Evaluation of the Guide to Action Care Home fall prevention programme in care homes for older people: protocol for a multi-centre, single blinded, cluster randomised controlled trial (FinCH)

Logan PA[1*], McCartney K[1], Armstrong S[1], Clarke A[2], Conroy S[3], Darby J[1], Gladman J[1], Godfrey M[5], Gordon AL[1], Irvine L[2], Leighton P[1], Mountain G[4], Robertson K[1], Robinson K[1], Sach T[2], Sims E[2], Horne JC[1]

*Correspondence: Pip.Logan@nottingham.ac.uk

[1] University of Nottingham, Nottingham, United Kingdom, [2] University of East Anglia, Norwich, United Kingdom, [3] University of Leicester, Leicester, United Kingdom, [4] University of Bradford, Bradford, United Kingdom, [5] Patient & Public involvement representative, Nottingham, United Kingdom

Abstract

Background: Falls in older care home residents are at least five times more frequent than in community dwelling adults and have higher direct costs. Care home research is limited but suggests that fall-related injuries might be prevented by fall prevention interventions such as the Guide to Action Care Homes (GtACH) Tool. We are conducting a multi-centre, cluster randomised controlled trial to evaluate the use of the GtACH tool with residents in care homes.

Methods & analysis: Adult care homes in England will be randomised on a one to one basis to training and use of the GtACH tool, or standard care. A total of 78 care homes and 1482 residents will be recruited with resident's participation based on the care homes randomisation. Outcome measures will be collected from care home records and incident report forms by researchers (blind to allocation) at baseline, three, six, nine and twelve months post randomisation. The primary outcome, rate of falls per participant in the three months prior to six months post randomisation, will be expressed as the number of falls per 1,000 resident days for each group. Secondary outcomes are i) the rate of falls per participant in the three months prior to nine and twelve months post randomisation, ii) number & type of fall injuries, iii) physical activity & mobility, iv) functional ability, v) quality of life, vi) cost-effectiveness, and vii) number of deaths. In addition, six care homes using the GtACH tool will be selected for process evaluation of GtACH assessments and actions.

Ethics & dissemination: Favourable ethical approval has been received from the NHS Health Research Authority and NHS sites. (Yorkshire & The Humber - Bradford Leeds Research Ethics Committee, 11/04/2016, ref: 16/YH/0111). Dissemination of findings will include quarterly newsletter updates to care home staff and residents, sponsor hosted events, community meetings, peer-reviewed publications and presentations at academic conferences.

Trial registration number: ISRCTN34353836. Protocol V6 14 November 2017

Keywords: Fall Prevention; Falls; Randomised Control Trial; Care Home research

Introduction

Background & rationale

415,000 people live in UK care homes (1). These facilities provide care either with or without registered nursing input and are referred to as care homes with or without nursing

respectively. Both categories of home match the international consensus definition of a nursing home (2). The majority of residents are aged over 80, have cognitive impairment, mobility problems and multiple medical conditions (3). Health and social care interventions may require modifications in order to work in the care home setting, either because of the configuration of disability and dependency amongst residents, or to work within the organisational setting of care homes (4).

One area where interventions might require to be designed with care homes specifically in mind is in the field of falls prevention. Community falls prevention interventions reduce falls and risk of falls by 30%, but literature to date has found no conclusive reduction in falls in care homes (5, 6). Care home specific research is scarce and the existing research is inconclusive (7, 8).

Current fall interventions rely on patient engagement and adherence to advice. These present difficulties in care homes, where 75% of residents are cognitively impaired (9) and non-targeted interventions with cognitively impaired older adults have not been successful (10, 11).

At a rate of 2.5 falls per year (12) there are 160,000 falls per year in care home residents (13). In care homes, nearly one in ten people who fall sustain a fracture (14), one in five are admitted to hospital (15) and one in five will die within a year (16) due to a fall related injury. One third of the UK's hip fractures occur in care home residents (15), which is devastating to residents and their carers, and costly to the NHS. Even when falls do not result in fractures, they frequently result in other forms of injury. They cause fear of falling which contributes to a cycle of functional decline and increasing dependency with associated care costs (17).

The Guide to Action for Falls Prevention - Care Homes (GtACH) intervention (18) aims to reduce fall rates by supporting care home staff to identify risk factors for falling pertinent for an individual and take action to reduce those risks. 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 (19). Initial proof of concept work (18) and a subsequent feasibility randomised controlled trial (RCT) have shown that GtACH is implementable and changes staff behaviour in line with gold standard practice (20). This study will determine whether the use of GtACH has an impact on clinical outcomes for care home residents that are at risk of falling.

Research aim and objectives

- The aim of the trial is to determine the clinical and cost effectiveness of the GtACH for fall prevention in care homes compared to usual care
- Complete a process evaluation to provide complementary insight into the use of GtACH and to contextualise trial findings

Methods

Trial design

We will undertake a multi-centre cluster randomised controlled trial to evaluate the GtACH fall prevention programme in UK care homes for older people. Care homes and residents will take part in the study for twelve months post randomisation. Outcome measures will be

collected at baseline and at three, six, nine and twelve months; See Figure 1 for a schematic diagram of the trial design.

