents in long term care? Cluster randomised controlled trial BMJ 337.

LAING BUISSON. 2009. Care of the Elderly People Market Survey, 2009. Available: www.laingbuisson.co.uk.

LARSON, L. & BERGMANN, T. F. 2008. Taking on the fall: the etiology and prevention of falls in the elderly. Clinical Chiropractic, 11, 148-154.

LEIBSON, C. L., TOSTESON, A. N., GABRIEL, S. E., RANSOM, J. E. & MELTON, L. J. 2002. Mortality, disability, and nursing home use for persons with and without hip fracture: a population based study. Journal of American Geriatric Society, 50, 1644-50.

LOGAN PA & ROBERTSON K 2010. Does identifying fall risk factors lead to appropriate interventions? .IAGG. Bolongna, Italy.

MANCA A, HAWKINS N, SCULPHER MJ. Estimating mean QALYs in trial-based cost-effectiveness analysis: the importance of controlling for baseline utility. Health Econ. 2005 May;14 (5): 487-96.

MOORE G, A. S., BARKER M, BOND L, BONELL C, HARDEMAN W, MOORE L, O'CATHAIN A, TINATI T, WIGHT D, BAIRD J. 2014. Process evaluation of complex interventions: Medical Research Councilguidance.2014 MRC Population Health Science Research Network.

MULHERN,B.,ROWEN,D.,BRAZIER,J.,SMITH,S.,ROMEO,R.,TAIT,R.,WATCHURST,C.,CHUA,K.C., LOFTUS, V. & YOUNG, T. 2013. Development of DEMQOL-U and DEMQOL-Proxy-U: Generation of preference-based indices from DEMQOL and DEMQOL-Proxy for use in economic evaluation. Health Technology Assessment, 17, 1-160.

NATIONAL INSTITUTE FOR HEALTH RESEARCH 2011. A pocket guide to good clinical practice, including the declaration of helsinki., Leeds, National Institute for Health Research.

NAYLOR,C.,IMISON,C.,ADDICOTT,R.,BUCK,D.,GOODWIN,N.,HARRISON,T.,ROSS,S.,SONOLA,L., TIAN, Y. & CURRY, N. 2013. Transforming our health care system: Ten priorities for commissioners. The King's Fund; Ideas that change healthcare [Online]. Available: http://www.kingsfund.org.uk/sites/files/kf/field/field_publication_file/10PrioritiesFinal2.pdf [Accessed 5th of December 2013].

NICE. 2015. Falls in older people: assessment after a fall and preventing further falls.
NICE: NATIONAL INSTITUTE OF CLINICAL EXCELLENCE. 2013. Guide to the methods of technology appraisal. . Available: http://www.nice.org.uk/media/D45/1E/GuideToMethodsTechnologyAppraisal2013.pdf.

NICOLA K GALE1*, G. H., ELAINE CAMERON3, SABINA RASHID4 AND SABI REDWOOD2 2013. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Medical Research Methodology 13, 117.

O'CATHAIN,A.,GOODE,J.,DRABBLE,S.J.,THOMAS,K.J.,RUDOLPH,A.&HEWISON,J.2014.Getting added value from using qualitative research with randomized controlled trials: a qualitative interview study. Trials, 15.

O'CATHAIN A, T. K., DRABBLE SJ, ET AL. 2013. What can qualitative research do for randomised controlled trials? A systematic mapping review. BMJ Open, BMJ Open 2013; 3: e002889. doi:10.1136/bmjopen-2013-002889. OFFICE OF PUBLIC SECTOR INFORMATION 2005. Mental Capacity Act.

OLIVER, D., CONNELLY, J. B., VICTOR, C. R., SHAW, F. E., WHITEHEAD, A., GENC, Y., VANOLI, A., MARTIN, F. C. & GOSNEY, M. A. 2007. Strategies to prevent falls and fractures in hospitals and care homes and effect of cognitive impairment: systematic review and meta-analyses. BMJ,334,82.

OLIVER, D., DALY, F., MARTIN, F. C. & MCMURDO, M. E. T. 2004. Risk factors and risk assessment tools for falls in hospital in-patients: a systematic review. Age and Ageing, 33, 122-130.

OLIVER,D. & HEALY,F. 2009. Falls risk prediction tools for hospital in patients: do they work. Nursing Times, 105, 18-21.

OLIVER, D., HOPPER, A. & SEED, P. 2000. Do hospital fall prevention programs work? A systematic review. Journal of American Geriatric Society, 48, 1679-1689.

PITKALA KH, POYSTI MM, LAAKKONEN ML, TILVIS RS, SAVIKKO N, KAUTIAINEN H & TE., S. 2013. Effects of the Finnish Alzheimer disease exercise trial (FINALEX): a randomized controlled trial. JAMA InternMed, 173, 894-901.

RAMSEY SD, WILLKE RJ, GLICK H, REED SD, AUGUSTOVSKI F, JONSSON B, BRIGGS A, SULLIVAN SD. Cost-effectiveness analysis alongside clinical trials II-An ISPOR Good Research Practices Task Force report. Value Health. 2015 Mar;18 (2): 161-72.

RAPP, K., BECKER, C., CAMERON, I. D., KÖNIG, H.-H. & BÜCHELE, G. 2012. Epidemiology of falls in residential aged care: analysis of more than 70,000 falls from residents of bavarian nursing homes. Journal of the American Medical Directors Association, 13, 187 .e1-187.e6.

RAPP, K., LAMB, S. E., KLENK, J., KLEINER, A., HEINRICH, S., KÖNIG, H.-H., NIKOLAUS, T. & BECKER, C. 2009. Fractures after nursing home admission: incidence and potential consequences. Osteoporosis International, 20, 1775-1783.

