Implementation of the ACTiON FALLS prevention programme (formerly GtACH) into UK care homes

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Short title: *Finch Implementation Study*

Acronym: *FinCH Imp National*

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SYNOPSIS

Title	Implementation of the ACTiON FALLSs prevention programme in UK care homes
Acronym	FinCH Imp National
Short title	Falls in Care Homes Implementation study
Chief Investigator	Professor Pip Logan
Objectives	• Establish local teams of researchers, care home owners, falls prevention specialists in four locations in the UK, that are likely to capture a range of cultural, economic and social differences. • Work with the ACTiON FALLS Collaboratives (AFC) and implement the ACTiON FALLS programme in 60 homes. Approximately, 15 care homes in each of the four regions. • Establish AFCs which will comprise care home, health and social care staff, researchers and stakeholders from each participating region • To understand the extent to which the collaborative approach has enabled effective implementation of the ACTiON FALLS programme across participating regions and homes. This will be achieved through measuring participation in collaborative events, the use of the ACTiON FALLs programme with residents, using the NoMAD instrument and barriers and facilitators using qualitative interviews. • Collect monthly falls data from up to 1,770 residents (anonymous) using routinely collected data. • Develop case studies at an individual resident, care home and regional level, of how the ACTiON FALLS programme has impacted on outcomes. • Develop a system allowing care homes to self-monitor their falls rates. • Develop an “adopt and spread” toolkit comprising the ACTiON FALLS implementation package, a “how to” guide for organisations to deliver the ACTiON falls at scale across single and/or multiple regions. • Establish ongoing ACTiON FALLS Collaboratives (AFC) communities of practice to sustain and develop use of the ACTiON FALLS programme. • Work with the Academic Health Science Network to explore sustainability of the ACTiON FALLS programme

Study Configuration	Multi-centre, mixed methods implementation study
Setting	The study setting is adult care homes (with and without nursing) in England
Sample size estimate	We aim to recruit 60 care homes across four geographical areas. East Midlands, Northumbria, SE London and West Midlands
Number of participants	• 60 care homes which will have a reach of up to 1770 care home residents • Up to 48 care home staff will take part in interviews • NoMAD survey results from up to 200 care home staff
Eligibility criteria	**Care Home Owners and staff inclusion criteria:** 1. Own Care Homes that hold long stay with old age and or dementia registration. 2. Care home staff willing to attend ACTiON FALLS Collaboratives (AFC) 3. Care home staff willing to provide consent 4. Care Homes in the UK **Care Home Owners exclusion criteria:** 1. Homes exclusively providing care for those with learning difficulties or substance dependency 2. Homes with contracts under suspension with health or social providers, or that are currently subject to safeguarding investigations 3. Homes with a significant proportion of beds taken up by health-service commissioned intermediate-care services **Care Home staff inclusion criteria** • Employed by a Care Home participating in FinCH Imp study • Employed in a caring role **Care Home staff exclusion criteria** • Not employed directly by the care home e.g., agency worker or student **Care Home residents' data** pertaining to number of falls in each participating care home will be collected anonymously and residents will not be consented or recruited
Description of interventions	The intervention is the ACTiON FALLS programme delivered to care home residents by care home staff who have been trained in the ACTiON Falls programme. The ACTiON falls programme is a systematic falls risk checklist and action programme which includes: • An ACTiON FALLS intervention reference manual • The ACTiON FALLS Checklist and decision support tool (formally known as GtACH)

	• Staff training and support from a Falls Lead Expert • Support to develop a Falls Champion role (care home staff) • A falls awareness poster • Access to the React to Falls web-based training, case studies and information • The React to Falls Mobile Application
Duration of study	24 months
Methods of analysis	Qualitative data will be analysed using thematic analysis in the first instance and then themed according to Normalisation Process theory (NPT). NoMAD questionnaire data will be used to explore how different staff groups and home structures impact on the implementation of the ACTiON FALLS programme. To explore if it can become a routine and sustained part of their work and how it can be embedded into daily practice. A mixed method evaluation of how the ACTiON FALLS will be embedded into the staff's usual work, will draw on interviews with owners; care home managers; staff and residents, commissioners, policy makers and stakeholders in the care home arena. Quantitative analysis will draw on the monthly falls data collected from care homes and anonymous falls data will be collected for each resident by the care homes and provided monthly.