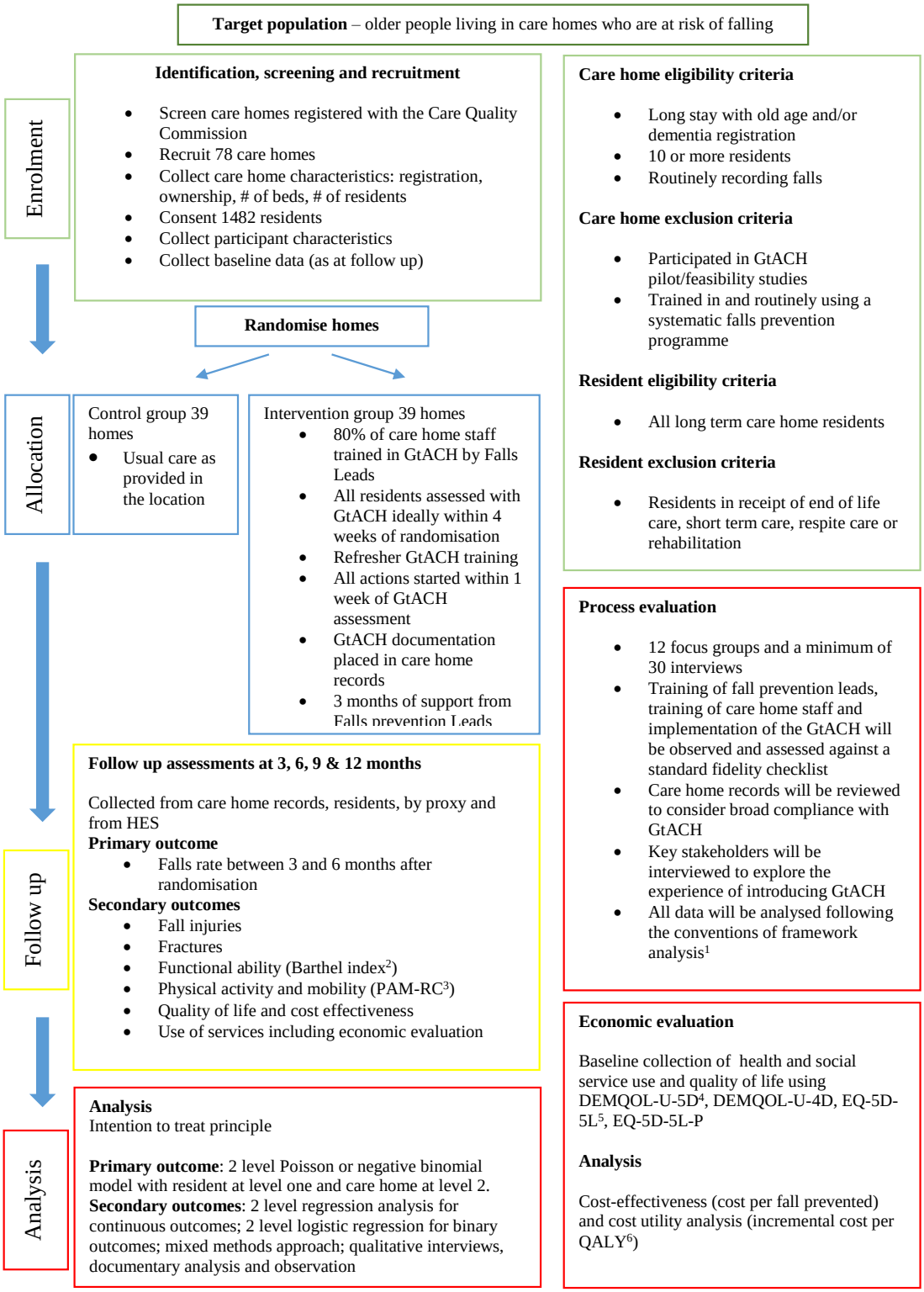

Figure 1 Schematic diagram of trial design

References
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Setting

We plan to recruit adult care homes and their residents from a broad geographical area in the UK, to capture a range of health and social contexts.

Sample size and recruitment strategy

This is based on the primary outcome of falls rate over the three month period, months four, five and six, post randomisation. The original total sample size estimate was for 1308 residents to be recruited from 66 care homes. This assumed a falls rate of 2.5 falls per year (0.625 falls in three months) in the control group (12), 80% power and a two-sided significance level of 5%, resulting in the need to recruit 189 residents per group in order to detect a 33% reduction in falls rate in the intervention group. Thirty three percent was chosen as this was the rate achieved by community based falls prevention interventions (5) and therefore deemed clinically significant. The sample size calculation was based on information obtained from the Whitney study which had a falls rate of 15 falls per year (20) but only recruited residents who had fallen recently. The adjustment for clustering assumed an average cluster size of 20 residents (27) and an intra-cluster coefficient (ICC) of 0.1 (27), giving a sample size of 549 residents per group. Incorporating a further 16% to the sample size to account for potential attrition (9), gave a total sample size of 1308 residents (654 to intervention group and 654 to control group).