ROBBINS,I., GORDON,A., DYAS,J., LOGAN,P.A. & GLADMAN,J. 2013.Explaining the barriers to and tensions in delivering effective healthcare in UK care homes: a qualitative study. BMJ Open, 3,10.

ROBERTSON K, LOGAN P, WARD M, POLLARD J, GORDON A, WILLIAMS W & J, W. 2012. Thinking falls-taking action: a falls prevention tool for care homes. BrJCommunityNurs..17, 206-9.

ROBERTSON, K., LOGAN, P., WARD, M., POLLARD, J., GORDON, A., WILLIAMS, W. & WATSON, J. 2012. Thinking falls-taking action: a falls prevention tool for care homes. British Journal of Community Nursing,17,206-209.

ROSPA: THE ROYAL SOCIETY FOR THE PREVENTION OF ACCIDENTS. 2013. Delivering Accident Prevention at local level in the new public health system. Part1:Context [Online].Available: http://www.rospa.com/about/currentcampaigns/publichealth/info/delivering-accidentprevention-context.pdf [Accessed 5th December2013].

ROWEN, D., MULHERN, B., BANERJEE, S., VAN HOUT, B., YOUNG, T. A., KNAPP, M., SMITH, S. C., LAMPING,D.L. & BRAZIER,J.E.2012. Estimating preference-based single index measures for dementia using DEMQOL and DEMQOL-Proxy. Value in health, 15, 346-356.

SACKLEY,C.M., WALKER,M. F., BURTON, C.R.,WATKINS, C. L.,MANT,J., ROALFE, A. K., WHEATLEY, K., SHEEHAN,B., SHARP,L., STANT,K.E., FLETCHER-SMITH,J., STEEL,K., WILDE,K., IRVINE,L. & PERYER, G. 2015. An occupational therapy intervention for residents with stroke related disabilities in UK care homes (OTCH): cluster randomised controlled trial. British Medical Journal, 350.

SCUFFHAM, P., CHAPLIN, S. & LEGOOD, R. 2003. Incidence and costs of unintentional falls in older people in the United Kingdom. Journal of Epidemiology and Community Health, 57, 740-4.

SHAH,S.M., CAREY,I.M., HARRIS,T., DEWILDE,S. & COOK, D.G. 2013. Mortality in older care home residents in England and Wales. Age and Ageing, 42, 209-215.

SHAW, F. E., BOND, J., RICHARDSON, D. A., DAWSON, P., STEEN, I. N., MCKEITH,I. G. & KENNY, R. A. 2003. Multifactorial intervention after a fall in older people with cognitive impairment and dementia presenting to the accident and emergency department: randomised controlled trial. bmj, 326, 73.

UNDERWOOD, M., LAMB, S. E., ELDRIDGE, S., SHEEHAN, B., SLOWTHER, A. M., SPENCER, A., THOROGOOD, M., ATHERTON, N., BREMNER, S. A., DEVINE, A., DIAZ-ORDAZ, K., ELLARD, D. R., POTTER, R., SPANJERS, K. & TAYLOR, S. J. 2013. Exercise for depression in elderly residents of care homes: a cluster-randomised controlled trial. Lancet, 382, 41-49.

WADE, D. & COLLIN, C. 1988. The Barthel ADL Index: a standard measure of physical disability? Disability & Rehabilitation, 10, 64-7.

WALKER, G. M., ARMSTRONG, S., GORDON, A. L., JOHN GLADMANA, ROBERTSON, K., WARD, M.,CONROY, S.,ARNOLD, G.,DARBY, J.,FROWD, N.,WILLIAMS, W.,KNOWLES, S.&LOGAN,P.A. 2015. The Falls In Care Home study (FICH): A feasibility randomised controlled trial of the use of a risk assessment and decision support tool to prevent falls in care homes. Clinical Rehabilitation under review.

WHITE, I. R., HORTON, N. J. & CARPENTER, J. 2011. Strategy for intention to treat analysis in randomised trials with missing outcome data.BMJ,342.

WHITNEY, J., CLOSE, J. C. T., JACKSON, S. H. D. & LORD, S. R. 2012a. Understanding Risk of Falls in People With Cognitive Impairment Living in Residential Care. Journal of the American Medical Directors Association, 13, 535-540.

WHITNEY, J., CLOSE, J. C. T., LORD, S. R. & JACKSON, S. H. D. 2012b. Identification of high risk fallers among older people living in residential care facilities: A simple screen based on easily collectable measures. Archives of Gerontology and Geriatrics, 55, 690-695.

WHITNEY, J., CLOSE, J. C. T., LORD, S. R. & JACKSON, S. H. D. In Press. The Physical Activity and Mobility in Residential Care (PAM-RC) scale.

WHO: WORLD HEALTH ORGANIZATION. 2007. WHO Global Report on Falls Prevention in Older Age. Ageing and Life Course, Family and Community Health [Online]. Available: http://www.who.int/ageing/publications/Falls_prevention7March.pdf.

WORLD MEDICAL ASSOCIATION 2001. World Medical Association Declaration of Helsinki. Ethical principles for medical research involving human subjects. Bulletin of the World Health Organization, 79, 373.

YANG, M., GOLDSTEIN, H., BROWNE, W. & WOODHOUSE, G. 2002. Multivariate multilevel analyses of examination results. Journal of the Royal Statistical Society:Series A(Statisticsin Society), 165,137-153.

ZIMMERMANN, C., SWAMI, N., KRZYZANOWSKA, M., HANNON, B., LEIGHL, N., OZA, A., MOORE, M., RYDALL, A., RODIN, G. & TANNOCK, I. 2014. Early palliative care for patients with advanced cancer: a cluster-randomised controlled trial.TheLancet,383,1721-1730.