ABBREVIATIONS

AE	Adverse Event
AFC	ACTiON Falls Collaboratives
CI	Chief Investigator overall
CF	Consent Form
CRF	Case Report Form
GCP	Good Clinical Practice
GtACH	Guide to Action Care Homes
NHS	National Health Service
NPT	Normalization Process Theory
QIC	Quality Improvement Collaboratives
PI	Principal Investigator at a local centre
PIS	Participant Information Sheet
PPI	Public and Person Involvement
REC	Research Ethics Committee
RA	Research Assistant
RCT	Randomised Controlled Trial
R&D	Research and Development department
TMG	Trial Management Group
TSG	Trial Steering Group
UoN	University of Nottingham

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STUDY BACKGROUND INFORMATION AND RATIONALE

Falls are a major cause of morbidity and mortality in older people. In the general population one third of people over 65 and half of those over 80, fall at least once a year (1). People living in care homes are more frail than community-based populations and for the approximately 400,000 people in the UK who live in care homes (2), falls are three times more common (3).

The personal and financial costs of falls are high, nearly 1 in 10 people who fall in care homes sustain a fracture (4) and 1 in 5 will die within a year due to a fall related injury (5). Hip fracture is the most common serious injury following a fall and the cost to the NHS of hip fracture alone is over one billion pounds per year and rising (6). Even falls not resulting in a fracture, frequently result in other forms of physical and psychological injury. Fear of falling, which often manifests following a fall, contributes to a cycle of functional decline and increasing dependency with associated care costs.

Preventing falls and injuries in those over 65 years of age is a public health priority (1) and The King's Fund recommends structured individualised patient-centred care in care home settings (7). The National Institute for Health and Care Excellence recommends identification of those at risk of falling followed by assessment and mitigation of falls risk factors (8).

In line with the design of complex interventions (Fig 1) recommended by the Medical Research Council (9) a falls prevention intervention was co-designed with care homes (10) and successful feasibility (11) and definitive trial (12) were completed. The Falls in Care Homes (FinCH) study was a large multi-centre randomised control trial (RCT) which investigated the effectiveness of the Guide to Action for Falls Prevention Care Homes (GtACH) programme. The FinCH trial found that the GtACH programme was cost-effective and reduced falls by 43% (13).

The process evaluation conducted concurrently with the FinCH RCT found intervention to be acceptable in a care home context, the one-hour training was well received and lead to increased falls awareness. However, not all components of the GtACH programme were implemented as per the protocol: the paper GtACH checklist was often not completed, the falls champion role was not filled and support from the Falls Lead (NHS role covering many homes) was limited. Plus, care homes identified that having to record falls information twice (once for the RCT and once for routine records) was a barrier.

The RCT concluded that in order to fully implement the GtACH programme it must first be aligned with Care home organisational priorities and local practice, the GtACH should be updated in format and method of delivery, 'top up' training should be available for care home staff, care homes should only use one Falls prevention programme, and care homes should be encouraged to delegate one member of staff as falls champion. This person should receive extra training.