During recruitment it became apparent that the average number of residents per cluster was slightly lower than expected (19 residents) and the size of the clusters were variable (coefficient of variation=0.5). Based on this new information, the design effect for the revised sample size calculation increased from 2.9 to 3.275, leading to a total sample size of 1474 residents after the adjustment for 16% attrition rate. This led to a need to recruit 39 care homes per arm.

Across all sites, it is anticipated that the rate of recruitment of care homes and residents will be five-six care homes and 18-19 residents per month. 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 owner/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.

Intervention and comparator

Details of intervention tool

Description

The GtACH Tool is a systematic falls risk assessment and action process, co-designed by University of Nottingham researchers in conjunction with care home and NHS staff, based on NICE (National Institute for Health and Care Excellence) clinical guidelines. It 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 has been published (20) although the GtACH manual (comprising assessment and action materials) has not been published.

The GtACH Intervention Tool comprises; training delivered by NHS Falls Leads to care home staff, a GtACH manual (comprising assessment and action materials) and a GtACH poster left in the homes.

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. The criteria for this role was expert experience in training on falls prevention programmes. Case studies and role play are used in the training. The training programme is not publically available to avoid contamination. A Falls Champion, defined as a liaison person, representing care home staff was identified in each care home. The Falls Champion and the Falls Lead will support the Care Home with any queries they have, following the training.

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; causes of falls; how to complete the GtACH; a Falls Incident Analysis template; 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.

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.

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 resident's care records.

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 four weeks of randomisation (and within two weeks of staff training being completed in the care home) 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 three- six months if there are no other changes.

Comparator

The comparator to the intervention will be usual care.

Randomisation, blinding and allocation concealment

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). 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 Clinical Trials Unit (NCTU) *via* a secure web-based randomisation service.

Falls Leads will use a remote, internet-based randomisation system to obtain the allocation for each home, and will inform the Falls Champion, the liaison person within the care home, of the allocated intervention arm. Participants, care home staff, site falls leads and research assistants (RAs) undertaking the process evaluation at the care homes will not be blinded to allocation. The RA 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 each home will occur after all residents within a home have given consent and all baseline data for that home has been collected. The RA who gathered the baseline information will confirm *via* the site expert (Falls Lead), who will deliver the training, that the care home is ready to be randomised.

The sequence of treatment allocations will be concealed from the study statistician until the main analysis is completed. The Trial Management Group (TMG) and the Data Monitoring Committee (DMC) will be un-blinded to the intervention. The chief investigator and principal investigators will have direct contact with the randomised care homes, although not with the participants. Independent members of the DMC will not have contact with either care homes or participants.

Ethics approval

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

Safety monitoring and 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, 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.

Fall rates will be monitored for harm and reported to the DMC and Trial Steering Committee (TSC) every three months after they have been collected. The DMC and TSC have the ability to recommend changes to the study protocol if fall rates are substantially higher than expected. The DMC 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.

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.

The monitoring of trial procedures is overseen by the trial sponsor, the University of Nottingham (reference 16020), email: sponsor@nottingham.ac.uk

Eligibility for entering the study

Care home eligibility criteria

Inclusion criteria

- Long-stay with old age and or dementia registration
- Ten 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

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 (Care Quality Commission) special measures at time of recruitment
- 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

Inclusion criteria

- 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

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)

- Employed by a care home participating in FinCH and selected for participation in the process evaluation
- Employed in a caring role.

Procedures/Sampling of resident records

Care home staff will distribute or post participant information sheets and study invitation letters to residents and/or relatives as appropriate. After a two week window, details of interested parties will be given to the researcher. The researcher will confirm eligibility, assess capacity and fully explain the study to the resident and/or relative. Before being enrolled in the study, informed written consent will be obtained in accordance with Research Ethics Committee (REC) guidance and Good Clinical Practice (GCP). Where a consultee is required, the consultee will sign a declaration if they believe that the participant would have wished to take part in the study had they had the capacity to state their preference. Residents who do not have capacity, and whose relatives did not respond to the invitation letter within two weeks, can also be enrolled onto the study. The care home manager will act as consultee in this instance.

Baseline assessments will be completed prior to randomisation. Subsequent assessments will be carried out at three, six, nine and twelve months following randomisation. Data will be collected by the blind to allocation researcher in the care home on paper case report forms (CRFs) and subsequently entered onto a secure password protected purposely designed electronic database. Each participant will be assigned a unique trial identity code number for use on CRFs, other trial documents and the electronic database.

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:

- Care homes without nursing provision; care homes with nursing provision
- Small care homes (less than 20 beds); medium sized care homes (20-40 beds); larger care homes (more than 40 beds)
- Independently owned care homes; corporate owned care homes
- Care homes in different locations (we will recruit in at least four 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 four-six month window.