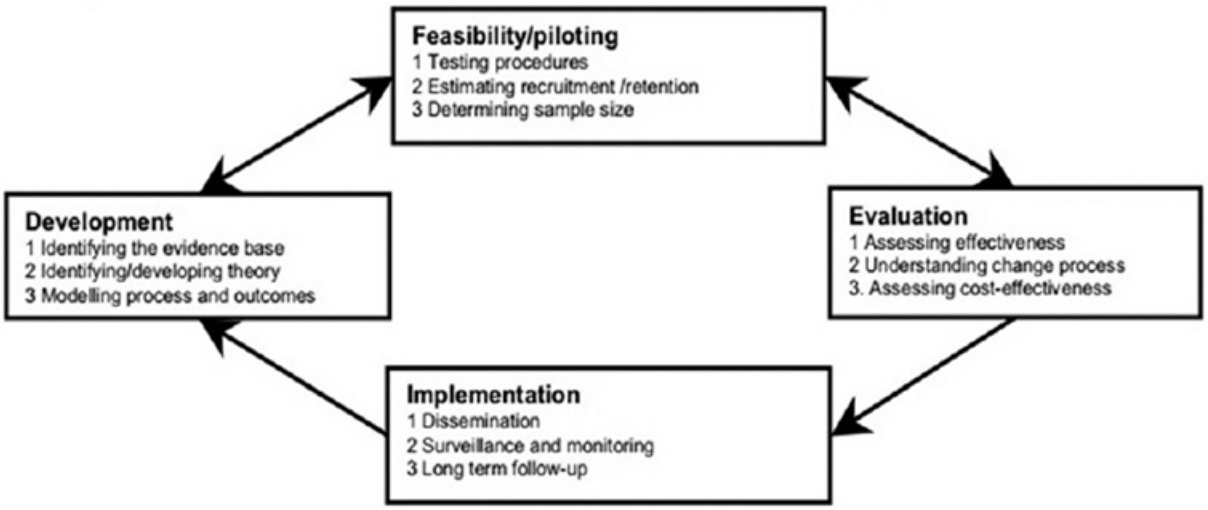

Fig 1 (**MRC 2019- needs full citation)**

To start addressing the implementation issues identified in the RCT, the FinCH Implementation East Midlands study (funded through ARC East Midlands) was completed. Stakeholder forums, qualitative interviews, clinical expertise and literature reviews were used to explore how care homes might introduce new interventions, how the intervention could be made ready for use in the real world in 2022 at scale and to test the feasibility of running a national implementation study during a COVID-19 pandemic.

The results of this single site implementation study resulted in a change of name for the programme from the GtACH programme to the ACTiON FALLS programme, the development of a digital version of the checklist; a smart phone app; a new paper manual for use in care homes; a new training programme to be delivered online and explored how falls data is routinely collected. Plus, the stakeholders of care home staff highlighted that the term 'Quality Improvement Collaborative' was not acceptable to care home staff and therefore the term ACTiON FALLS Collaboratives (AFC) is used in this protocol.

The implementation study found that if the ACTiON FALLS programme is to be used routinely it needs to be embedded into care home systems. A whole team approach reflecting on good practice, makes a difference. A Falls Champion role is effective with ongoing support and investment. Additional digital resources were acceptable and appropriate for use within the care home and the evidence underpinning these resources was updated. There is an increased use of mobile phones to facilitate good communication in care homes after the COVID-19 experience.

However, interviews and focus group are difficult to conduct as capacity issues emerge, after COVID-19. Attendance at events and care home forums are also reduced due to the impact of COVID-19. On-line platforms may help in resolving these issues.

The aim of the national study is to broaden this knowledge to enable implementation across a range of care homes with diverse social, cultural and economic diversity.

STUDY OBJECTIVES AND PURPOSE

Aim:

To research the best implementation techniques to enable adoption and spread of the ACTiON FALLS programme across care homes four english regions.

Research questions:

1. How do care homes (and parent organisations) best implement the ACTiON FALLS programme?
2. What are the real-world barriers and facilitators to care homes when using ACTiON FALLS?
3. Can ACTiON FALLS yield the same successful trial outcomes and how is this sustained (opportunity costs)?
4. How do increase spread and uptake of ACTiON FALLS?
5. How do care home staff remain skilled to use the ACTiON FALLS programme?

PRIMARY OBJECTIVES

Primary Objectives:

- Establish local teams of researchers, care home owners, falls prevention specialists in four locations in the UK, likely to capture a range of cultural, economic and social differences.
- Work with the ACTiON FALLS Collaboratives (AFC) and implement the ACTiON FALLS programme in 60 homes. Approximately, 15 care homes in each of the four regions.

- Establish AFC will comprise care home, health and social care staff, researchers and stakeholders from each participating region
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- To understand the extent to which the collaborative approach has enabled effective implementation of the ACTiON FALLS programme across participating regions and homes. This will be achieved through measuring participation in collaborative events, reviewing the use of the ACTiON FALLs programme with residents, responses from the NOMAD instrument and using qualitative interviews.

- Collect monthly falls data from up to 1,770 residents (anonymous) using routinely collected data.

- Collect case studies at an individual resident, care home and regional level, of how the ACTiON FALLS programme has impacted on outcomes.

- Develop a system allowing care homes to self-monitor their falls rates.

- Develop an “adopt and spread” toolkit comprising the ACTiON FALLS, the implementation package, a “how to” guide for organisations to deliver the ACTiON FALLS at scale and pace across single and/or multiple regions.

- Establish ongoing AFC communities of practice to sustain and develop use of the ACTiON FALLS programme.

- Work with the Academic Health Science Network to explore sustainability of the ACTiON FALLS programme

STUDY DESIGN

STUDY CONFIGURATION

This implementation research study will use the Normalisation Process Theory to guide the collection and analysis of data. Four regions: East Midlands, West Midlands, South London and the North-East of the UK, with the PIs and Research Assistants employed by local Universities and representing the ARCs. recruiting care homes and care home staff, interview staff and collect anonymous data from care home residents. The data from each of the four sites will be brought together to compare and contrast findings and to produce the final tool kit.

Quality Improvement Collaboratives (known as ACTiON FALLS collaboratives within this study) will be used in each site to bring care home staff, researchers, clinicians and policy makers together to develop implementation tools and techniques. Feedback from AFC will inform the quality improvement cycle. Therefore, the ACTiON FALLS programme will be adapted for functional use concomitantly. Local NHS Falls Leads will train care home staff to use the ACTiON FALLS programme.

Data will be collected via:

- Observation and field notes from AFC meetings.
- Interviews and focus groups of Care home staff in the homes
- NOMAD questionnaires completed by care home staff
- Anonymised falls rate data provided by participating care homes on a monthly basis
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Primary endpoint
The primary endpoint for the study will be evidence following the completion of care staff interviews of the adoption of the ACTiON FALLS programme within participating care homes.
Secondary endpoint
Following completion of the final AFC event, whether implementation of the AFC events has supported care homes to implement a multifactorial falls programme.

Stopping rules and discontinuation
The rules for discontinuation for the study, take into account the current and potential future pressure which are created by the Covid-19 pandemic. The study has embedded flexibility around timings to provide Care homes every opportunity to be involved either in person or remotely.

A review of recruitment targets will be carried out if less than 25% homes are recruited within 3 months of initiating recruitment and less than 50% within 6 months of recruitment. As part of this review we will discuss with the SMG and funder and take their advice about stopping the study.

STUDY MANAGEMENT

The Trial will be managed from a central coordinating centre at University of Nottingham supported by ARC East Midlands, ARC West Midlands, ARC South London and ARC North East. A trial management group composed of all co-applicants will meet monthly to oversee day to day management of the study. The Chief Investigator has overall responsibility for the study and shall oversee all study management. The data custodian will be the Chief Investigator.

DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

The study duration will be 18 monthsstarting January 2022. Care home owner participant recruitment will start at the end of January 2022. Each participating home will be enrolled in the study for a period of 12 months. The end of the study will be the last data collection point (12 months following the last home is recruited).

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Expressions of Interest

Up to the end ofJanuary 2022 the study researchers from each site will invite expressions of interest from care homes within their locality. Local area teams will introduce care homes owners and managers to the ENRICH events, social media and other industry forums. This will provide sufficient time for care homes to consider their involvement prior to consent being sought.

Recruitment

Sixty care homes will be recruited from four ARC sites: East midlands (23), West Midlands (5), South London (16) and North East (16) by the local site teams. The UK average is 29.5 residents per care home which should provide falls data on 1770 residents (13). Care homes will be encouraged to express their interest in participating through promotion and introduction to the study at ENRICH events, care home forums, social media and telephone call from the study team. Homes that express an interest in taking part will be reviewed against the eligibility criteria to confirm that they meet the entry criteria. It will be explained to the care homes, that entry into the study is entirely voluntary 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.

Care homes who decide to take part will be asked to sign an agreement which sets out the expected tasks involved in participating from both the Care Home and the research team.

All staff employed by participating care homes will be invited to complete two NOMAD questionnaires (at two different timepoints) and results from this survey will indicate which care home staff will be invited to take part in the interviews. Research staff from each study site will contact staff for interview directly based on contact information provided for this purpose on the NOMAD survey. 12 interviews per research site will be completed.

All staff from participating care homes will be invited to attend up to two AFC events, attendance to these events will be voluntary but care home managers will be asked to encourage staff to attend.

NHS Falls leads who have provided training to participating care homes as part of their role will be contacted by the central research team and asked to take part in a single focus group.

Eligibility criteria

Care Home inclusion criteria

- Long stay with old age and or dementia registration
- Routinely record falls in resident personal records and on incident sheets

Care Home exclusion criteria

- 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

Care Home staff inclusion criteria

- Employed by a Care Home participating in FinCH Imp study
- Employed in a caring role

Care Home staff exclusion criteria

- Not employed directly by the care home e.g., agency worker or student

Falls Leads Inclusion criteria

- Participated in ACTiON FALLS trainer training
- Provided ACTiON FALLS training in at least one participating care home

Falls lead Exclusion criteria

- None, provided inclusion criteria are met

Expected duration of participation

Participating care homes, staff and residents will be enrolled in the study for 12 months.

Participant Withdrawal

Care Home staff can withdraw from the study at their own request or at the discretion of the investigator.