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

- Two staff focus groups will take place in each evaluation care home. Focus group (1) following completion of the local GtACH training and (2) three 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 six 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 six 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.

Data collection

Monitoring

The Norwich Clinical Trials Unit (NCTU) will monitor data collection and data quality at all sites through centralised monitoring using site logs and the trial database. Queries raised will be directed to the site RAs and escalated to monthly Trial Management meetings as appropriate.

Analysis methods

Analyses will be undertaken on an intention to treat (ITT) basis (28) 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 statistical analysis plan which will be finalised prior to the start of the analysis. 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.

The primary outcome, rate of falling over the three month period prior to six months post-randomisation, will be expressed as the number of falls per 1,000 resident days for each group. This period was chosen to give time for the intervention to be implemented after training, while acknowledging that people in care homes have short life expectancies. 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 choice of model to be used will be dependent on the dispersion of the data. 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) fall rate for the three months before the baseline assessment; ii) baseline fall and other variables that are associated with falling. All rates during the three month period prior to nine and twelve 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.

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 (29). If data are missing at random and the amount of missing data is small (less than 15%), imputations may not be required. Full details of all analyses will be provided in the Statistical Analysis Plan.

Economic evaluation

A within-trial economic evaluation will be used to estimate the cost effectiveness of the GtACH approach to preventing falls compared to usual care (an absence of a systematic and coordinated falls prevention process) in UK care homes. An NHS and personal social services perspective will be adopted as used in the NICE reference case (30). We will identify and measure resources used to deliver the intervention (training, staff time and materials), as well as wider resource use that may change as a consequence of the intervention being delivered. Medications and community health care will be captured from care home records at baseline, three, six, nine and twelve months, while secondary care data will be requested from NHS Digital. All resource use items will be valued using published unit costs for the most recent price year. The primary economic analysis will be a cost utility analysis from the NHS and personal social services perspective, where outcome choice in the base case will be determined with reference to the available evidence on the use of the EQ-5D-5L and DEMQOL-U in this population available at the time of finalising the Health Economics Analysis Plan (HEAP). The health-related quality of life aspect of the Quality-Adjusted Life Year (QALY) will be measured using EQ-5D-5L proxy and DEMQOL-P-U and for all residents (25) and the EQ-5D-5L and DEMQOL-U (where available for residents with capacity for self-report) as recommended by Mulhern (24, 31). Both versions of the forms will be collected where possible for each participant and used for secondary analyses to explore the impact of choice on conclusions reached. The choice to use both quality of life measures reflects the fact that the DEMQOL utility value sets 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 Health-Related Quality of Life (HRQL) in care home populations can be problematic in terms of achieving good response rates due to high cognitive impairment *(32)*. We value the EQ-5D-5L-P in the analysis in line with NICE recommendations at the time of analysis (33). QALYs will be estimated using linear interpolation and area under the curve analysis with and without baseline adjustment (26, 34). A cost-effectiveness analysis using the primary trial outcome falls rates, will also be undertaken in order that the cost-effectiveness of this intervention can be compared directly with other fall prevention cost effectiveness estimates based on fall rates.

The economic evaluation will be discounted, reflecting the twelve month time horizon of the trial. Neither costs nor benefits will be discounted reflecting the twelve 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 (35-37). 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.

Process evaluation analysis

The process evaluation will seek to demonstrate those contextual factors and processes which impact upon the implementation of the GtACH tool; it will identify those settings where GtACH is easily adopted and those features which are a barrier to GtACH implementation. It will also consider the extent to which GtACH is being used consistently within and across care home settings, and illustrate the views and opinions of key stakeholders about the adoption of GtACH.

All data (interview, focus groups, observations and field notes) will be transcribed in full, anonymised and handled using the N'Vivo software package.

A framework analysis approach (21) will be used to organise the data. Coding of early observations, interviews and focus groups will support the generation of an initial analytic framework, which is likely to include separate tables for 'training', 'implementation', and 'integration'. Each table will include a number of themes and sub-themes generated from within the data. All data will be charted to this framework, with tables, themes and sub-themes revised and adapted when data indicates that this is necessary.

Once all data has been charted in this way tables can be interrogated to address study objectives. This stage of analysis will focus upon building conceptual models which connect the context in which data was collected (type of care home, size of care home, ownership of care home, *etc.*) and the outcomes which are manifest therein (successful use of GtACH, partial use of GtACH, reduction in falls, *etc.*). Analysis will consider the detailed, specific insight offered by stakeholders (staff, managers, residents, *etc.*) in order to identify (and interpret) possible mechanisms which might mediate the relationship between a specific context and particular outcome. For example, existing falls management policies might hamper the introduction of the GtACH, staff with an interest in falls might ease the introduction and adoption of GtACH, *etc.*

This style of data management/analysis will enable consideration of specific topics (such as patient factors, professional interactions, resources, organisational change) whilst maintaining the potential to consider each care home separately (*i.e.* the data set will allow both broad generalisation as well as the identification of specific, contextual factors).