Informed consent

Care home staff who agree to take part in the interviews and Falls leads who take part in the focus group provide written or verbal informed consent. Written Informed Consent Form will be signed and dated by the participant before they enter the trial. The Investigator will explain the details of the study 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.

Verbal consent will be as above, but instead of signing the consent form, the researcher will read out the consent statements and ask the participant to confirm their consent to each one. This will be audio recorded on a separate file.

The NoMAD questionnaires will begin with information outlining what the NoMAD is and inform care staff that completing and returning their questionnaire will indicate their consent to take part.

The invitation to the AFC events will be sent with a corresponding AFC information sheet which will explain that attending the AFC event will indicate their consent for anonymous field notes and observations to be taken. Care home staff will be asked to read the information sheet prior to attending.

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.

STUDY REGIMEN

ACTiON FALLS programme

The ACTiON falls programme is a systematic falls risk checklist and action programme which includes:

- An ACTiON FALLS intervention reference manual
- The ACTiON FALLS Checklist and decision support tool (formally known as GtACH)
- Staff training and support from a Falls Lead Expert
- Support to develop a Falls Champion role (care home staff)
- A falls awareness poster
- Access to the React to Falls web-based training, case studies and information
- The React to Falls Mobile Application

Once a care home has made an expression of interest in taking part in the study the study team will check their eligibility against the inclusion and exclusion criteria. Purposive sampling will be utilised to ensure that a variety of home registrations, sizes and ownership participate. It is valuable to understand how these factors will impact on the implementation of the ACTiON FALLS programme, and it is also important to have balanced feedback from a variety of homes.

Each eligible home will receive information from the study team about what is involved, and consent will be sought from the Care Home manager. Once consent has been received, the local site research team will provide participating care homes with the ACTiON FALLS research manual, access to the ACTiON FALLS electronic and hard copy decision tool, falls awareness poster and information about accessing the React to falls mobile app.

Local NHS/ Social Care Falls Leads will liaise with participating care homes to provide training in the use of the ACTiON FALLS programme. Where possible this training will be face to face, however, the study team has made provision for online training via VOIP connection if required due to Covid-19 restrictions. Where necessary, multiple training sessions will be held at each home to include as many staff as possible. It is aimed that at least 70% of care staff from each home will receive the ACTiON FALLS training.

Throughout the study, falls leads will be available to be contacted by participating care homes for support and advice about using the ACTiON FALLS programme. Falls leads will also proactively contact the care homes via telephone to offer support and to offer top-up training for care home staff.

Local NHS or social care Falls Leads will be trained by experts in the ACTiON FALLS programme from the coordinating team in Nottingham, via a face to face or online two-hour training event. They will be given all material needed to provide training to care home staff in their site.

PIS will be provided and consent for individual staff participation will be sought prior to any data collection events e.g., interviews, NoMAD questionnaire and AFC event participation.

ACTiON FALLS Collaborative (ACF) Events

These ACF events are also known in research terms as Quality Improvement Collaborations (QIC), but in our first implementation study we found that care home staff were wary of attending QIC as they did not know what they were going to be about.

Participating homes will be invited to attend up to three AFC events throughout their 12-month participation. Care homes will be requested to send the same staff to each event where possible to enable consistency. There will be no limit on how many staff participating homes can send to each AFC event. However, care homes will be encouraged to send a variety of staff from different care home roles e.g., carer, manager, owner, falls champion.

All participating care homes will be send an invitation for all staff to attend the AFC events, a AFC specific participant information sheet (PIS) will accompany the invite. Those attending the event will be asked to read the PIS prior to attending. The PIS will indicate that attendance of the event will indicate that they consent to anonymous observations and field notes being taken by researchers.

It is anticipated that care home recruitment will take place over several months, therefore AFC events will consist of care homes at different stages of their study participation. AFC events will be held locally within the geographical location of the study sites or via VOIP systems e.g., Microsoft Teams.

At least two researchers will complete observation and field notes at each AFC event. These notes will then be analysed concomitantly, in order to provide direction for the quality improvement cycle.

The AFC events will guide the quality improvement cycle and allow the implementation of the ACTiON FALLS programme to be adapted and reviewed throughout the 18-month study period. AFC events will be based upon the Plan Do Study Act (PDSA) cycle. These will take the form of workshops which last for two hours. Each event will be structured around activities designed to build relationships between different professional backgrounds, encourage feedback from care homes on the barriers and facilitators of using the ACTiON FALLS programme, and exploring how the ACTiON FALLS programme delivery may be adapted for local application. Each event will also include training and dissemination of research in relevant topics. AFC events will be facilitated by members of the research teams.

Each AFC event will end with an agreed set of action points which will be then disseminated to participating care homes and undergo qualitative analysis as part of the study data.

NoMAD Questionnaire

The NoMAD tool is a 23-item questionnaire for assessing implementation of complex interventions from the perspective of people directly involved in the change in practice(14). It is based around the constructs of Normalisation Process Theory.

Participating care homes will receive copies of the NoMAD questionnaire twice during their 12 month participation, once following their training and once at approximately 9 months after starting using the ACTiON FALLS programme. On each occasion the questionnaires will be sent out prior to AFC events. Researchers from the local sites will visit care homes and ask staff to complete the questionnaire and return directly to research staff. Reminders and a further opportunity to complete the NoMAD will be given at the AFC event. The questionnaire will begin with information outlining what the NoMAD is and inform care staff that completing and returning their questionnaire will indicate their consent to take part.

In return for staff time in completing the questionnaires, individuals who complete both NoMAD questionnaires (at the two different time points) will receive a £10 shopping voucher.

The questionnaire will ask for a name and contact email or telephone number if staff wish to receive the voucher.

Interviews and Focus Groups
Respondents will be purposively selected from the NoMAD returns and invited to take part in interviews. This is to allow a variety of staff at differing levels of confidence and ACTiON FALLS readiness to be sampled. Researchers trained in qualitative interview skills will aim to include a variety of stakeholders in roles such as, managers, owners and care staff. Interviews will also involve a range of staff roles, including falls champions. Up to 12 staff will take part in interviews at each study site. Interviews will explore staff experiences of using the ACTiON FALLs programme and perceived determinants of use. Interviews will take place either face to face, telephone or via VOIP platforms such as Microsoft Teams. Researchers from the central co-ordinating site in Nottingham will support the site research assistants in collecting this data. Care staff who participate in an interview will receive a £10 shopping voucher for their time.

NHS falls leads who have provided training and support will be invited to take part in a focus group either face to face or online. The focus group will be conducted by research staff trained in focus group research. The focus group discussion will include asking the falls leads about their experiences in providing training and support to care home staff in the use of the ACTiON FALLS programme.

Both care staff interviews and Falls Leads focus groups will be audio recorded and transcripts will be anonymised at the point of transcription, with each participant assigned a participant ID number. Transcription will be carried out by a University of Nottingham approved transcriber who has an appropriate Confidentiality agreement in place with the University of Nottingham.

Care Home falls data
Each month Care home managers from participating homes will be asked to send falls data to the central site research team. This will include number of falls and number of residents per month. All care home records will only be accessed by care home staff who would usually access that data as part of their job role and any identifying information redacted at the site before transferring to the University of Nottingham. Participating homes will also be asked to provide monthly falls data for the preceding 6 months prior to attending the ACTiON FALLS staff training.

Compliance

Due to the nature of the implementation study, the willingness of a participating care home to engage with aspects of the ACTiON FALLS programme and be involved in discussions around its use. forms a significant portion of the study outcomes. Therefore, acceptable compliance will be assessed as active participation at AFC events (at least one member of staff attending each AFC, 70% of care home staff in a caring role, attending ACTiON FALLS training, monitored by an attendance register. However, care homes which do not achieve this level of compliance will not be removed from the study (unless they withdraw). Where a Care home is unable to achieve this level of compliance, researcher will talk to care home managers in order to understand the barriers to participation. Understanding these barriers is an important aspect of the implementation of ACTiON FALLS, therefore, care homes will not be removed for non-compliance, rather this will be used within the learning for the study.

Criteria for terminating the study

Participation for each home will last for 12 months. Due to the nature of implementation research, care homes who are unable to continue using the ACTiON FALLs programme will

continue participation where they are able, as understanding why care homes feel they cannot use the intervention is an important finding.

In the event a care home withdraws participation (or is unable to continue), the care home will not be replaced. The care home will be made aware that data collected on the care home and staff participants at that care home to date, cannot be erased and may still be used in the final analysis.

Recruitment will be undertaken over a 9-month period, and recruitment progress will be reviewed each month by the Study Management Group (SMG). The SMG will review recruitment targets, training of care home staff, usage of the ACTiON FALLS programme and attendance of the AFC events. Strategies to increase recruitment and adherence will be implemented if required. 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 SMG as appropriate in making this decision. Should the study be terminated, the research data will not be destroyed.