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 TMG, and the final version will be agreed by the TSC 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 (38). 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. 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 the Enabling Research in Care Homes (EnRICH) network to identify potential research users, other researchers, policy makers, commissioners, clinicians, care home managers and staff, care home residents and relatives. Further consultation will be undertaken with the Collaboration for Leadership in Applied Health Research and Care East Midlands (CLAHRC-EM) and the East Midlands Academic Health Sciences Network (EMAHSN) which will enable dissemination through their regional and national networks.

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.

Strengths & limitations of this study

- This is the largest randomised controlled trial of a falls prevention intervention in care homes in the UK
- This is the largest randomised study of any intervention conducted solely in care homes in the UK
- Stratification by geographical location and care home types help to reduce bias
- Having a wide range of care homes helps increase generalisability of the results to the UK but is limited in countries with other care home structures

Declarations Section:

Favourable ethical approval was gained to conduct this study. Consent procedures are detailed in the methods section. Consent for publication will be sought from the National Institute for Health Research (NIHR) once this manuscript is accepted for publication. Availability of the data and material, if appropriate will be provided on request from the Chief Investigator, Professor Pip Logan. There are no known competing interests at the time of this manuscript was submitted. Funding was provided by NIHR Health Technology Assessment Programme (NIHR HTA Programme 13/115/29). Authors contributed in the following ways: Professor Pip Logan, was responsible for writing the original protocol, reviewed versions and edited the final draft. Karen McCartney, wrote the first draft of this manuscript and added

contributing comments. Contributors added expertise; Sarah Armstrong and Allan Clarke (statistics); Janet Darby and Paul Leighton (Process Evaluation) Tracey Sach and Lisa Ivine (Health Economics); Erika Sim (Trial Management); Simon Conroy, Adam Gordan, John Gladman, Gail Mountain, Katie Robinson, Kate Robertson; Jane Horne contributed to each version of the manuscript adding scholarly knowledge on clinical trials and specifically the FinCH trial procedures.

Acknowledgements: We would like to acknowledge the working contributions from the wider FinCH trial team working over ten sites nationally.

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Appendices

1. Consent form_ resident v2.1 24.08.16

2. Declaration_ consultee v3 06.12.16

3. FinCH PIS_ CH residents v3 03.05.17

4. Resident short information sheet v1.1 20.04.16

5. FinCH PIS_ consultee v3 25.07.16

Appendices

Appendix 1

The University of Nottingham
UNITED KINGDOM • CHINA • MALAYSIA

NHS Trust Header

FinCH

RESIDENT - CONSENT FORM
(Version 2.1 24 Aug 2016)

Title of Study: FALLS IN CARE HOMES STUDY (FinCH)
REC ref: ***(to be added after approval given)***

Name of Researcher:

Name of Participant:

Name of Care Home: _____

Participant Identification Number: ☐☐/☐☐/☐☐☐

Please initial box

1. I confirm that I have read and understand the information sheet version number 2.0 dated 07 Jul 2016 for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that relevant sections of my care home notes, GP notes, and data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research team, regulatory authorities, or from the NHS Trust where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐
4. I agree to a researcher observing the delivery of the new treatment if given. ☐
5. I agree to my GP or other care professionals being informed of my participation in this study and to allow clarification of medication data from my GP records where necessary. ☐
6. I agree to hospital and social care information about me being requested from National Data providers such as the Health and Social Care Information Centre. ☐
7. I agree to my contact details and a copy of this consent form being held securely and confidentially by FinCH coordinating centre/Norwich Clinical Trials Unit. ☐
8. I am happy to be contacted about participating in additional research interviews which are part of this study ☐
9. I agree to take part in the above study. ☐
10. I agree to continue participating in the study if I lose capacity before the end of the study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

Original for site file. 4 copies:- 1 for participant, 1 for participants care home notes 1 for care home study file and 1 for Norwich CTU Trial Office

Appendix 2

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

NHS Trust Header

FinCH

CONSULTEE DECLARATION FORM
(Version 3 06 Dec 2016)

Title of Study: FALLS IN CARE HOMES STUDY (FinCH)
REC ref: ***(to be added after approval given)*** **Name of Researcher:**

Participant Identification Number: ☐☐/☐☐/☐☐☐

I (Consultee name)_____
agree to the participation of (Participant's name)_____ **Please initial box**

1. I the above named consultee have been consulted about the above named participant's participation in this research project. I have read and understand the consultee information sheet version number 3.0 dated 25 Jul 2016 for the above study and have had the opportunity to ask questions. ☐
2. I understand that I can request that he/she is withdrawn from the study at any time, without giving any reason, and without their medical care or legal rights being affected. I understand that should I withdraw them from the study, then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that relevant sections of their Care Home notes, GP notes and data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to their taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from their participation in this study. I understand that their personal details will be kept confidential. ☐
4. I agree to a researcher observing the use of the Guide to Action in Care Homes tool if given to him/her. ☐
5. I agree to their GP or other care professional being informed of their participation in this study and to allow clarification of medication data from GP records where necessary. ☐
6. I agree to Hospital and Social Care information about him/her being requested from National Data providers such as Health and Social Care Information Centre. ☐
7. I agree to my contact details and a copy of this declaration form being held securely and Confidentially by FinCH coordinating centre/Norwich Clinical Trials Unit. I agree that the staff from the local FinCH trial team may contact me by telephone or post. ☐
8. I agree to him/her being asked to participate in interviews about their experiences of the new treatment if given. (optional) ☐
9. In my opinion he/she would have no objection to taking part in the above study. ☐

_____ _____ _____
Name of Consultee Date Signature

Please indicate if: personal consultee ☐ or nominated consultee ☐

Relationship to patient _____

_____ _____ _____
Name of Person taking declaration Date Signature

Original for site file. 4 copies:- 1 for participant, 1 for participants care home notes 1 for care home study file and 1 for Norwich CTU Trial Office

Appendix 3

Participant Information Sheet - Residents

(Version 3 3 May 2017)

Title of Study: **Falls in Care Homes (FinCH)**

Name of Researcher(s): xxxxxxxxxxxxxxxxxxxxxxxx

Invitation

We would like to invite you to take part in a research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

We would like to tell you more about the study and why we think it is very important. The purpose of the study is to understand more about how we can help stop elderly people falling over. Falls lead to broken limbs, bruises and people generally feeling afraid. Falls do happen in care homes, and we want to understand why and how they happen.

We already have been using a new treatment for elderly people living in their own homes and we want to use it to see if it helps prevent falls in care homes. This treatment helps us look at care. We will learn if you are eating and drinking well, taking exercise, have proper footwear, mobility aids and devices to enable you to call carers if you need help.

We will train and support care home staff in some homes to deliver this new treatment as part of the normal day to day care.

Why have I been invited?

You are being invited to take part because you are residing in a care home which has consented to take part in the study. We are inviting approximately 1308 participants, from 66 care homes, like you to take part.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form (if appropriate – as completion and return of a Questionnaire can be taken as consent). If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?

When you have decided if you wish to take part in the study or not please tell a member of the care home staff.

The researcher will visit the home, come and see you and explain the study and make sure you understand this invitation sheet. If you give your consent the researcher will ask you to sign the consent form. You will be asked for your consent to collect information from your care home records about your current health, any previous falls you may have had and how you manage each day. Once all data from everyone who wishes to participate in your care home has been collected, your care home will be allocated to implement the new treatment or care as usual. If your care home is allocated to receive the new treatment, staff in your home will be trained to carry out a personal assessment and suggest changes that may prevent you having falls in the future. You will be asked to consent to allow a researcher to observe care home staff assessing you for the new treatment and delivering actions arising from the assessment. The assessment may be repeated every 3 months, or more often if you have a fall.

At 3, 6, 9 and 12 months after the care home has been allocated to the new treatment or care as usual, the researcher will visit you to complete some questionnaires and collect information from your care home records about your current health, any falls you have had in the previous three months and how you manage each day. We will also ask care home staff to complete 2 short questionnaires to capture their perception of your quality of life initially and then again 3, 6, 9 and 12 months later.

If you agree we would like to find out about how the NHS and Social Care Services have assisted you, for example any hospital visits you may have had. We will do this my requesting data about you from information that is held for all patients in England by national data providers such as the Health and Social Care Information Centre.

A small group of people will be asked to participate in an interview with a researcher to talk about their experiences of the new treatment.

The proposed study will compare falls rates in homes where staff are trained to use the new treatment with homes that are providing usual care. In each care home we will ensure managers, staff and residents or their named person give consent to provide information. Then the participating care homes will be randomly allocated to either the new treatment or usual care. If allocated to the new treatment, care home staff will attend the training and all residents will be offered the assessment and actions.

1. Expenses and payments

Participants will not be paid to participate in the study.

2. What are the possible disadvantages and risks of taking part?

As your carers will be trained to enable you to receive the treatment we do not envisage any harm from your taking part in the study. There are no major harms other than any minor injuries you might get from doing some gentle exercise.

3. What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study may help reduce the chance of falling over for other care home residents in the future.

4. Can I still continue in the study if I become unable to make decisions for myself?

5.

Being able to make an informed decisions about whether you wish to take part in the study is often referred as having 'capacity' to make decisions for oneself. Sometimes people who live in care homes lose the ability to make decisions for themselves through illness. Should you agree to participate in the study, we will ask you to confirm that you agree to continue participating in the study if you lose capacity before the end of the study.

6.

7. What happens when the research study stops?

The care homes that have been trained to use the falls prevention intervention can continue to use it. The residents will not be asked any further questions.

8. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting

[CONTACT DETAILS FOR R&D Office]

Will my taking part in this study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some parts of your care records and the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the care home will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (address, telephone number) will be kept for 3 months after the end of the study so that we are able to contact you about the findings of the study (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

As professionals interested in your welfare, if you say anything to the researchers or they find anything in the care home about you or your care that they think puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

If you have a concern about any part of this study, you should ask to speak to the researchers who will do their best to answer your questions. If this does not deal with your concern then you can contact **[Insert: Site Principal Investigator],** whose contact details are given at the end of this sheet.