ANALYSES

Methods

The qualitative analysis will be conducted by the research team based at the University of Nottingham

Qualitative data consisting of:

- Observations and field notes taken at AFC events
- Interview and focus group transcriptions

This data will undergo a two-stage analysis, initially using an inductive thematic analysis to pull out key themes. These themes will then undergo a second analysis by positioning them within the NPT constructs. This two-stage analysis process is supported by other NPT research (15,16)). Data will be stored and managed using QSR NVIVO 12 software. The coding of qualitative data will be completed by the research team and supported by a PPI member who has received training in the task.

Themes from AFC events will be analysed concomitantly as soon after each event as is practicable.

In line with the study aim, the monthly fall data will be explored and modelled against time by means of Poisson regression to investigate the trajectory of AFC effectiveness over 12 month period of study time. The home staff individual level measures, collected from NOMAD questionnaire, will be summarized by job type, measurement time, and/or geographic area, at both staff individual and home level. Multilevel modelling, either linear or nonlinear where appropriate with home as level two analytical unit, will be performed to:

1) Summarise the response

2) Check the home level variability relative to the total variability for all NOMAD items on staff views on A) how the AFC impact on their work, and B) their expectations about whether AFC could become a routine part of their work, at both the beginning and the end of the study.

Any influential factor effects on NOMAD item response will be investigated by including the relevant variable(s) as covariate(s) in multilevel modelling. Influence of possible missingness on results will be checked by means of sensitivity analysis with all missingness imputed with

Bayesian algorithm, under Missing At Random assumption for data missing mechanism which will be informed by then data exploratory prior any statistic modelling. The then latest version Stata and appropriate software for multiple imputation will be used for data analysis. all data analysis will be conducted on UoN computer with code and outputs files being backed up to UoN secure server.

We will evaluate the feasibility of obtaining falls rate data from other care homes outside of the four study sites which can act as a comparator to the ACTiON Falls study sites. This data is regularly collected by the Care Quality Commission and therefore may be available via a Freedom of Information request to the CQC.

Health Economics/ return on investment
A full economic evaluation of the ACTiON Falls programme was conducted alongside the randomised controlled trial, which included individual-level data on resource use and quality of life outcomes [12]. This analysis showed that the programme was likely to be cost-effective at the standard NICE willingness to pay threshold of £20,000 per quality adjusted life year, and estimated that the cost per fall averted was £191.

Whilst the economic evaluation alongside clinical trial has already demonstrated the potential for the programme to be cost-effective, the costs incurred may change when the programme is implemented and sustained in a real world setting. As well, the care homes recruited within the controlled trial are likely to be of higher quality and have more capacity to deliver the programme (given that they are undertaking research) than the average care home. Another key difference, is that in this analysis, data is collected only at the care home level.

We seek to evaluate the costs associated with the short-term implementation and the longer-term sustainment of the ACTiON Falls programme. This is of importance, as other implementation studies have cited cost as a potential barrier to implementation.

Each study site will have governance over how the ACTiON falls intervention is implemented and will thus tailor the programme to meet local needs. We will cost the variations in implementation strategy across each of the sites, based on feedback of such changes from the research study assistants. Costs are likely to include: training of staff, delivery of the AFC events and production of ACTiON Falls materials. This will be supplemented by information collected at the AFC events, interviews and focus groups, where care home staff will be asked about the time taken to implement the ACTiON Falls intervention, as well as any other costs incurred.

The implementation costs will be compared to those calculated in the within trial economic evaluation, and updated cost-effectiveness estimates will be made.

We will also explore who is willing and likely to bear such costs if the intervention is to be implemented outside of a research context. This will be explored in the interviews and focus groups.

Sample size and justification

Given the study aims to implement the AFC program in routine care home practice, one key study objective will be examining whether AFC could yield the same successful trial outcomes (12) . With reference to the FinCH RCT result, to detect the true value of such an home level monthly average number (6.88) with SD=15.73 of fall at 95% level of confidence with margin of error (MER) of the estimate set as MER=4, ie the 95% confidence interval of monthly home level average number of fall is [2.88 to 10.88], 60 care homes will have to be recruited. After

considering the study budget, geographic and social economic diversity, influence of Covid pandemic, the study team decided to recruit 60 cares home participating the proposed study.