If you remain unhappy and wish to complain formally, you can do this through **[R&D Contact address and tel]**

9. What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

10.Involvement of the General Practitioner/Family doctor (GP)

Consent will be also be sought to notify your GP (or other health care practitioner) of your participation in the FinCH study and to allow clarification of medication data from GP records where necessary.

What will happen to the results of the research study?

It will take 3 years to complete the study. The findings will then be published in clinical journals.

Who is organising and funding the research?

The research is being organised by the University of Nottingham, led by Professor Pip Logan, in conjunction with Norwich Clinical Trials Unit and is being funded by the National Institute for Health Research, Health Technology Assessment funding scheme.

Pip Logan, Chief Investigator, Professor of Rehabilitation Research
University of Nottingham Medical School
School of Medicine Division of Rehabilitation and Ageing
Queens Medical Centre, Derby Road
Nottingham, NG7 2UH
Phone: 0115 823 0235 Email: pip.logan@nottingham.ac.uk

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Yorkshire and The Humber – Bradford Leeds Research Ethics Committee.

11.Further information and contact details

If you have any further questions about this study please do not hesitate to contact:

[Insert: Site Principal Investigator name]
[PI address and contact details]
and
[Insert: Local Researchers name]
[Local Researchers address and contact details]

Appendix 4

The purpose of the study is to understand more about how we can help stop elderly people falling over.

We are already using a new treatment for elderly people living in their own homes and we want to use it to see if it helps prevent falls in care homes. This treatment helps us look at care.

If you agree to take part we will ask you questions and collect information from your care home written notes about any falls you may have had and how you manage each day. It is your decision whether or not to take part.

We will train and support care staff in some care homes to deliver this new treatment as part of normal day to day care. The treatment involves such things as exercises, appropriate foot wear and plenty of drinks.

We do not envisage any harm from your taking part in the study as the care home staff will be trained to give the new treatment and it is already used in people living in their own homes.

If you have a concern about this study, please speak to the researchers who will do their best to answer your questions. If this does not deal with your concern then you can contact [*local PI name to be inserted*], whose contact details are given at the end of this sheet.

Just tell us and you can withdraw from the study. You don't have to give an explanation. We will still use the information we have already gathered, but won't bother you any further. And it won't affect any other aspect of your care.

It will take 3 years to complete the study. A report on the findings will be sent to you if you wish, your care homes and published in clinical journals.

The research is being organised by the University of Nottingham, led by Professor Pip Logan, who is working with Norwich Clinical Trials Unit and is being funded by the National Institute for Health Research, Health Technology Assessment funding scheme. [Contact: Pip Logan, Chief Investigator. Phone: 0115 823 0235 Email: pip.logan@nottingham.ac.uk]

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the National Research Ethics Service Committee.

If you have any further questions about this study please do not hesitate to contact:

[Local Researcher: Name and telephone number]

[Local PI name and Local PI telephone number]

Appendix 5

Consultee Information Sheet

(Version 3 25 July 2016)

Title of Study: **Falls in Care Homes (FinCH)**

Name of Researcher(s): xxxxxxxxxxxxxxxxxxxxxxx

Invitation

The staff who regularly care for your relative/friend in the care home where they live feel your relative/friend is unable to decide for himself/herself whether to participate in this research.

In order to help in our decision, we value and appreciate the importance of your opinion about whether your relative or friend would want to be involved. You may know of hers or his wishes and feelings about taking part in research and we would give precedence to these.

If you decide your relative/friend would have no objection to taking part we will ask you to read and sign a consultee declaration. We will then give you a copy to keep. We will keep you fully informed during the study so you can let us know if you have any concerns or you think your relative/friend should be withdrawn.

If you decide that your friend/relative would not wish to take part it will not affect the standard of care they receive in any way.

If you are unsure about taking the role of consultee you may seek independent advice.

We will understand if you do not want to take on this responsibility.

How do I find out more if I am approached to be a consultee?

Further information is available in the Department of Health's 'Guidance on nominating a consultee for research involving adults who lack capacity to consent'.

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_083133.pdf

This is also available from the research team, please ask if you would like a copy.

The following sections provide information about the study. This information is the same as would have been provided to your relative/friend.

What is the purpose of the study?

This 3 year study is being carried out to compare falls rates in homes where staff are trained to use the Guide to Action in Care Homes tool (GtACH) with homes that are providing usual care. Sixty six care homes and 1308 residents will be recruited from six sites across England. The Manager of the Care Home in which your relative/friend lives has given consent for the study to take place. We are now approaching residents to ask for them to consent to participate in the study. Following this, the participating care homes will be randomly allocated to either the GtACH process or usual care. If allocated to the GtACH process, care home staff will attend the training and all residents will be offered the assessment and actions.

Why has my relative/friend been chosen?

Your relative/friend is being invited to take part because they are resident in a Care Home which has consented to take part in the FinCH Study. We are inviting 1308 participants, in 66 care home, like your relative to take part**.**

Does my relative/friend have to take part?

We would like you to think very carefully about whether or not this person would have wanted to join the study. If your opinion is that he/she would have decided to take part, you will be asked to sign a declaration form indicating your view allowing your relative/friend to participate in the study. If you later decide that he/she no longer wishes to take part, please inform us and he/she will be withdrawn from the study. You do not

need to give a reason and it will not affect the standard of care your relative/friend receives.

What will happen to my relative/friend if they take part?

All the homes that participate in the study have a 50:50 chance of receiving the falls intervention training provided by an NHS falls clinical specialist who will be attached to the home for a three month period (on top of any existing services the home receives). However, the computer will randomly decide, as if by the toss of a coin, whether your relative/friends' home receives the training.

If you indicate that your relative/friend would like to take part, they will be assessed at 3, 6, 9 and 12 months. The assessment includes asking the care home staff about any falls your relative/friend may have had and looking through the care home records for any evidence of falls. We will also ask care home staff to complete 2 short questionnaires to capture their perception of your relative/friends quality of life initially and then again 3, 6, 9 and 12 months later.

If you agree we would like to find out about how the NHS and Social Care Services have assisted your relative/friend, for example any hospital visits they may have had. We will do this by requesting data about your friend/relative from information that is held for all patients in England by national data providers such as the Health and Social Care Information Centre.

If your relative/friend's care home is allocated to receive the falls prevention training. Your relative/friend may be assessed about their risk of falling by the care home staff, who will deliver falls prevention interventions according to their needs. We will ask you to consent to agree to a researcher observing this assessment and delivery of any prevention interventions. The assessment will cover questions about day to day activities, medications, footwear, glasses.

The intervention may include:

- Providing a piece of equipment or adapting something (such as a grab rail next to the toilet)
- Providing advice
- Providing activities, which he/she will practice with the resident
- Providing exercises for your relative/friend to practice.

Is there anything I will be asked to do?

A small group of people will be asked to participate in observations or an interview with a researcher to talk about their experiences of the new treatment. As a consultee you will be invited to accompany your relative/friend if you wish.

Expenses and payments

Participants will not be paid to participate in the study.

What are the possible disadvantages or risks of taking part?

There is no evidence that the falls prevention interventions put individuals at risk. The care home staff would not ask your relative/friend to do things that he/she would not want to do. Your relative/friend is free to stop at any time. At worst, the services the care home staff offers may not be effective and so your relative/friend would have no benefit.

What are the advantages of taking part?

We cannot promise the study will help your relative but the information we get from this study may help to prevent residents falling in care homes in the future.

What happens when the research study stops?

The care homes that have been trained to use the falls prevention intervention can continue to use it. The residents will not be asked any further questions.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting

[Insert - R&D contact details]

Will their participation in the study be kept confidential?

We will follow ethical and legal practice and all information about your relative will be handled in confidence.

If your relative joins the study, some parts of their care notes, GP notes and the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to your relative as a research participant and we will do our best to meet this duty.

All information which is collected about your relative during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about your relative which leaves the hospital will have your relative's name and address removed (anonymised) and a unique code will be used so that they cannot be recognised from it.

Your relative's personal data (address, telephone number) will be kept for 3 months after the end of the study. All other data (research data) will be kept securely for 7 years. After this time your relative's data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your relative's confidentiality, only members of the research team will have access to their personal data.

What will happen if I do not want my relative to carry on with the study?

Your relative's participation is voluntary and you are free to withdraw them at any time, without giving any reason, and without their legal rights being affected. If you withdraw your relative, then the information collected so far cannot be erased and this information may still be used in the project analysis.

Involvement of the General Practitioner/Family doctor (GP)

Consent will be also be sought to notify your relatives GP (or other health care practitioner) of their participation in the FinCH study and to allow clarification of medication data from GP records where necessary.

What will happen to the results of the study?

It will take 3 years to complete the study. The findings will then be published in clinical journals.

Who is organising and funding the research?

The research is being organised by the University of Nottingham and is being funded by the National Institute for Health Research, Health Technology Assessment funding scheme.

Pip Logan, Chief Investigator, Professor of Rehabilitation Research

University of Nottingham Medical School

School of Medicine Division of Rehabilitation and Ageing

Queens Medical Centre, Derby Road

Nottingham, NG7 2UH

Phone: 0115 823 0235 Email: pip.logan@nottingham.ac.uk

Who has reviewed this study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect participant's interests. This study has been reviewed and given favourable opinion by the Yorkshire and The Humber – Bradford Leeds Research Ethics Committee.

Contact for further information

If you have any further questions about this study please do not hesitate to contact:

[Insert: Site Principal Investigator name]

[PI address and contact details]

Or

[Insert: Local Researchers name]

[Local Researchers address and contact details]

You will be given a copy of the information sheet and a signed declaration form to keep.

Thank you for reading this