ADVERSE EVENTS

This is a low-risk intervention. No specific risks, untoward incidents or adverse events were reported during the FinCH RCT. The ACTiON FALLs programme provides recommendations that actions are taken, these are all routine activities delivered in care homes and community service. It is the combination and systematic approach which makes the ACTiON FALLS programme unique.

ETHICAL AND REGULATORY ASPECTS

ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will not be initiated before the protocol, consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), the respective National Health Service (NHS) or other healthcare provider's Research & Development (R&D) department, and the Health Research Authority (HRA) if required. 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 is 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 study 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 UK Department of Health Policy Framework for Health and Social Care, 2017.

INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent for 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 shall both sign and date the Consent Form before the person can participate in the study. The participant will receive a copy of the signed and dated forms and the original will be retained in the Study records.

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

RECORDS

Study Forms

The following documents will be utilised within the study:

- NoMAD questionnaire: Will be completed by care home staff, each staff member will be provided with a form containing a unique identifier. Forms will then be collected from the care homes by a member of the research team. An online version of the questionnaire will be provided by JISC for participants who have a preference to complete the questionnaire this way.
- Falls data return
- Training register
- Attendance at AFC's events

Each participant will be assigned a study identity code number, for use on study documentation, other study documents and the electronic database.

Study documents will be treated as confidential documents and held securely in accordance with regulations. Study documents shall be restricted to those personnel approved by the Chief or local Investigator and recorded as such in the study records.

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 Investigator shall sign a declaration ensuring accuracy of data recorded in the study documents.

Source documents

Source documents shall be filed at the investigator's site and may include but are not limited to, consent forms, study records, field notes, interview transcriptions and audio records. A study document may also completely serve as its own source data. Only study staff shall have access to study documentation other than the regulatory requirements listed below.

Direct access to source data / documents

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

DATA PROTECTION

All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent and will adhere to GDPR. The study documents will only collect the minimum required information for the purposes of the study. Study documents will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the study staff and investigators and any relevant regulatory authorities (see above). Computer held data including the study 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).

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

QUALITY ASSURANCE & AUDIT

INSURANCE AND INDEMNITY

The Parties shall each maintain all proper insurance or equivalent indemnity arrangements to cover liabilities arising from its participation in the Study, in respect of any claims brought by or on behalf of a study Participant.
The University of Nottingham as research Sponsor indemnifies its staff with both public liability insurance and clinical trials insurance in respect of claims made by research subjects.

STUDY CONDUCT

Study conduct may be subject to systems audit for inclusion of essential documents; permissions to conduct the study; CVs of study 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, timeliness of visits); accountability of study materials and equipment calibration logs.

STUDY DATA

Monitoring of study 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.

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

RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Code of Research 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 study 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 anonymised audio recordings, study databases and associated meta-data encryption codes.

DISCONTINUATION OF THE STUDY BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice as appropriate in making this decision.

STATEMENT OF CONFIDENTIALITY

Individual participant 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.

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.

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

PUBLICATION AND DISSEMINATION POLICY

The main study report will be drafted by members of the study steering committee, and the final version will be agreed by the committee before submission for publication, on behalf of the collaboration. 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 (care home staff and members of the QIC). 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. 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 and funder'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 ARC Wessex collaboration website.

USER AND PUBLIC INVOLVEMENT

Our stakeholder groups will have a lead person in the Hub site and a PPI person in each locality (four sites) to broaden lay perspectives of local knowledge. The Principal Investigator for each site will liaise with local stakeholder 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.

A named researcher will support the stakeholder team and manage the budget. The stakeholder team will receive induction, and, where indicated, ongoing training. One PPI representative will receive qualitative analysis training and assist with the thematic analysis. We envisage this will add broader and diverse perspectives to the data.

A care home manger and PPI member will also sit on the study steering group Funding has been included as part of the ARC award for all PPI involvement.

A national stakeholder group will be established and will meet four times a year. This will include members of the currently established East Midlands group and will be expanded to include stakeholder members in all four sites. The aim of this group comprising, care home staff, clinical falls leads, commissioners, for example, will feedback on the ongoing findings of the study and feedback with their own unique perspectives.

STUDY FINANCES

Funding source

This study is funded by NIHR Applied Research Collaboration Wessex

Participant stipends and payments

Care home staff participants will receive a £10 shopping voucher for completion of two NoMAD questionnaires and another for taking part in an interview.

If AFC events are held face to face, travel costs to and from the venue will be paid.

SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: (name)_____

Signature:_____

Date: _____

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